# Evaluating the effect of a dynamic shoulder subluxation orthosis on shoulder pain and shoulder subluxation

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The main objective of this study is to evaluate the effect of the dynamic shoulder orthosis on the shoulder pain and glenohumeral subluxation.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Muscle disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49685

**Source**
ToetsingOnline

**Brief title**
Evaluation of a dynamic shoulder subluxation orthosis

### Condition

- Muscle disorders

**Synonym**
partial dislocation of the shoulder joint, shoulder subluxation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Twente
**Source(s) of monetary or material Support:** Ministerie van OC&W,Hankamp Rehab

## Intervention

**Keyword:** orthosis, shoulder, shoulder pain, subluxation

## Outcome measures

### Primary outcome

The main study parameters are: (1) the shoulder pain scores before and during the intervention, and (2) the acromiohumeral distance without and with orthosis.

### Secondary outcome

The secondary study parameters are: pain-free range of motion, arm activity, shoulder function, device usage and user satisfaction

# Study description

### Background summary

Shoulder subluxation is a partial separation of the humeral head and the glenoid. Shoulder supports, also known as braces or orthoses, are frequently prescribed to patients with glenohumeral subluxation (GHS). Clinical objectives for prescribing a shoulder brace include, among others, a reduction of stress in the passive structures from gravitational pull during standing or walking, maintenance of a proper glenohumeral alignment and shoulder pain reduction. A dynamic shoulder subluxation orthosis has been developed to reduce the stress on the soft tissue around the shoulder complex without limiting the retaining range of motion of the arm, such that shoulder pain is reduced and the functional recovery of patients with remaining arm function is not inhibited.

### Study objective

The main objective of this study is to evaluate the effect of the dynamic shoulder orthosis on the shoulder pain and glenohumeral subluxation.

### Study design

Interventional study

### Intervention

The study population is provided a shoulder orthosis for the duration of two weeks. In the week before the orthosis fitting, the population will not use any intervention.

### Study burden and risks

Participants have to visit the University of Twente once for the intermediate assessment session. The other assessment sessions will be conducted at the patient*s home. During each assessment session, multiple outcome measures are collected. During the first week of the study, the patient will not receive any intervention. During the second and third week of the study, the patient will use a customized shoulder orthosis that can provide an upward force to the arm to reduce the gravitational pull of the arm weight on the shoulder. Risks associated with the use of the device are limited, as the patient is in full control of the magnitude of the force provided by the mechanism to the arm.

## 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

- >= 18 years
- Suspicion of subluxation of the glenohumeral joint
- Chronic shoulder pain (> 6 months)
- Having given written informed consent prior to undertaking any study-related procedures

## Exclusion criteria

- Unable to understand and follow simple verbal commands
- Inability to sit upright in a chair without arm supports for at least 15 minutes consecutively
- Inability to let the affected arm unsupported for one week
- Irritated skin in the application area of the orthosis
- Recent shoulder or arm operation (<6 months before participation in the study)

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-02-2021 |
| Enrollment: | 13 |

| | |
|---|---|
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Dynamic shoulder subluxation orthosis |
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 12-10-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 18-04-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 |
|---|---|
| CCMO | NL74819.091.20 |