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A randomized controlled trial evaluating effects on health for individuals with mobility disability: eHealth vs. standard care

Submission date
04/02/2018

Recruitment status
No longer recruiting

Registration date
03/04/2018

Overall study status
Completed

Last Edited
08/06/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Young adults with mobility disability (MD) are less likely to take part in regular physical activity (PA) compared with their able-bodied peers, and inactive adults with MD are 50% more likely to report one or more chronic diseases compared to those who are physically active. Despite the vast amount of research published in the field of PA interventions, little attention has been on interventions aiming to increase PA among individuals with MD. This study aims to evaluate the effect of an eHealth programme compared to standard care lifestyle exercise programme.

Who can participate?
Adults aged 18-35 with mobility disability

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the first group receive a 12 week eHealth walking and exercise programme delivered via smartphone apps. The other group receive standard care individualized lifestyle exercise and dietary programme, lead by healthy educators and personal trainers in face to face weekly sessions. Participants have outcomes measured before the programme, at programme midpoint (6 weeks), end point (12 weeks) and one year after completion.

What are the possible benefits and risks of participating?
Participants may benefit from health improvements from increased physical activity. Participation is associated with low risk from low intensity physical activity and VO2max testing. Blood samples are taken by a nurse.

Where is the study run from?
TWITCH Healthcare AB (Sweden)

When is the study starting and how long is it expected to run for?
August 2017 to April 2019

Who is funding the study?
Swedish Research Council for Health, Working life and Welfare (FORTE) (Sweden)

Who is the main contact?
Dr Daniel Berglind (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
An eHealth based health program vs. a standard care health program randomized controlled trial for individuals with mobility disability

Study objectives
An eHealth based exercise program entails similar increases in moderate to vigorous physical activity, at 12 weeks and at 12 months' follow-up, compared with a standard care supervised lifestyle exercise programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stockholm Ethical Review Board, 06/09/2017, ref: 2017/1206-31/1

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Participant information material can be found at: https://www.twitchhealth.se/wp-content/uploads/Informationsbrev.-RCT-MD.-webb.pdf

Health condition(s) or problem(s) studied
Self-reported mobility disability

Interventions
A block randomized control design allocates the sample of young adults with MD into two equal groups. Those in the eHealth group have a low-cost 12 week walking and exercise programme delivered via smartphone apps (a walking app, an exercise app and a food photography app). These also provide training/health advice and feedback. The other group receive a 12 week standard care individualised lifestyle exercise and dietary programme delivered by health educators and personal trainers. This includes face to face counselling and weekly personal trainer led sessions.

The 12 weeks' trial will examine the efficacy of an eHealth vs. a standard care exercise program on PA level (primary outcome) and as secondary outcomes effects on health related quality of life, musculoskeletal pain, perceived stress, symptoms of depression, eating behavior, workability, body composition and fitness. Examinations will be performed at baseline, midpoint (week 6), at the end of the intervention (week 12) and 12 months' post intervention.

Intervention Type
Behavioural

Primary outcome measure
Levels of moderate to vigorous physical activity (MVPA) measured by the Actigraph GT3X+ accelerometer at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention

Secondary outcome measures

1. Health related quality of life is measured by SF-36 at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
2. Musculoskeletal pain is measured by visual analogue scale (VAS) at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
3. Perceived stress is measured by the perceived stress scale at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
4. Symptoms of depression is measured by the Beck Depression Inventory-II baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
5. Eating behavior is measured by a 24 hour recall questionnaire at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
6. Workability is measured by the symptom of depression questionnaire (SDQ) at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
7. Body composition is measured by bioelectrical impedence (BIA), weight, height, and waist circumference measures at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
8. Fitness is measured by the Elin-Ekbom-Bak submaximal VO2max test at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention
9. Blood samples will be taken for genetic/epigenetic analysis at baseline, 6 weeks (midpoint of intervention), 12 weeks (endpoint of intervention) and 12 months post intervention.

Overall study start date
01/08/2017

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Classified with a mobility disability, acquired within the past three years
2. Aged 18-35 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants

110

Total final enrolment
110

Key exclusion criteria
1. Problems walking

Date of first enrolment
01/03/2018

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Sweden

Study participating centre
TWITCH Healthcare AB
Stockholm
Sweden
11323

Sponsor information

Organisation
Karolinska Institute

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Sponsor type
University/education

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ROR

https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name
Swedish Research Council for Health, Working Life and Welfare, FORTE (Forskningsrådet om Hälsa, Arbetsliv och Välfärd)

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journals.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Daniel Berglind, daniel.berglind@ki.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/04/2018		Yes	No
Results article	results	04/02/2020	06/02/2020	Yes	No
Results article	Secondary analysis	03/02/2022	08/06/2023	Yes	No

Results article	16/11/2020	08/06/2023	Yes	No