Wheels intervention study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21833

Source
Nationaal Trial Register

Brief title
D-ACT Wheel

Health condition

Wheelchair dependent individuals

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: NWO, FAPESP

Intervention

Outcome measures

Primary outcome

Physical behavior measured by Fitbit will be the primary outcomes. Registered steps combined with measured heart rate is calculated into the amount of kilocalories burned by a population specific formula.

Secondary outcome

Body composition: self reported weight, BMI and waist circumference.

Nutrient intake: Food diary of three consecutive days to determine consumed kilocalories and macronutrients (carbohydrates, protein, fat) at the three measurement occasion.
Questionnaires: Health related quality of life (SF36-E), Pittsburgh sleep quality index (PSQI), State of change towards physical activity and nutrition (SAS), Body satisfaction questionnaire, Exercise self-efficacy scale (ESES), Checklist individuals strength (CIS20R).

Study description

Background summary

Evaluate the effectiveness of a newly developed lifestyle platform designed specifically for wheelchair dependent individuals with spinal cord injury or lower limb amputation. The platform could support users towards a healthier lifestyle by providing feedback, monitoring options and other tools. The platform is focuses on improving physical activity behavior, physical fitness, strength and nutrition habits which possibly could lead to changes in body composition, improved health and quality of life and reduced risks on secondary health problems.
The platform includes the combination of a mobile application and website which are connected to a smartwatch (Fitbit). Feedback, monitoring, information and exercise examples are presented in the application. Energy intake can be logged and energy expenditure is estimated based on a population specific formula. This provides users to gain insight in their daily energy balans.
A double-baseline controlled trial is proposed, starting with a 12 weeks control period, followed by a 12 weeks intervention period. Each participant will act as their own control. Throughout the whole study period of 24 week participants are asked to wear a Fitbit. Three measurements are scheduled, before the control period, after control/before intervention period, after intervention period.

Study objective

The use of the newly developed lifestyle platform supports a transition towards a more healthier lifestyle for wheelchair dependent individuals with spinal cord injury or lower limb amputation.

Study design

Participants are asked to fill in the questionnaire in their first week and wear a Fitbit smartwatch. After 1 week, participants will receive access to an online platform/application which includes tool to improve lifestyle for the next 12 weeks. At the end of the 12 weeks all questionnaires are administered again.

Intervention

1 week control period followed by a 12 weeks intervention period where a lifestyle platform is

introduced as a tool to improve the lifestyle.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 75 years
- Dependent on a manual wheelchair (daily use of the wheelchair at longer distances of 500m or more).
- Access to a smartphone or tablet with internet connection.
- Does not meet the minimum requirements of SCI guidelines for adults (at least: 3 times a week moderate to vigorous intensity for 30 minutes; at least: 2 times a minimum of 3 different strength exercises with additional resistance).

Exclusion criteria

- Severe co-morbidities (Diabetes type II individuals can only be included when sugar levels are in control).
- Insufficient knowledge of the Dutch language to understand the purpose of the study and the content of the mHealth platform.
- Not available for a period of 24 weeks in a row (absent for more than 3 weeks consecutively during the 24 weeks period).
- Pregnant.
- Musculoskeletal injuries of the upper extremities that negatively influence performance of intervention exercises and wheelchair propulsion.
- Presence of pressure ulcers that prevents participants from exercising.
- Presence of pacemaker.

- Negative advise from physician to be physical active without supervision based on a medical screening.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49244

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8225
CCMO	NL72119.078.19
OMON	NL-OMON49244

Study results