Levels of physical fitness and physical activity in children and adolescents after moderate to severe burn injury.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37712

Source
ToetsingOnline

Brief title
Physical fitness and activity in children and adolescents after burn injury

Condition

- Skin and subcutaneous tissue disorders NEC
- Lifestyle issues

Synonym
burns; burn injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Bijdrage in materiële

kosten door de Nederlandse BrandwondenStichting;enkel t.b.v. aanschaf apparatuur voor dit onderzoek.

Intervention

Keyword: activity, burns, children, fitness

Outcome measures

Primary outcome

Physical fitness

- Cardiorespiratory endurance, expressed as VO2peak (ml/min) and relative for

weight (ml/kg/min)

Physical activity

- Daily activity, expressed as activity counts

Secondary outcome

Physical fitness

- Cardiovascular endurance

* HRpeak

* %HR01 and %HR02

* WRpeak

- Muscular strength

* Force (Newton) per muscle group

- Flexibility

* Range of motion (degrees) per movement

- Body composition

* BMI (kg/m2)

* Percentage fat mass

Physical activity

* Score on questionnaire 'Beweeggedrag'

Health-Related Quality of life

* Score on Dutch version of Burn Outcome Questionnaire

* Score on the PedsQL Multidimensional Fatigue Scale

Relevant demographic information, burn and treatment characteristics will be mainly acquired from patient files in the cooperating burn centers/hospitals and replenished from the questionnaires. Use of medication, as well as medical background, will be asked for beforehand, using the Exercise Preparticipation Screening.

Study description

Background summary

Burn injuries have a major impact on the patient*s physical and psychological functioning and the consequences may persist for years after the injury. There are indications that physical fitness and physical activity may be affected in children after a severe burn injury. This knowledge is, however, incomplete and not generalizable to the majority of children with burns. Population-specific knowledge on physical fitness and activity is necessary to detect which children show (or are at risk for) diminished physical functioning after burn

injury.

Study objective

The objective of the current study is to determine and describe the level of physical fitness and the level of physical activity in Dutch children and adolescents after burn injury. With this a scientific fundament can be established for further improvement of individualized rehabilitation for children with burn injury who are at risk for diminished physical functioning. Through this, we aim to contribute to the optimisation of multidimensional outcomes after burns.

Study design

In this cross-sectional descriptive study the levels of physical fitness and activity in children after burn injury are determined and compared to Dutch reference values.

Study burden and risks

Physical fitness assessments are performed only once; after screening for contra-indications, risks are negligible. By using the mobile exercise lab the inconvenience and time of travelling are negligible. Total duration of physical fitness assessments is about 1,5 hour. Physical activity monitoring is without risk and the inconvenience of wearing the accelerometer is low. Questionnaires can be filled out when and where it suits the participant*s convenience. In summary, risks are negligible and the burden of participation seems minimal.

This study is only possible including this specific population, since burns have very specific, multidimensional consequences and because children*s physiological and psychological response differs from adults*. Children can benefit individually through becoming aware of their fitness and activity levels and the importance of it. The group benefit mainly appears on improvements in the domain of individualized rehabilitation and with that better physical functional outcomes for pediatric burn patients in the (near) future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- children in the age of 6 up to and including 18 years
- admitted to one of the three Dutch burn centers between 6 months and 5 years ago
- burn injury involving at least 10% of the total body surface area (% TBSA) and/or hospitalized at least 6 weeks
- at least 2 months after discharge at time of assessments

Exclusion criteria

- extensive pre-existing comorbidity or (mental) disabilities
- no signed informed consent (by the parents and/or children >12 years)
- insufficient Dutch language proficiency

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2012
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL40183.042.12