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A self-management intervention aimed to increase an active lifestyle in persons with a long-term spinal cord injury to: the HABITS (Healthy active behavioural intervention in spinal cord injury) study

Submission date
31/08/2015

Recruitment status
No longer recruiting

Registration date
07/09/2015

Overall study status
Completed

Last Edited
03/09/2015

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The spinal cord is a bundle of nerve fibres which is encased in a bony column (known as the spine). It is the most important link between the brain and the other nerves in the body (peripheral nervous system). Damage to the spinal cord (spinal cord injury, SCI) can lead to serious consequences. SCI can range from mild to severe, and can cause a partial or total loss of movement, often leaving people with life-long disability. People with a SCI are often not very active, as they are usually confined to a wheelchair. This study is part of a research programme to help encourage people with a long-term SCI to become more physically active. The programme works by giving people the tools, skills and support to have a healthy and active lifestyle, as well as helping them to cope better with day to day life. The aim of this study is to find out whether a programme such as this can help people suffering from a long-term SCI to become more active and become more independent.

Who can participate?
Adults who have been suffering from SCI for at least 10 years and are not very active.

What does the study involve?
Participants are randomly allocated into one of two groups. Participants in the first group (intervention group) are enrolled in a 16 week self-management course designed to help them lead a more active lifestyle. These courses consist of one home visit, five group meetings, and five individual sessions and each participant is given a personal counselor to help them through the process. Participants in the second group (control group) are given information about how to have an active lifestyle in the form of one meeting and an information booklet. Levels of physical activity are measured using questionnaires at the start of the study, at the end of the intervention period (week 16), and six months after the intervention (week 42).

What are the possible benefits and risks of participating?
Participating in this study is beneficial as having an active and healthy lifestyle is important good general health. The skills taught to participants will help them to maintain an active lifestyle long-term. There are not significant risks of participating, as all patients will still receive normal care. Participating will cost time and some physical effort for all patients in terms of the tests, questionnaires and keeping a diary.

Where is the study run from?
1. Rijndam Rehabilitation Centre (Netherlands)
2. De hoogstraat Rehabilitation Centre (Netherlands)
3. Roessingh Rehabilitation Centre (Netherlands)
4. Adelante Rehabilitation Centre (Netherlands)

When is the study starting and how long is it expected to run for?
January 2011 to December 2014

Who is funding the study?
1. Netherlands Organisation for Health Research and Development (Netherlands)
2. Fonds NutsOhra (Netherlands)

Who is the main contact?
1. Ms Hedwig Kooijmans (Scientific)
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2. Dr Johannes Bussmann (Scientific)

Study website
www.scionn.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized controlled trial of a self-management intervention aimed to increase an active lifestyle in persons with a long-term spinal cord injury: the HABITS (Healthy Active Behavioural IntervenTion in SCI) study

Acronym
HABITS

Study objectives
This intervention will show beneficial effects on:
1. A more active lifestyle
2. Self-management skills, such as proactive coping, problem-solving ability and self-efficacy
3. That participants with improvements in self-management skills will show more favourable effects on active healthy lifestyle than participants who do not improve in self-management skills.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasmus MC Medical Ethics Committee, 14/10/2011, ref: MEC-2011-225

Study design
Double-blinded multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Spinal cord injury

Interventions
Study participants were randomized to a 16 week self-management intervention consisting of one home-visit, 5 group-meetings, 5 individual sessions and a personal counselor in order to improve self-management skills that would facilitate behavior change towards an active lifestyle, or to a control group that only received information about an active lifestyle by one meeting and a booklet.

Intervention Type
Behavioural

Primary outcome measure
1. Objectively measured physical activity, is assessed by the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD), at baseline, 16 weeks and 42 weeks.
2. Subjectively measured physical activity is measured at baseline, 16 weeks and 42 weeks, by two accelerometer-based devices (ActiGraph GT3X+) [34]. One accelerometer attached at the wrist, the other to the spokes of one wheelchair wheel with special Velcro bands. Based on the results of the two accelerometers, a custom-made algorithm in MatLab differentiates between self-propelled wheelchair driving and other activities.

Secondary outcome measures
1. Self-management skills (self-efficacy, proactive coping) are measured at baseline, 16 weeks and 42 weeks with two scales:
1.1. The SCI exercise self-efficacy scale, measures self-reported self-efficacy for various types of physical exercise in individuals with SCI
1.2. The Utrecht Proactive Coping Competence scale , which assesses an individual’s experienced competency with regard to the various skills associated with proactive coping.
2. Stages of exercise change is measured at baseline, 16 weeks and 42 weeks using the Questionnaire University of Rhode Island continuous measure to assesses the six stages of change for regular exercise (based on the Trans-theoretical model)
3. Attitude, which is measured using the Exercise: Decisional Balance questionnaire at baseline, 16 weeks and 42 weeks. This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behavior.

Overall study start date
01/01/2011

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Spinal cord injury (for at least 10 years)
2. Aged between 28-65 years
3. PASIPD score (Physical activity scale for individuals with physical disabilities) lower than the 75th percentile of a Dutch SCI population
4. Ability to use a hand-rim wheelchair

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Progressive disease or severe co-morbidities
2. Psychiatric problems that would interfere with the study
3. Insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods
4. No intention to change exercise behaviour in the next 6 months

Date of first enrolment
01/05/2012

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Rijndam Rehabilitation Centre
Rotterdam
Netherlands
3015 LJ

Study participating centre
De hoogstraat Rehabilitation Centre
Utrecht
3583 TM

Study participating centre
Roessingh Rehabilitation Centre
Enschede
7500 AH

Study participating centre
Adelante Rehabilitation Centre
Hoensbroek
6432 CC

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMW)

Sponsor details
Postbus 93 245
Den Haag
Netherlands
2509 AE

Sponsor type
Government

Organisation
Fonds NutsOhra

Sponsor details
Postbus 229
Amsterdam
Netherlands
1000 AE

Sponsor type
Other

Organisation
Netherlands Organisation for Health Research and Development

Sponsor details

Sponsor type
Not defined

Website
http://www.zonmw.nl/en/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Fonds NutsOhtra

Results and Publications

Publication and dissemination plan

The results of this study will be presented in international scientific journals. Results will be orally presented at national and international congresses.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other