Validation of the Dutch version of the Hip Outcome Score

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47747

Source
ToetsingOnline

Brief title
Dutch Validation HOS

Condition

- Joint disorders

Synonym
hip pain, impingement hip

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Vakgroep Orthopedie RdGG

Intervention

Keyword: Hip, Ouctome, Score, Validation

Outcome measures

Primary outcome

The primary endpoints are internal consistency, reliability, construct validity

and content validity of the Dutch version of the HOS.

Secondary outcome

The secondary endpoints are the smallest detectable change (SDC) and the

minimal clinical important difference (MCID), 6 months postoperatively.

Study description

Background summary

Patient Reported Outcome Measures (PROMs) are increasingly being used to evaluate clinical outcome in orthopedics. However, most orthopedic assessment tools are predominantly developed for elderly patients. Since the early 1990s femoroacetabular impingement (FAI) and labral tears are recognized as a cause of groin pain in young active adults. FAI, first described by Ganz, is a morphological abnormality of the acetabulum (pincer FAI), the femoral head and neck (cam FAI), or a combination of these two deformities. Over the last decade, hip arthroscopy has become a popular procedure for the treatment of FAI and labral tears. These young and active patients are limited at a high level of activity. To measure outcome and results of arthroscopic surgery for FAI, questionnaires should be focused on activities of these patients, in daily life and during sports. Therefore, these patients require other PROMs than those developed for patients with osteoarthritis for the outcome assessment of hip arthroscopy. The Hip Outcome Score (HOS) is an example of a questionnaire focused on activities and sports and is considered a valid tool for measuring function in individuals who have undergone hip arthroscopy. The HOS was developed for patients between the ages of 13 and 66 years. Items were generated by physicians and physical therapists and reduced by factor analyses. The HOS consists of two domains, a domain containing questions about activities of daily living (ADL), containing 19 questions and the sports domain, containing 9 questions. Three further questions are not utilized towards final score. The questions are rated on a Likert scale from 0 to 4. There is an

additional *not applicable* (N/A) box for patients to tick when their activities are limited by causes other than the hip. The potential top score is 68 for ADL and 36 for sports. The scores are divided by highest potential score and multiplied by 100 to achieve a percentage score in each subscale. 100% is the maximum score in both domains.
Martin and Philippon provided evidence of validity for the HOS as an outcome instrument in hip arthroscopy in 2006. Tijssen recommends the HOS for evaluating patient after hip arthroscopy for FAI in a review in 2011. Many authors have used the HOS to describe post-operative results after hip arthroscopy for FAI. The HOS scored best on agreement, internal consistency, test re-test reliability, constructs validity, interpretability and measurement error.

Despite its wide use in the international literature, the Hip Outcome Score is not translated into the Dutch language nor is it validated for the Dutch language.

Study objective

The objective of this study is to evaluate the internal consistency, reliability, constructs validity and floor and ceiling effects of the Dutch version of the HOS questionnaire in patients with FAI and/or labral tears. Moreover, the minimal clinical important difference (MCID) after 6 months in the Dutch population will be determined.

Study design

First, we will conduct a forward/backward translation in accordance with guidelines on cross-cultural adaptations (Guillemin et al.). The final version will be made by the research team and will be tested on 20 patients.
Next, at three different time points, multiple questionnaires will be administered to the study sample:
- Translated HOS
- HAGOS (Hip and Groin Outcome Score)
- mHHS (modified Harris Hip Score)
- iHOT-12
- NRS for pain

The second administration will be doen 7 days after the first administration, both preoperatively. The third administration will be six months after surgery.

Study burden and risks

Patients will complete five questionnaires at three timepoints: two preoperative administrations and on postoperative administration. There are no risks related to participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who:
- are 18-65 years of age
- have physical examination and radiological examination suspect for FAI
- Inclusion will not interfere with standard care for FAI
- provided informed consent
- understand the Dutch language

Exclusion criteria

Patients who:
- have had prior surgery to the hip for FAI

- have pathological fracture or other metastatic pathology
- refuse to particpatie
- do not speak the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	30-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-02-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26525
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61937.098.17
OMON	NL-OMON26525

Study results

Date completed:	19-03-2021
Actual enrolment:	136

Summary results
Trial ended prematurely