Wheels intervention study

Gepubliceerd: 12-12-2019 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21833

Bron
NTR

Verkorte titel
D-ACT Wheel

Aandoening

Wheelchair dependent individuals

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: NWO, FAPESP

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

1 week control period followed by a 12 weeks intervention period where a lifestyle platform is introduced as a tool to improve the lifestyle.

Contactpersonen

Publiek

Vrije Universiteit
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49244
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten