The level of physical activity and participation in society of adolescents with chronic musculoskeletal pain.

Published: 04-03-2009 Last updated: 06-05-2024

1. Is there a difference between the level of activities and participation among adolescents with chronic musculoskeletal pain as compared with the activity and participation level of adolescents not suffering from chronic pain?2. What is the impact...

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33956

Source ToetsingOnline

Brief title Adolescents with chronic pain.

Condition

• Musculoskeletal and connective tissue disorders NEC

Synonym Chronic pain syndrome; musculosketal pain syndrome

Research involving Human

Human

Sponsors and support

Primary sponsor: Stichting Revalidatie Limburg Source(s) of monetary or material Support: Ministerie van OC&W

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Intervention

Keyword: activity, adolescents, pain, participation

Outcome measures

Primary outcome

- Activities in daily life (SQUASH).
- Participation in society (CAPE and PAC).

Secondary outcome

- Pain catastrophizing (PCS-C).
- Pain intensity (VAS).
- Depressive symptoms (CDI).
- Pain-related disability (FDI).

Study description

Background summary

Previous research has demonstrated that children and adolescents frequently experience and report chronic pain. Among school children up to 25% is suffering of chronic or recurrent pain of three months or longer. In a substantial part of these cases no specific cause can be identified for the pain condition. Common complaints encountered in non-specific pain are headache, musculoskeletal pain, abdominal pain and back pain. Girls more often report pain than boys and the incidence peaks during adolescence. Until recent years, evidence based knowledge on chronic pain in childhood and adolescence was scarce, especially in comparison with evidence on chronic pain in adulthood. However, as a result of increasing consideration on the fact that many children and adolescents with chronic pain will grow into adults disabled by chronic pain involving high societal costs, more research has been undertaken on this subject over the past few years.

Nevertheless, a few subject areas remain underexposed. Firstly, only a minority of the published studies on this subject concern musculoskeletal pain in specific. In previous research, children and adolescents presenting with headache or abdominal pain accounted for the majority of the study population. Although these are the most common pain localisations among children and adolescents in general, most referrals to rehabilitation medicine are children and adolescents presenting with musculoskeletal pain. Therefore, for rehabilitation medicine it would be relevant to focus on this non-specific pain condition and to increase knowledge of this group of patients.

Secondly, the effect of chronic pain on the functioning of children and adolescents suffering from it has not been studied properly. Most studies published on this area focused predominantly on the negative consequences of chronic pain as a study outcome, such as impairments and disability. However, according to the the International Classification of Functioning, Disability and Health (ICF, WHO 2001), a framework developed by the WHO to describe functioning and disability at both individual and population level, functioning is seen in a more holistic view and is described in positive instead of negative terms. Based on this model, functioning is seen in relation to health conditions, personal and environmental factors, and has two components: *body functions and structures* and *activities and participation*. Activities refers to executing daily life tasks and activities, whereas participation refers to the actual involvement in specific life situations, ie social engagement. Evidence based knowledge on the functioning of children and adolescents with chronic pain in positive terms such as *activities and participation* is scarce in comparison with knowledge on negative outcomes such as disability, defined as problems in executing daily life tasks and activities. Therefore, it would be interesting to chart the level of activities and participation of children and adolescents with chronic pain, such as mobility, self-care, carrying out domestic and everyday actions and tasks and carrying out actions required to engage in education.

Finally, our knowledge about factors influencing the functioning of children and adolescents with chronic pain in general and more specific, factors influencing their level of activities and participation in society is still underdeveloped. Although many children and adolescents experience acute pain, only a minority of these develop chronic pain and become disabled by it, i.e. experiencing problems in executing daily tasks and activities. Previous studies have tried to identify factors related to the development and maintenance of chronic pain and pain related disability in adolescence, such as low pain thresholds, previous pain experience and maladaptive coping strategies. In order to better understand why only a minority develop a chronic pain problem and to identify factors of influence it is necessary to hypothesize a model of pain and interacting factors. A traditional biomedical approach is insufficient to explain chronic pain and its associated disability. Numerous studies among adults with chronic pain suggest that behavioral and biopsychosocial factors contribute to the development and maintenance of chronic pain. The fear-avoidance model explains how and why adults with acute musculoskeletal pain develop a chronic pain syndrome. Although this model has not been used to explain the development of chronic pain in children and adolescents until now, it seems reasonable that this model is also applicable to this group. Therefore, in the present study we chose this model in order to better

understand the chronic pain problem in children and adolescents. According to the fear-avoidance model, pain is interpreted as either non-threatening or threatening, leading to two different pathways. In the first situation rapid confrontation with daily activities is likely to occur, promoting functional and fast recovery. In contrast, when pain is catastrophically (mis)interpreted as threatening, a vicious circle may be initiated. These dysfunctional interpretations of pain give rise to pain-related fear and associated behaviors in order to reduce fear and anxiety in the short term, such as avoidance behavior and hypervigilance. In other words, when patients experiencing acute pain interpret their pain as threatening, fear of movement and injury occurs. The expectation of negative consequences of increasing their physical activity may be the reason to avoid physical activities, on long term leading to disability, i.e. problems in executing daily tasks and activities, and disuse, defined as performing at reduced level of physical activity in daily life. In addition to the development of disability and disuse, avoidance of daily physical activities may also result in depressive symptoms according to the fear-avoidance model. It is imaginable that disability, disuse and depressive symptoms will lead to a lower level of participation in society.

Until recently, it was assumed that pain intensity did not play an important role in the fear-avoidance model. However, more recent literature on the fear-avoidance model shows that this assumption is not true for adults with acute low back pain and that pain intensity in itself has a considerable contribution in explaining disability.

In view of the above mentioned, it is imaginable that the components or factors of the fear-avoidance model, such as pain-related fear, pain catastrophizing, avoidance behavior, depressive symptoms and pain intensity, have a negative influence on the level of activities and participation in society of children and adolescents with chronic pain. Although this seems presumable, there is no evidence based knowledge on this area among children and adolescents with chronic pain. Because of the feasible implications regarding understandig of pediatric chronic pain and its management it is considered relevant to evaluate this. One possible way to analyze this is to investigate the influence of pain-related fear, pain catastrophizing, avoidance behavior, depressive symptoms and pain intensity on the level of activities and participation.

Therefore, the present study aims to determine the level of activities and participation among children and adolescents with chronic musculoskeletal pain in comparison with children and adolescents not suffering from chronic pain. Further, the second objective of this study is to assess factors influencing the level of activities and participation of children and adolescents suffering from chronic musculoskeletal pain. We chose to analyze the impact of three factors or components from the fear-avoidance model, ie pain catastrophizing, pain intensity and depressive symptoms. Hypotheses:

 Adolescents with chronic pain have lower level of activities in daily life and a lower level of participation in society as compared to healthy peers.
A higher level of catastrophizing, pain intensity and a depressive symptoms will result in a lower level of activities in adolescents with chronic pain.
A higher level of catastrophizing, pain intensity and depressive symptoms will result in a lower level of participation in society in adolescents with chronic pain.

Study objective

 Is there a difference between the level of activities and participation among adolescents with chronic musculoskeletal pain as compared with the activity and participation level of adolescents not suffering from chronic pain?
What is the impact of pain catastrophizing, pain intensity and depressive symptoms on the level of activities in daily life of adolescents suffering from chronic musculoskeletal pain?

3. What is the impact of pain catastrophizing, pain intensity and depressive symptoms on the level of participation in society of adolescents suffering from chronic musculoskeletal pain?

Study design

Patient control study in a cross sectional design.

Study burden and risks

The burden for the adolescents will be restricted to the one-only filling-in of a questionnaire. This takes about 90 minutes. The questionnaire consists of the following measurement instruments:

- Demographic and medical variables: age, gender, duration of pain, education, absence from school, hobbies, family type, presence of family members with chronic pain and comorbidity will be recorded.

- Pain Catastrophizing Scale for Children (PCS-C): catastrophic thinking about pain will be assessed with the Dutch version of the Pain Catastrophizing Scale for Children (PCS-C) (Crombez et al., 2003). This instrument consists of 13 items describing different thoughts and feelings that children may experience when they are in pain. Children rate how applicable each of the described thoughts and feelings are when they are in pain using a 5-point scale (0-4). Total scores are obtained by summing the ratings for each item. The PCS-C has shown to be a reliable and valid instrument for children aged 9 to 15 (Crombez et al., 2003).

- Visual analogue scale (VAS): the intensity of current pain will be assessed with a 10 cm visual analogue scale (VAS) with the endpoints *no pain* and *a lot of pain*. The pain severity VAS has a good reliability and validity in

children 9-15 years old (McGrath, 1987).

- Children*s Depression Inventory (CDI): depressive symptoms will be measured by the Dutch version of the Children*s Depression Inventory (CDI) (Kovacs, 1981). The CDI is a self-report inventory that assesses symptoms of depression in children and adolescents. It is suitable for youths aged 7 to 17. It contains 27 self-report items on five subscales (negative mood, interpersonal problems, ineffectiveness, anhedonia, negative self-esteem), representing depressive symptoms. Each item is rated on a 3-point scale and summed to obtain a total score. Higher scores indicates higher levels of depressive symptoms. The CDI has been found to have acceptable reliability and good validity (Smucker et al., 1986) (Claar & Walker, 2006) (Eccleston et al., 2006). - Functional Disability Inventory (FDI): pain-related disability will be assessed with the Dutch version of the Functional Disability Inventory (FDI) (Walker and Greene, 1991) (Dutch version: Crombez et al., 2003). The FDI is a self-report inventory for children that measures perceived difficulty in performing a number of activities in the domains of school, home, recreation and social interactions. It is designed to be applicable to a broad range of illnesses and varying levels of severity. The instrument consists of 15 items concerning perceptions of activity limitations during the past two weeks. The items are rated on a 5-point scale (0-4). Total scores are obtained by summing the ratings for each item. Higher total scores indicate greater disability. The reliability and validity has been demonstrated in research (Walker & Greene, 1989) (Claar & Walker, 2006) (Eccleston et al., 2006).

- Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) (Wendel-Vos et al., 2003): the SQUASH is a reliable and valid questionnaire developed by the Dutch National Institute of Public Health and the Environment to assess habitual physical activity in an adult population. It consists of questions concerning the frequency and duration of habitual physical activity in 4 domains, i.e. commuting activities, leisure time activities, household activities and activity at work and school. The SQUASH is designed for persons 16 years and above. There is also a modified version of the SQUASH especially designed for adolescents: the Activity Questionnaire for Adults and Adolescents (AQuAA). The Dutch translation of this questionnaire is in validation and the publication will be expected in short term. In the current study we will use the modified version of the SQUASH to measure the physical activity. -General Questionnaire Children*s Rehabilitation Pain and Fatigue (Westendorp, 2007): this Dutch instrument measures the level of physical activity of adolescents. It is designed especially for children suffering from chronic pain and contains a section titled *Sports/ hobby*s* measuring the level of activities in this group. Unfortunately, it has not been validated until now. - Children*s Assessment of Participation and Enjoyment (CAPE) and the Preferences for Activities of Children (PAC) (King et al., 2007): for measuring the level of participation in society the Dutch translation of these 2 complementary questionnaires will be used. Both self-report inventories consist of 55 items and are appropriate to measure participation in recreation and leisure activities outside of school for children and adolescents aged 6 to 21. They provide information about 5 types of activities: recreational, active

physical, social, skill-based and self-improvement activities. The CAPE provides information about 5 dimensions of these 5 types of participation, i.e. diversity, intensity, where, with whom and enjoyment. The PAC is a additional measure for a sixth dimension, i.e. preference for activities. The English version of the CAPE and PAC have been found to have good validity (King et al., 2007). The Dutch translation of these questionnaires are in validation and the publication of the validation study will be expected in short term.

In addition, the healthy peers will be asked to fill in a questionnaire including the demographic variables, the SQUASH, the additional measure for level of activities and the CAPE and PAC. The pain related measures will no be included in this questionnaire. Therefore, it will take less time to fill in the questionnaire (70 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years)

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

Inclusion criteria

- Age 12 to 21 years.
- Musculoskeletal pain with a duration over 3 months.

- No specific somatic (reumatoid, neurological or orthopedic) disorder could be diagnosed as the cause of the current pain problem.

Exclusion criteria

- Age younger than 12 years or older than 21 years.
- Duration of pain shorter than 3 months.
- Localisation of pain outside the musculoskeletal system.
- A specific somatic disorder is diagnosed as the cause of the current problem.

Study design

Design

Observational non invasive
Other
Non-randomized controlled trial
Open (masking not used)

Primary purpose: Other

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	100
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC SRL Stichting Revalidatie Limburg (Hoensbroek)

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 NL23577.022.08