# WHeelchair ExercisE and Lifestyle Study

Published: 15-12-2017 Last updated: 12-04-2024

To systematically develop a mobile lifestyle application + counseling program for wheelchair users with a spinal cord injury or lower limb amputation. The intended application is aimed at promoting physical activity, healthy eating habits and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Injuries NEC
Study type	Interventional

# **Summary**

#### ID

NL-OMON46713

**Source** ToetsingOnline

Brief title WHEELS

### Condition

- Injuries NEC
- Spinal cord and nerve root disorders
- Bone and joint therapeutic procedures

#### Synonym

'leg amputation', 'lower limb amputation', paraplegia, 'spinal cord injury', tetraplegia

#### **Research involving**

Human

#### **Sponsors and support**

Primary sponsor: Hogeschool van Amsterdam Source(s) of monetary or material Support: RAAK-publiek subsidie (Regieorgaan SIA;onderdeel van NWO)

#### Intervention

**Keyword:** lower limb amputation, mobile lifestyle application, spinal cord injury, wheelchair user

#### **Outcome measures**

#### **Primary outcome**

- Process factors: usability, ease of use and satisfaction with the app. These factors are measured using semi-structured interviews.

The app to be developed will consist of 3 modules that focus on: 1) healthy physical behaviour (physical activity); 2) healthy eating habits; and 3) healthy relaxation and sleep habits. For evaluation of these 3 modules the primary study parameters are as follows:

#### Module 1

Physical activity will be measured using an activity monitor (acceleromete).
The participants will wear this monitor as a watch around the wrist for five
consecutive days (24 hours a day). The accelerometer data will be collected
before, halfway and after the intervention. In addition, physical activity will
be measured with an exercise diary that the participants can complete in the
app.

#### Module 2

- Total daily energy intake is measured with a 3-day food diary that will be completed before and after the intervention.

2 - WHeelchair ExercisE and Lifestyle Study 13-05-2025

- Body composition (bio-impedance analysis), body-mass index and waist circumference are measured before and after the intervention.

#### Module 3

- The sleep-wake rhythm will be measured with the same accelerometer with which physical activity is measured. From the accelerometer data the following parameters will be distilled: total sleep time (time in bed), sleep period (actual minutes of sleep), nocturnal awakening and sleep efficiency (ratio between the total sleep time and the sleep period).

#### Secondary outcome

Secondary study parameters:

- Physical activity will be measured with the Physical Activity Scale for

Individuals with Physical Disabilities (PASIPD).

- Multidimensional fatigue will be measured with the 20 items of the Individual Strength Checklist (CIS20R)

- Self-efficacy will be measured with the Dutch version of the General Self

Efficacy Scale (10 items) and the Spinal Cord Injury Exercise Self Efficacy

Scale (10 items).

- Health-related quality of life will be measured with the SF-36E. In this

enabled version of the SF-36 the items of the physical functioning scale are

adapted for use in wheelchair users.

# **Study description**

#### **Background summary**

Physical inactivity, excessive weight and low vitality are highly prevalent in wheelchair users with a spinal cord injury or lower limb amputation. During clinical rehabilitation, they receive support in developing a healthy lifestyle, however in the transfer from rehabilitation to the home setting they face many challenges that hamper its maintenance. Therefore, professionals are looking for a flexible approach with which they can respond to the individual wishes and needs of their clients. They see a great deal of potential in the use of a mobile lifestyle application. This enables them to set up a stimulating program together with the client and to monitor the progress or lack thereof. At the moment, however, there is no lifestyle application available that can be used to promote an active lifestyle, a healthy diet and healthy sleep and relaxation habits in wheelchair users.

#### **Study objective**

To systematically develop a mobile lifestyle application + counseling program for wheelchair users with a spinal cord injury or lower limb amputation. The intended application is aimed at promoting physical activity, healthy eating habits and healthy sleep and relaxation habits, and can be used blended or stand-alone. After development of the application and counseling program, these will be evaluated through a pilot study.

#### Study design

Intervention stuidy (small pilot study). Thirty wheelchair users will use the mobile lifestyle application for 12 weeks. They will use the app to set individual lifestyle goals (aimed at healthy physical activity, eating and relaxation/sleep behaviour) that they then try to achieve. Half of participants will use the app 'stand-alone'. The other half will use the app 'blended' with distant lifestyle counselling from a professional. The participants will be randomly assigned to one of the two groups. Because the two groups are relatively small we will not study differences between the groups. However, we will use semitructured interviews to examine whether the two groups experience differences in ease of use and satisfaction. This provides information whether the app is suitable for both 'stand-alone' and 'blended' use.

#### Intervention

The participants will use the app to set individual lifestyle goals (aimed at healthy physical activity, eating and relaxation/sleep behaviour) that they then try to achieve. Half of participants will use the app 'stand-alone'. The

other half will use the app 'blended' with distant lifestyle counselling from a professional. At the start of the intervention, all participants receive instruction about, and demonstration of, the use of the app.

The participants in the 'blended' lifestyle counselling group are assigned a lifestyle coach. The intervention starts with a face-to-face consultation (30 minutes) in which the coach and participant set individual lifestyle goals. The coach then contacts the participant after 3, 6 and 9 weeks to discuss the progress and, if necessary, to adjust the program. These counselling moments last 10-15 minutes and take place via the app, telephone, skype or e-mail. After 12 weeks, the program ends with a face-to-face interview (10-15 minutes).

The participants in the 'stand-alone' group will use the app independently. The app provides them with a personalized lifestyle advice based on personal characteristics and individual lifestyle goals. These participants will also use the app to work on their lifestyle for 12 weeks.

#### Study burden and risks

- 1 x visit to the rehabilitation centre for the sports medical examination (only applies to participants for which the researcher deems this necessary based on their medical background [1 hour]), instruction on the use of the activity monitor, bio-impedance analysis (BIA) and height and weight measurement (30 minutes).

-  $1 \times 1$  x visit to the rehabilitation centre for instruction on use of the app (1 hour). Participants for whom this is a problem receive this instruction at home.

- 1 x visit to the rehabilitation centre for an interview to measure usability, ease of use and satisfaction (45 minutes), BIA and weight measurement, and to hand in the activity monitor (15 minutes).

- Completing 2 questionnaires (before and after the intervention, 30-45 minutes each)

- Completing a 3-day food diary before and after the intervention.

- Wearing the activity monitor around the wrist 3 times for 5 days and nights: before, halfway and after the intervention .

There are no significant health risks associated with participation.

# Contacts

Public Hogeschool van Amsterdam

Dokter Meurerlaan 6

Amsterdam 1067 SM NL **Scientific** Hogeschool van Amsterdam

Dokter Meurerlaan 6 Amsterdam 1067 SM NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- Spinal cord injury or lower limb amputation
- At least partly wheelchair dependent
- Time since clinical rehabilitation \* 1 year (chronic phase)
- Age \* 18 years
- Access to a smartphone or tablet with internet connection and able to control it.

- Inactivity as defined by a reference score of <30 metabolic equivalent (MET) h/week on the Dutch Physical Activity Scale for Individuals with Physical Disabilities (PASIPD)

### **Exclusion criteria**

- Cognitive impairments that impede use of the mobile lifestyle app.
- Physical impairments that impede use of the mobile lifestyle app.
- Progressive disease
- Psychiatric disorders that impede participation.

# Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	07-01-2019
Enrollment:	30
Туре:	Anticipated

# **Ethics review**

Approved WMO Date:	15-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

# **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

ССМО

**ID** NL64035.048.17