The Shoulder Diary

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Primary Objective To describe how patients experience the first eight weeks after shoulder arthroplasty, regarding pain and pain medication, shoulder function and quality of life. To determine the direct effect of patients' expectations on...

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON25734

Source
NTR

Brief title
Shoulder diary

Condition

- Bone and joint therapeutic procedures

Health condition

Dairy, Shoulder arthroplasty, Expectations, Postoperative trajectory Dagboek, Schoudervervanging, Verwachtingen, Postoperatief beloop

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep, afdeling orthopedie
Source(s) of monetary or material Support: Reinier de Graaf Gasthuis, Delft

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

The main endpoints are postoperative pain, shoulder function, quality of life and patient satisfaction

Secondary outcome

Not applicable

Study description

Background summary

SUMMARY

Background: To improve outcomes after shoulder arthroplasty (SA) it is essential to know which factors influence the outcome of SA. In total knee arthroplasty (TKA) and total hip arthroplasty (THA) research, the focus on the influence of psychological factors such as expectations, catastrophizing and optimism, as well as central sensitization (CS) and central pain modulation (CPM), increased in the last years. The effect of these constructs on the short-term and long-term outcomes is not completely clear: evidence regarding the effect of expectations on outcomes is inconsistent, while there is some evidence that catastrophizing and optimism influence or predict outcomes after surgery in general, and for TKA and THA in particular. For SA, very few studies have been performed on these topics. Therefore, it remains unclear whether these psychological constructs have similar effects in SA patients. Furthermore, it is still uncertain if an association between expectations and outcomes provides unique information on the role of expectations independent from catastrophizing, optimism, CS or CPM, or if these constructs interact with expectations.

Objective: The primary objectives of this study are to describe how patients experience the first eight weeks after shoulder arthroplasty with regard to pain, pain medication, shoulder function and quality of life, and to determine the direct effect of patients' expectations on postoperative pain, shoulder function, quality of life and satisfaction scores, controlled for catastrophizing and dispositional optimism. The secondary objective is to determine the

direct effect of early postoperative pain on persistent postoperative pain at six months, while controlling for or taking into account modifying or mediating effects of factors that were found to have an effect on early postoperative pain itself.

Study design: A multicenter prospective observational cohort study.

Study population: Patients who are scheduled to undergo SA at the orthopedic department of participating hospitals or at the participating orthopedic clinics. Primary study parameters/outcome: The main endpoints are postoperative pain, shoulder function, quality of life and patient satisfaction

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Since this study is solely an observational study in which patients complete questionnaires and will not undergo additional assessment compared with usual care, the burden of participation consists only of filling in sets of questionnaires at baseline, six months postoperatively and twelve months postoperatively. In addition, a daily diary will be kept for the first eight weeks, which will take approximately three minutes per day. We do not expect any risks associated with participation. There is no direct benefit for the participants.

Study objective

Primary Objective To describe how patients experience the first eight weeks after shoulder arthroplasty, regarding pain and pain medication, shoulder function and quality of life. To determine the direct effect of patients' expectations on postoperative pain, shoulder function, quality of life and satisfaction scores, while controlling for or taking into account modifying or mediating effects of catastrophizing and dispositional optimism (and, for the outcome 'pain', Central Sensitization Inventory score as well). Secondary Objectives To determine the direct effect of early postoperative pain on persistent postoperative pain at six months, while controlling for or taking into account modifying or mediating effects of factors that were found to have an effect on early postoperative pain itself

Study design

T0: Pre-operatively

T1: During the 8 weeks after surgery

T2: 6 months post-operatively

T3: 1 year post-operatively

Intervention

T0: 8 short questionnaires

T1: The dairy with quentions about pain, shoulder function, quality of life and sleep.

T2: 9 short questionnaires

T3: 9 short questionnaires

The questionnaires are about expectations, pain, shoulder function, quality of life and complaints

Contacts

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Eligibility criteria

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

Inclusion criteria

• Age 18 years or older

• Scheduled to undergo total shoulder arthroplasty (TSA), reversed shoulder arthroplasty (RSA) or hemiarthroplasty (HA)

• Able to provide written informed consent

Exclusion criteria

• Cognitive impairment

• Difficulty with the Dutch language

• Receiving SA for acute fractures

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2018
Enrollment:	220
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	28-08-2017
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
NTR-new	NL6639
NTR-old	NTR6825
Other	MEC ZWH : 17-117 (niet WMO plichtig)

Study results