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Self-management training: a controlled investigation of its effectiveness in improving coping skills, mood and quality of life with patients with acquired physical disability

Submission date
10/02/2015

Recruitment status
No longer recruiting

Registration date
19/02/2015

Overall study status
Completed

Last Edited
20/02/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People with acquired physical impairments, such as limb amputation and spinal cord injury, commonly experience additional problems including pain, anxiety and depression. These problems can prevent them from participating fully in society and can diminish their quality of life (QoL). Traditionally, attempts to improve well-being for people with physical impairments have focused on treatment of these problems after they have become established. Opportunities for early intervention to manage pain and other problems before they become chronic are typically missed.
Self-management (SM) interventions have been developed in the context of patient-centred care, where patients are empowered to take a central role their health and well-being. SM interventions aim to provide patients with the necessary skills and confidence to deal with health-related problems and to manage negative emotions. SM has been used widely in chronic illnesses in which pain and disability are common. However, SM has not been used as a preventive intervention during the early rehabilitation phase following physical impairment.
The aim of our research is to investigate how well an SM programme works for the prevention of disabling secondary conditions and improvement of QoL following the onset of significant physical impairment. The key objective is to improve health and wellbeing. As the impact of acquired physical impairment extends beyond the individual patient to families and friends, improving health and quality of life for the patient will have positive spill over effects for families, friends and wider communities.

Who can participate?
Adults with limb amputation or spinal cord injury.

What does the study involve?
Participants are randomly allocated to one of two groups: receiving usual care plus the “Next Steps UK and Ireland self-management programme” or receiving usual care only.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
National Rehabilitation Hospital, Ireland

When is the study starting and how long is it expected to run for?
From February 2011 to July 2014.

Who is funding the study?
National Health Research Board (Ireland)

Who is the main contact?
Dr Deirdre Desmond
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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
HRB_HSR/2010/12

Study information

Scientific Title

Promoting quality of life and preventing secondary disability following acquired physical impairment: a controlled trial of a self-management intervention

Study objectives
1. Compared to standard treatment alone, individuals who receive the self-management intervention plus standard care will have lower levels of depressive and anxiety symptoms, and improved positive affect and positive mindset.
2. Compared to standard treatment alone, individuals who receive the self-management intervention will have higher levels of participation and health related quality of life.
3. Changes in both primary and secondary outcomes will correlate strongly with the intermediate outcome of self-efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Rehabilitation Hospital Ethics Committee, Maynooth University Ethics Committee

Study design
Single-centre controlled clinical trial (two group block randomized design)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with acquired physical impairment (spinal cord injury and limb amputation)

Interventions
Participants were allocated to control or intervention groups according to timing of admission. Control group participants received usual care. Participants in the intervention group received usual care plus the 'Next Steps UK & Ireland self-management programme'.

Intervention Type
Behavioural

Primary outcome measure
1. Pain: Brief pain Inventory
2. Depressive Symptoms: Hospital Anxiety and Depression Scale

3. Positive Affect: Positive and Negative Affect Schedule Positive States of Mind scale
Data collected on admission to rehabilitation, 7 weeks later and at 6 months post-programme.

Secondary outcome measures
1. Restrictions in Activities and Participation: WHODAS-II and the Community Participation Indicators
2. Self-management knowledge, skills, confidence: Patient Activation Measure (SF)
3. Quality of Life: WHOQoL
Data collected on admission to rehabilitation, 7 weeks later and at 6 months post-programme.

Overall study start date
01/02/2011

Completion date
01/12/2015

Eligibility

Key inclusion criteria
Inclusion criteria consist of (1) being aged 18 years or older; (2) having limb amputation or spinal cord injury; (3) English speaking; (4) no more than 3 weeks previous inpatient rehabilitation for the current condition; onset of index injury/condition within 1 year.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
Exclusion criteria: unable to provide informed consent; severe cognitive impairment; presence of any other serious health condition that attending physician believes limits their ability to participate in the study.

Date of first enrolment
01/08/2011

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Ireland

Study participating centre
National Rehabilitation Hospital
Ireland

Sponsor information

Organisation
Maynooth University

Sponsor details
Co.Kildare
Maynooth
Ireland
Maynooth

Sponsor type
University/education

Website
https://www.maynoothuniversity.ie/research

ROR
https://ror.org/048nfjm95

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland)

Results and Publications

Publication and dissemination plan

Primary outcome data will be presented at the International Society for Prosthetics and Orthotics World Congress in June 2015. We anticipate peer review publication by the end of 2015.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available