Stop-rule management in patients with sub-acute chronic pain (WRUEP): a randomized controlled and replicated single-case experimental ABCD design.

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To test if a new intervention, aimed at learning to use stop-rules in a flexible way(Stop Rule Management, SRM), has a more positive effect on the disability and quality of life of patient with non specific WREUP, than a regular rehabilitation...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32917

Source
ToetsingOnline

Brief title
Stop-rule management in work related upper extremity pain

Condition

- Other condition

Synonym
Repetitive Strain Injury (RSI), Work Related Upper Extremity Pain (WRUEP)

Health condition

Chronische pijn

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Vernieuwingsimpuls subsidie nummer 453-04-003.

Intervention

Keyword: Chronic pain, Mood as input, Stop-rules, Task performance

Outcome measures

Primary outcome

Functional disability (UEFS, DASH)

Quality of life (SF-36)

Participation and autonomy (IPA)

Secondary outcome

o Demographic variables (sex, age, education, onset of pain, smoking habits,

previous treatments, co-morbidity)

o Stop-rules (HASQ)

o Pain related fear (TSK, PHODA-UE)

o Pain catastrophizing (PCS)

o Mood (PANAS)

o Responsibility (RQ)

o Physical activity in daily life (Actiwatch, PARQ)

o Pain intensity (MPQ-SF)

o Tenacious goal pursuing (TGPS)

Study description

Background summary

Chronic musculoskeletal pain comprises an important problem in health care and society. The fear-avoidance model has been successfully tested in chronic pain patients with avoidance behaviour, but this model appears less applicable in pain disability associated with task persistence and overuse often seen in patients with non-specific Work Related Upper Extremity Pain (WREUP). The aim of the present study is to test a novel integrative model that is based on the *mood as input* paradigm, which may account for both pain responses: task escape/avoidance and task persistence, both within and between individuals. *Mood as input* theory assumes that the informational value of the mood, rather than the mood itself, determines whether participants persist at a certain task. The basic tenet is that escape/avoidance or persistence during a task is a function of the interaction between two relatively independent factors: mood and stop-rule.

Study objective

To test if a new intervention, aimed at learning to use stop-rules in a flexible way(Stop Rule Management, SRM), has a more positive effect on the disability and quality of life of patient with non specific WREUP, than a regular rehabilitation program (REV).

Study design

A randomized controlled and replicated single case experimnetal ABCD design (A: pretest, B and C: SRM and REV, in order determined by randomization, D: follow up).

Intervention

Subjects will be offered two treatments: stop-rule management (SRM, experimental treatment) and regular rehabilitation (REV, controll treatment)

Study burden and risks

Subjects will complete a set of questionnaires (4 times) and wear an Actiwatch during 1 week (4 times). Treatment consists of 20 hour Stop Rule Management and 22 hour regular rehabilitation. Both treatments are aimed to reduce disability and increase quality of life. During treatments, activities will be performed (work, leisure, household), in which the risks are similar to those experienced life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Non-specific pain or other symptoms in neck, shoulder, elbow, arm, wrist, hand (or combination)
2) The onset or ongoing of pain is related to work, household or other unpaid activities (for example study or education)
3) Patients experience:
. complaints (pain, local tiredness, cramping, tingling or dull feeling) during activities, but decreasing when ending the activity.
· complaints (pain, tendon-/muscle irritation, aggravated feeling, insomnia and reduced strength) after work, that decrease during evenings or weekends.
· ongoing complaints (pain, swelling, pressure pain, loss of functional abilities, changes in skin colour, temperature, dull or tingling feeling)
4) Patients have complaints for at least 6 weeks.

5) Patients are aged between 18-65 years old and have an adequate ability to fill in Dutch questionnaires.

Exclusion criteria

1) Specific complaints (biceps tendinitis, bursitis around the elbow, carpal tunnel syndrome, cervical hernia, cubital tunnel syndrome, m. Dupuytren*s syndrome, epicondylitis lateralis cubiti, epicondylitis medialis cubiti, frozen shoulder, Guyon*s canal syndrome, instability of the shoulder or elbow, labrum glenoidale ruptures, local arthritis (no RA) in an upper extremity joint, Oarsman*s wrist, radial tunnel syndrome, Raynaud*s phenomena, rotator cuff ruptures, subacromial impingement syndrome (rotator cuff syndrome, tendonitis and bursitis around the shoulder), Complex Regional Pain Syndrome-I, suprascapulair compression, triggerfinger, Quervain*s syndrome)
2) Complaints caused by acute trauma.
3) Involvement in a law suit regarding work-disability.
4) Psychopathology, assessed with the Symptom Checklist (SCL-90). Scores on IN-SEN-HOS-PSNEUR should not be *high* or *very high* compared with the norms of the group outpatient psychiatric clients.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2009
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	08-04-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
Other	candidatenumber 4326
CCMO	NL24339.068.08