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Soft extra muscle glove study for spinal cord injury

Submission date
31/05/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
10/03/2020

Condition category
Nervous System Diseases

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

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 spinal cord injury (SCI) can suffer from significantly impaired hand function. Conventional hand therapy is usually offered in the relatively early stages of SCI but individuals with long-term SCI still experience significant problems which affect activities of daily living (routine activities that people tend do every day without needing assistance) and quality of life. This study is looking at a unique device called the soft extra muscle (SEM) Glove. The SEM glove detects the voluntary effort to grasp an object and proportionally 'strengthens' the hand to complete the grasping function. The aim of this study is to test the benefits of the SEM Glove as an assistive device and a rehabilitation device.

Who can participate?
Adults with tetraplegia (partial or total loss of use of all four limbs and torso) who have had SCI for at least one year.

What does the study involve?
All participants are provided with a SEM Glove unit to use for activities of daily living for a total of 12 weeks in their own homes. Participants visit the National Spinal Injuries Centre at the start of the study and after six, 12 and 18 weeks in order to complete assessments of function, pain and independence, as well as questionnaires about their quality of life and the usability of the glove.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their performance of activities of daily living. Long-term use of the glove may also have a long-term rehabilitative effect. There are no notable risks involved with participating.

Where is the study run from?
National Spinal Injuries Centre (UK)

When is study starting and how long is it expected to run for?
January 2016 to April 2018

Who is funding the study?
1. Anatomical Concepts (U.K.) Limited (UK)
2. Bioservo Technologies AB (UK)
3. Stoke Mandeville Spinal Research (UK)

Who is the main contact?
Dr Julian Taylor
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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
31283

Study information

Scientific Title
Clinical trial of the Soft Extra Muscle Glove to assess orthotic and long-term functional gain following chronic incomplete tetraplegia: A longitudinal mixed methods study

Study objectives
The aim of this study is to test the benefit to chronic spinal cord injury (SCI) individuals wearing a unique assistive device called the soft extra muscle (SEM) Glove.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, 22/05/2016, ref: 16/LO/1007

Study design
Both; Design type: Device, Cohort study; Longitudinal interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Neurological disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the abdomen, lower back, lumbar spine and pelvis

Interventions
Participants will be provided with a SEM Glove unit to use for activities of daily living for a total of 12 weeks.

Using questionnaires, neurophysiological and functional measures, the participants will be assessed before, at 6, 12 weeks and followed after 18 weeks of using the glove in their own homes. The functional outcome measures will be performed with and without the participants wearing the glove during the baseline recording and at 12 weeks

Intervention Type
Other

Primary outcome measure
Hand function is measured using dynamometry and Toronto Rehabilitation Institute hand function test at baseline, 6 week,12 weeks and 18 weeks.

Secondary outcome measures
1. Pain is measured using the Visual analogue scale (VAS) at baseline, 6 week,12 weeks and 18 weeks.
2. Sensation is measured using The Rivermead Assessment of Somatosensory Performance (RASP) at baseline and 12 weeks
3. Spasticity is measured using Modified Ashworth Scale (MAS) test:- at baseline, 6 week,12

weeks and 18 weeks.
4. Spinal cord injury level is measured using the American Spinal Injury Association Impairment Scale (AIS) at baseline and 12 weeks
5. Performance and satisfaction rating of selected activities is measured using Canadian Occupational Performance Measure (COPM) at baseline and 12 weeks
6. The level of independence is assessed using the self-care sub-scale of spinal cord independence measure (SCIM) at baseline and 12 weeks
7. Quality of life is measured using the short form 36 at baseline and 12 weeks
8. The usability of the glove is assessed using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) at 12 weeks

Overall study start date
25/01/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Aged 18-65 years
2. Incomplete tetraplegia (spinal level C2 – C8) , AIS grade C or D
3. At least 12 months post SCI (chronic)
4. Reduced muscle power resulting in reduced grip/pinch strength

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 15; UK Sample Size: 15

Total final enrolment
15

Key exclusion criteria
1. Known neurological condition, comorbidity (eg. brain injury).
2. A person unable to understand verbal or written information in English.

Date of first enrolment
01/11/2016

Date of final enrolment
30/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Spinal Injuries Centre
Stoke Mandeville Spinal Research
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Sponsor information

Organisation
Buckinghamshire Healthcare NHS Trust

Sponsor details
Amersham Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/037f2xv36

Funder(s)

Funder type
Industry

Funder Name
Anatomical Concepts (U.K.) Limited

Funder Name
Bioservo Technologies AB

Funder Name
Stoke Mandeville Spinal Research

Results and Publications

Publication and dissemination plan
Publication is planned in a high-impact peer reviewed journal.

Intention to publish date
21/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Bethel.Osuagwu@smsr.org.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3.0	08/06/2016	01/06/2017	No	Yes
Results article	results	05/03/2020	10/03/2020	Yes	No
HRA research summary			28/06/2023	No	No