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

Submission date Recruitment status Prospectively registered 14/02/2005 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 14/02/2005 Completed [X] Results [] Individual participant data Last Edited Condition category Musculoskeletal Diseases 26/02/2021

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 Netherlands 6446 RM

Sponsor information

Organisation

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

Sponsor details

Laan van Nieuw Oost Indië 334 P.O. Box 93245 The Hague Netherlands 2509 AE +31 (0)70 349 5111 info@zonmw.nl

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