# Recovery of physical functioning after burns

Published: 20-09-2022
Last updated: 25-09-2024

To identify potential rehabilitation needs of adult patients with burns we aim to:1) investigate the course of physical fitness, physical activity and fatigue after discharge. 2) identify factors that can predict the recovery, or lack thereof, at an...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON56836

**Source**
ToetsingOnline

**Brief title**
Recovery after burns (RETURN)

### Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC
- Skin and subcutaneous tissue disorders NEC

**Synonym**
burn injury, burns

**Health condition**

brandwonden

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Martini Ziekenhuis
**Source(s) of monetary or material Support:** Nederlandse Brandwonden Stichting

## Intervention

**Keyword:** activity, burns, fatigue, fitness

## Outcome measures

### Primary outcome

Change from hospital discharge to at 12 months post discharge in:

Physical fitness

Aerobic capacity

- Maximal workload (W)

- Maximal workload relative for bodyweight (W/kg)

Muscular strength

- Grip strength (kg)

- Isometric muscle strength: of the knee extensors and elbow flexors (N)

Flexibility

- Active and passive ROM (degrees) will be assessed using a goniometer

Body composition

- Body Mass Index (BMI) (kg/m2)

- Waist circumference (cm)

**Secondary outcome**

Physical activity

- Activity performance: accelerometry (activity counts)

- Perceived capability of activity: score on Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaire physical functioning

- Activity limitations: score on Patient Specific Functional Scale

Perceived benefits and barriers to exercise: Exercise Benefits/Barriers Scale (EBBS)

Self-management: the Partners in Health Scale (PIH-NL)

Burn injury-associated pain intensity: Visual Analogue Scale (VAS)

Perceived fatigue: score on PROMIS questionnaire fatigue

Participation

- return to work: score on questions in the burn outcome registry

- social role: score on PROMIS questionnaire satisfaction with social role and activities

Health-Related Quality of life: score on the EQ-5D-5L+cognitive dimension

# Study description

### Background summary

The ultimate goal of burn care is to assist patients in returning to their pre-injury level of functioning, while maximizing their emotional and cosmetic outcomes. Achieving adequate, if not pre-injury, levels of functioning is of course important on the short term. Additionally, there is a growing understanding of the importance of maintaining certain levels of physical fitness and physical activity throughout life to prevent disability, morbidity later on in life. Various studies confirm the clinical and burn survivors* experiences that the level of functioning prior to the injury is not always achieved again. Knowledge concerning the recovery of physical fitness and interventions to improve it is predominantly based on studies involving children with severe burns. Knowledge concerning adults with less extensive burns is lacking.
Achieving adequate physical fitness may be a goal in itself in view of proven health benefits. However, for the vast majority of patients and for society in general its relevance is found in its - expected- contribution to being able to be active, participate in life, and health related quality of life (HRQoL).
There is scarce evidence concerning the relationship between recovery of physical fitness and activity, participation and quality of life. Besides fitness other factors will also play a role. In patients with burns one of these factors may be fatigue, which is an often-heard complaint.

### Study objective

To identify potential rehabilitation needs of adult patients with burns we aim to:

1) investigate the course of physical fitness, physical activity and fatigue after discharge.
2) identify factors that can predict the recovery, or lack thereof, at an early stage.
3) investigate how the recovery of physical fitness, physical activity, fatigue, participation and HRQoL are related.

### Study design

Prospective observational study with a 12 month follow-up

### Study burden and risks

The risks and inconvenience of participation are kept as low as possible.
To minimally burden the participants with additional travel time, the physical

fitness assessments will, wherever possible, be scheduled in combination with routine follow-up appointments. Completing the questionnaires will take time, but can be done online, or on paper if preferred, and throughout a full week at the participants* convenience. Wherever possible, assessments and their timing have been chosen to coincide with those that are part of care as usual at the burn centre. The exericse test (Steep Ramp Test) only takes 2 to 3 minutes, hence the burden and risk is low. Additionally, before testing, participants are screened for any contra-indiciations for maximal exerise testing. The other physical fitness assessments i,e. muscular strength, body composition, and flexibility, are also safe and non-invasive. Physical activity monitoring with an accelerometer is without risk and the inconvenience of wearing the accelerometer is low, as it is a very small and low-weight device, worn as a waistband on the hip.

## 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

• age 18 - 67 years,
• admitted to the burn centre of the Martini Hospital in Groningen,
• acute burns of 5% total body surface area or more or a length of stay of more than 1 week, or
both, or
• acute burns on the lower extremity who have been immobilized for more than 1 week, and
treated solely or in part at the outpatient clinic,
• signed informed consent.

### Exclusion criteria

• extensive (pre-existing) morbidity unrelated to the burn injury,
• insufficiently proficient in Dutch or English to the extent that clear communication is not possible.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-01-2023 |
| Enrollment: | 99 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 20-09-2022 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 25-06-2024 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL80661.100.22 |
| Other | OND1370405 |