# The (cost-)effectiveness of dynamic bracing versus standard care alone in patients suffering from osteoporotic vertebral compression fractures

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1. Effect evaluationTo assess the effectiveness of dynamic bracing on quality of life in patients suffering from an osteoporotic vertebral compression fracture (OVCF).2. Economic evaluationTo examine whether dynamic bracing compared to standard care…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Fractures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54417

**Source**
ToetsingOnline

**Brief title**
Dynamic bracing for OVCFs

### Condition

- Fractures

**Synonym**
Osteoporotic vertebral compression fracture, spinal fracture

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** ZonMw,Bauerfeind

## Intervention

**Keyword:** Cost-effectiveness, Dynamic bracing, OVCF, Quality of life

## Outcome measures

### Primary outcome

The primary outcome parameter is quality of life at one year after intervention, as measured by the Quality of Life Questionnaire of the European Foundation for Osteoporosis (Qualeffo-41).

### Secondary outcome

Secondary outcome parameters are pain as measured on the visual analogue scale (VAS), functional disability as measured on the Oswestry Disability Index (ODI), the amount of pain medication used, cost-effectiveness, static sagittal alignment as measured on an X-ray and recurrence fracture rate of OVCFs. For a subgroup of patients gait and postural balance and physical activity and gait speed in daily life will be assessed.

A trial-based economic evaluation will be performed according to published guidelines, based on empirical data obtained in the RCT. This economic evaluation will involve a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). The economic evaluation will be performed from the societal perspective, including costs inside and outside the healthcare sector, as well as from a health care perspective. The time horizon of the economic evaluation will be one year. Health-related quality of life is considered an important outcome in this study. Therefore, a cost-utility

analysis will be performed with the number of quality adjusted life years (QALYs). The cost analysis will be performed according to Dutch guidelines for cost calculations. Hospital resource use from moment of randomization such as the research nurse*s time, outpatient visits, surgery, and pain treatments will be registered by means of Case Report Forms (CRFs). Use of medication during the intervention period will be closely monitored in the CRF. For costs outside the hospital, such as visits to the GP, paramedic care, productivity losses and out-of-pocket costs, patients will be asked to fill out cost questionnaires at all follow-up moments. Costs will be calculated by multiplying resource use with standard unit prices. Sensitivity analyses and bootstrap analyses will be performed to investigate the uncertainty surrounding the cost-effectiveness ratios. Based on the bootstrap results, cost-effectiveness acceptability curves will be constructed, showing for a wide range of cost-effectiveness threshold values, the probability that dynamic bracing is cost-effective.

All outcome parameters will be obtained at baseline, after 6 weeks, 3, 6 and 9 months and 1 year after baseline. The data for the subgroup analysis will be obtained at baseline, after 6 months and 1 year after baseline.

## Study description

**Background summary**

OVCFs are the most common fractures among the elderly causing pain and long term morbidity. After an incident OVCF there is a 20% risk of an additional fracture in the next year. After a fracture, the disproportionate height loss from the anterior vertebral body results in wedging. Wedge accumulation over

multiple thoracolumbar levels may lead to subsequent spinal deformity (vertebral fracture cascade). Spinal deformity has a profound impact on health, such as physical and pulmonary function, pain and disability, postural control, and mortality. Treatment of OVCFs should aim to break the downward spiral of recurrent fractures and to prevent the subsequent progression of global sagittal malalignment. Furthermore, it should intend to prevent or slow down the decline in postural control, thereby limiting the increased risk of falling in these frail patients.

Treatment generally includes a mix of analgesics, preventive osteoporosis medication and physical therapy (Richtlijn Osteoporose en Fractuurpreventie). However, for many patients current conservative treatment fails to provide adequate relief of pain and disability, nor does it prevent subsequent spinal deformity to end the vicious cycle of the vertebral fracture cascade.

Prevention of an increased anterior bending moment on the trunk is of high clinical importance to minimize overload on the anterior part of the spine (vertebral bodies) and thus to prevent new vertebral fractures. As was shown in our pilot study, six weeks of continuous bracing resulted in a more upright posture (i.e. decrease in anterior bending moment). This is clinically relevant since even a small increase in thoracic kyphosis results in a significant rise in vertebral compressive loading, and in an earlier study we found that a greater kyphosis angle is independently associated with increased risk of incident OVCFs.

We therefore hypothesize that dynamic bracing improves sagittal alignment and thereby decreases the risk of novel vertebral fractures. Currently, the use of conventional, rigid spinal orthoses is extremely limited in patients suffering from osteoporosis due to the suspected subsequent atrophy of the trunk muscles and restricted respiration leading to low patient compliance. The dynamic orthosis has been developed as an alternative to the standard three-point orthosis, aiming to overcome the disadvantages of a rigid brace. It shares the same biomechanical principle of the rigid three-point support, however with a less rigid immobilization and a dynamic behaviour allowing biofeedback activation of the dorsal lumbar musculature. In a comparative study, patients with a dynamic orthosis had more reduction in pain and a greater improvement in quality of life and respiratory function, with equal effectiveness in stabilizing the fracture, and fewer complications (39% versus 12%).

Since OVCFs are an increasing health problem with serious clinical consequences, high-quality studies on the management of OVCFs are warranted. A large, RCT to determine whether dynamic bracing is (cost)-effective for patients is a necessity to fill the gap in the conservative treatment of OVCFs. The results of such a trial are important for both patients and treating physicians (general practitioners, orthopaedic surgeons, trauma surgeons, internal medicine specialists, rheumatologists, and physical therapists) who are consulted by OVCF patients, and currently have no treatment options for

pain and disability except for pain medication.

## Study objective

1. Effect evaluation
To assess the effectiveness of dynamic bracing on quality of life in patients suffering from an osteoporotic vertebral compression fracture (OVCF).
2. Economic evaluation
To examine whether dynamic bracing compared to standard care alone in patients suffering from OVCFs is preferable in terms of costs, effects and utilities from a societal perspective.
3. Process evaluation
To assess the feasibility of dynamic bracing, with the aim of analysing the extent to which it was performed according to protocol, the attendance and adherence of patients, and the opinion of patients, their relatives and care professionals.

## Study design

In this Dutch, prospective, multicenter randomized controlled trial two methods of conservative treatment for patients suffering an OVCF will be compared. The control group will receive usual care, whereas the intervention group will receive usual care combined with a dynamic semi-rigid thoracolumbar orthosis. The study will consist of three parts (a clinical effectiveness evaluation, an economic evaluation and a process evaluation), each with its own objectives and research questions.

## Intervention

INTERVENTION: A dynamic thoracolumbar orthosis, the Spinova Osteo®, will be used additional to usual care.
CONTROL: Usual care will be provided according to the treating physician and may comprise pain control with analgesics, early rehabilitation and preventive osteoporosis medication.

## Study burden and risks

Dynamic bracing is expected to be safe. There are no additional visits at the outpatient clinic or investigations in comparison to standard care. We expect a benefit for the patients who are in the intervention group since we expect the brace to provide better pain relief in comparison to standard care alone.
For patients included in the Maastricht University Medical Center gait quality and postural balance will be assessed using the computer-assisted rehabilitation environment (CAREN, Motek-force Link). The risk of the gait analysis is negligible. A safety harness provides protection against falling. It will avoid subject falling on or off the treadmill while performing

training. The safety harness is secured with a lifeline to the ceiling. The gait analysis compromises the only burden; all other interventions are equal to normal clinical practice. The gait analysis will take approximately 60 to 90 minutes.

# 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

- Postmenopausal woman;
- A symptomatic thoracolumbar osteoporotic vertebral compression fracture (less than 6 weeks old);
- Eligible for questionnaires with sufficient understanding of the Dutch written language.

### Exclusion criteria

- Man
- Unstable vertebral fractures amenable for operative treatment;
- Neurologic deficit;
- Severe spinal deformity (scoliosis);
- Infection;
- Malignancy requiring current treatment;
- Psychiatric or mental disease;
- Insufficient cognitive or language skills to complete the questionnaires.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-01-2021 |
| Enrollment: | 98 |
| Type: | Actual |

### Medical products/devices used

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| Generic name: | Spinova Osteo Orthosis |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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| Date: | 16-10-2020 |

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| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 04-04-2023 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 24180
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL74552.068.20 |
| Other | NL8746 |