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Evaluation of an education and activation programme to prevent chronic shoulder complaints: design of a randomised clinical trial

Submission date
14/02/2005

Recruitment status
No longer recruiting

Registration date
14/02/2005

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
904-65-901

Study information

Scientific Title
Evaluation of an education and activation programme to prevent chronic shoulder complaints: design of a randomised clinical trial

Study objectives
An education and activation programme in addition to usual care is more effective in increasing patient perceived recovery and reducing functional limitations than usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Shoulder complaints

Interventions
Usual care:
Usual care was applied according to the Dutch College of General Practitioners (DCGP) guidelines for shoulder complaints (version 1999). Management during the first two weeks consists of a wait-and-see policy with information and advice about shoulder complaints, possibly supplemented with analgesics or nonsteroidal anti-inflammatory drugs. If this approach has little or no effect, up to three corticosteroid injections can be given. Physiotherapy is considered for complaints persisting after six weeks or more. If the shoulder complaints persist, referral to a hospital-based specialist may be considered.

Education and activation programme in addition to usual care:
The focus of the Education and activation programme was to maintain or induce the proper cognitions by education and to stimulate adequate behaviour by means of advice on activities of daily living using principles of operant conditioning. The Education and activation programme

consisted of a minimum of two sessions and a maximum of six follow-up sessions over a period of six weeks. Each session could last up to 20 minutes.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient perceived recovery after six and 26 weeks.

Secondary outcome measures
Change in functional limitations of activities of daily living after six and 26 weeks.

Overall study start date
01/01/2000

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Patient with shoulder complaint at rest and/or elicited by movement
2. 18 years and older
3. New episode of shoulder complaints

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
111

Key exclusion criteria
1. Other episodes of shoulder complaints in previous 12 months
2. Prior fractures and/or surgery of the shoulder
3. (Suspected) referred pain from internal organs
4. Confirmed extrinsic cause
5. Inability to complete a questionnaire independently
6. Presence of dementia or other severe psychiatric abnormalities

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Mercuriusstraat 27
Brunssum
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6446 RM

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Sponsor details
Laan van Nieuw Oost Indië 334
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Sponsor type
Research organisation

Website
http://www.zonmw.nl/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type

Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Study protocol	16/02/2005		Yes	No
Results article	results	15/11/2007	26/02/2021	Yes	No