Towards better understanding of FCE performance in different societal contexts

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Differences in the healthcare, workplace, legislative, and personal systems (see figure) as well as evaluator and patient characteristics may better explain differences in FCE results

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20068

Bron
NTR

Aandoening

FCE, Multicountry, musculoskeletal pain, bio-psycho-social

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
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Groningen, The Netherlands
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Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

FCE results:

- Floor to waist lifting (kg)
- Six minute walking test (meters)
- Grip strength (kg)

Toelichting onderzoek

Achtergrond van het onderzoek

A considerable amount of research has been conducted on Functional Capacity Evaluation (FCE) performance. Evidence is accumulating on a bio-psycho-social model influence; differences in age, gender, self-efficacy, motivation, country, and mother language have been found associated with FCE performance. Previous research has focused on biological and psychological factors; however, studies on social factor's influence are lacking. The present project aims to provide better understanding of the societal variables that affect FCE results.

This is a cross-sectional study, developed as close as possible to 'care as usual'. Patients enrolled will be between 18 and 65 years of age, diagnosed with non-specific sub-acute or chronic pain, and undergo FCE as part of routine clinical care. Bio-psycho-social data and FCE characteristics will be collected from different countries, institutions and evaluators. Patients are asked to fill a short questionnaire about pain intensity, factors associated with pain, work ability, and disability. Clinicians are asked to complete two data collection forms: one with patient and FCE characteristics; and another one with information about themselves, including an adapted Back Beliefs Questionnaire. A core set of lifting, and walking or handgrip strength test will be measured.

Collected data will be de-identified. It will be sent periodically to country liaisons who will de-identify patients and clinicians, merge data, and send to the principal investigator. The data collection phase will last 6 months. Country liaisons are in charge of adapting the protocol to their country guidelines and regulations, and coordinating data collection.

Doel van het onderzoek

Differences in the healthcare, workplace, legislative, and personal systems (see figure) as well as evaluator and patient characteristics may better explain differences in FCE results

Onderzoeksopzet

September 2015 - March 2016: study conduct, including data entry.

Onderzoeksproduct en/of interventie

The study is designed as 'care as usual' for the patients, and as close as possible to care as usual for clinicians.

FCE will be performed according to regular protocols, with a mandatory core set of tests: low lifting (all patients), and walking or handgrip strength (clinician’s decision depending on the affected region or work demands). Other tests can be performed for FCE, but data will not be collected for this study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients:

- Aged between 18 and 65 years old

- Diagnosed with non-specific sub-acute or chronic pain

- Undergo FCE as part of routine clinical care/evaluation

Clinicians:

- Trained to perform a standardized FCE

- More than 1 year of experience and more than 20 FCEs performed on the target group

- Sufficient understanding of the English language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients:

- Pregnant, retired or on permanent sick-leave

- Presenting specific diagnoses related to the musculoskeletal system, and/or with relevant medical co-morbidity such as unstable cardiovascular conditions

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5237
NTR-old	NTR5494
Ander register	: METc 2015-233

Resultaten

Samenvatting resultaten
N/A