Wheels lifestyle intervention study.

Published: 03-04-2020
Last updated: 20-06-2024

Primary objective:Does the use of the application support a positive lifestyle development?Secondary objectives:Does the use of the application support an increase in physical activity levels?Does the use of the application has a positive influence...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49244

Source
ToetsingOnline

Brief title
D-ACT Wheel project

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
Rolstoel gebruikers

Health condition

Beenamputatie(s), andere rolstoel gebonden mensen.

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: NWO;FAPESP

Intervention

Keyword: Application, Lifestyle, Wheelchair users

Outcome measures

Primary outcome

The primary study parameter will be the physical activity behaviour of the participants, whether this has changed overtime during the intervention period. Physical activity will be monitored overtime by a Fitbit Charge 3 during the whole study period. The outcome measure used is the amount of registered daily 'steps' which is subsequently transferred and calculated and estimated into amount of burned Kcals by a population specific formula.

Secondary outcome

The following secondary outcomes will be used:

Nutritional habits: three day diary of amount of kcal consumed and percentage macronutrients (%carbohydrates, %fat, %protein).

(Health related) Quality of life and sleep quality with the following questionnaires: SF36E, ESES, PSQI, CIS20R, SAS, body satisfaction.

Self reported body composition: weight in kg's, height in cm's, wait circumference in cm's, BMI.

User experience: SUS questionnaire.

Study description

Background summary

An active lifestyle is known to be beneficial for a person*s health. This seems even more important for wheelchair users because it also influences their level

of functioning. Physical inactivity, obesity and low vitality are, however, common among such users with spinal cord injury (SCI) or lower limb amputation (LLA), and are risk factors for secondary health problems and a reduced quality of life. It is, therefore, important that wheelchair users are being encouraged to achieve and maintain an active lifestyle during and after inpatient rehabilitation. Despite encouragement during inpatient rehabilitation, it is difficult for wheelchair users with SCI or LLA to maintain the adopted activity level once discharged. One of the reasons for this is the limited availability in professional guidance after discharge, which often leads to a decrease in physical activity after discharge, resulting in increased risks to develop obesity and secondary health problems. Additional guidance is clearly necessary after inpatient discharge to facilitate an active lifestyle in wheelchair users with SCI or LLA. Additional support to fill this gap can be achieved through mobile health (mHealth).
mHealth provides the opportunity to support and monitor an active lifestyle on individual and group level. Benefits of mHealth include easy access to information and advice, feedback, self-monitoring, social support, reinforcement and goal setting, and it is a promising tool in supporting changes in lifestyle related behavior, such as diet and physical activity behavior. The use of such techniques on lifestyle related determinants mediates in the potential effectiveness of the mHealth platform. However, determinants of physical activity can vary between populations and are different in individuals with a disability or who are wheelchair dependent. So far, there is no mHealth platform for this specific target group. An existing lifestyle platform was therefore adapted based on the intervention mapping protocol. Modifications were made to the wishes and needs of wheelchair users with SCI or LLA together with professionals working with them. Due to different barriers and facilitators for physical activity in daily life in wheelchair users, different strategies are necessary. Behavioral change strategies were developed and implemented in the lifestyle platform based on focus group outcomes.
It remains unclear which effect the platform has on the physical behavior and lifestyle on wheelchair users. Therefore a double-baseline controlled trial is proposed to investigate the effect of the platform on wheelchair users to gain insight in possible changes in physical activity, nutritional habits, strength, body composition and quality of life.

Study objective

Primary objective:
Does the use of the application support a positive lifestyle development?

Secondary objectives:
Does the use of the application support an increase in physical activity levels?
Does the use of the application has a positive influence on body composition?
Does the use of the application has a positive influence in nutritional habits?
Does the use of the application has a positive influence on sleep quality?

Study design

A so called 'one group prestest posttest' design is suggested in which each participant is measured before and after the intervention period.
All outcomes are measured with a pre-post test design, except data collected with the Fitbit.
Participants will perform all measurements one week in advance before the intervention period (questionnaires and self-reported body composition) and will start wearing the Fitbit during this week.
After wearing the Fitbit for one week, participants will receive access to the WHEELS application to support a positive lifestyle change. De registered Fitbit data during the week before the intervention study on physical activity and sleep will be used as pre intervention data. This data can then be used as comparison of the physical and sleep behavior throughout the intervention period.
after the 12 weeks have passed, participants will be asked to perform the same questionnaires and when possible self-reported body composition measurements with an additional questionnaire to gain insight about their experience and satisfaction about the application.

Intervention

During the first week participants will be asked to start wearing the supplied Fitbit as much as possible (day and night) and perform all questionnaires that will be presented digitally.
After the first week, participants will receive access to the WHEELS platform in order to support them with a change towards a more healthy lifestyle. The platform, a combination of an application and a website connected with a Fitbit, could provide support in improving their lifestyle on physical activity, nutritional habits and sleep & relaxation, which will act as the intervention.This Fitbit will provide the user feedback on activity level and sleep quality. During the 12 week intervention period, participants are asked to wear the Fitbit as much as possible. Throughout the whole process the research team will remain available for support and questions regarding the use of the application and Fitbit.
After the 12 week intervention period, participants are asked to finish all questionnaires again.

Study burden and risks

Considering that potential participants are screened with the ACSM risk profile questionnaire before the start of the intervention study, limited risks are present for participants to get involved in physical activity without supervision.

Possible benefits of participating in this intervention study is an improved

lifestyle, possibly on multiple aspects. If the intervention is effective, beneficial changes can occur on physical activity level, body composition, nutritional habits, sleep quality, health and/or quality of life. Participants will keep access to the application after completing the study.
Therefore the time needed and burden during this research are justified, since it might possibly benefit the health of the participant eventually.

No direct in-person contact with any researcher is needed, in order to minimalize possible risks of the COVID 19 virus. All measurements can be administered and measured at home and are self-reported.

Contacts

Public
Reade

Overtoom 283
Amsterdam 1054HW
NL
Scientific
Reade

Overtoom 283
Amsterdam 1054HW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 application
- Not available for a period of 13 weeks in row (absent for more than 3 weeks consecutively)
- Pregnant
- Musculoskeletal injuries of the upper extremities that negatively influence performance of intervention exercises and wheelchair propulsion.
- Presence of pressure ulcers
- Presence of pacemaker
- Negative outcome (classified as high risk) on the ACSM risk profile screening.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21833
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72119.078.19