

TSK-C: measuring fear of movement in children and adolescents

Published: 04-05-2007

Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Somatic symptom and related disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30957

Source

ToetsingOnline

Brief title

TSK-C

Condition

- Somatic symptom and related disorders

Synonym

kinesiofobia, pain related fear

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adolescents, children, fear of movement, pain

Outcome measures

Primary outcome

The reliability of the TSK-C will be investigated by means of a confirmatory factor analysis. If the results are different from the adult version, reliability will be re-investigated by means of an exploratory factor analysis. The content validity of the TSK-C will be reviewed by experts on pain and fear of movement.

The construct validity will be investigated by comparing the TSK-C to five other questionnaires, being the PCS-C, the STAIC, the FDI and the CDI-S. All questionnaires are expected to correlate significantly to each other.

Finally, the healthy group will be compared to the patient group. It is expected that the patient group or a subgroup will show elevated scores on the TSK-C and other questionnaires. This will be tested by means of a student's t-test.

Secondary outcome

n/a

Study description

Background summary

It is common knowledge that children and adolescents experience pain on a regular basis. However, the high prevalence of chronic pain in children and adolescents is a reason for concern. Chronic pain increases with age and is mostly reported by children and adolescents between the age of 12 and 15 years

old. In addition girls tend to report more chronic pain than boys. Chronic pain has a negative impact on the quality of life of children and adolescents and is also of negative influence on their family life. Different studies have shown that psychosocial factors, such as anxiety, stress, coping, neuroticism and modeling are of influence on the development and maintenance of chronic pain. However, these factors do not provide additional information on etiology or underlying mechanisms.

The Fear-Avoidance model (FA-model) has proven its' predictive value in explaining the transition from acute to chronic musculoskeletal pain in adults. There are several reasons that this model can also be applied to children and adolescents. First of all, children and adolescents with chronic pain report higher levels of anxiety than healthy children and adolescents. More specific, higher levels of catastrophizing in girls are related to higher levels of pain intensity and disfunction. Furthermore, treatments consisting of relaxation or cognitive behavioural therapy have proven their efficacy in reducing the level and frequency of chronic pain in children and adolescents.

Study objective

To investigate whether the FA-model can be applied to children and adolescents with chronic pain, the relevant questionnaires needed to assess all variables in the model need to be modified in order to be user-friendly for children. Most questionnaires already have been modified, but there is no questionnaire yet to measure "kinesiofobia" (fear of movement) in children and adolescents. Objective: is the TSK-C a user-friendly and valid instrument to measure fear of movement in children between the age of 8 and 16 years old.

Study design

The data will be collected by means of a single assessment of the TSK-C and five additional questionnaires that are related to various dimensions of chronic pain. Filling in the questionnaires will take about 15 minutes.

Study burden and risks

In our opinion there are no risks associated with this research project. The burden is restricted to a minimum by only including 6 questionnaires and an expected time frame of 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age between 8 and 16 years old
patients: a-specific pain complaints

Exclusion criteria

- non fluent in dutch
- children in special education programs
- patients: presence of chronic fatigue syndrome

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-06-2007

Enrollment: 250

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 04-05-2007

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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

CCMO

ID

NL16971.068.07