

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	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 26/02/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Patient perceived recovery after six and 26 weeks.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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
Netherlands
6446 RM

Sponsor information

Organisation

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

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

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?
Results article	results	15/11/2007	26/02/2021	Yes	No
Protocol article	Study protocol	16/02/2005		Yes	No