

# Naprapathy or evidence-based care provided by a physician for patients with non-specific low back and/or neck/shoulder pain: a randomised controlled trial

**Submission date**  
12/09/2006

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
30/10/2006

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
18/05/2022

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

## 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

N/A

# Study information

## Scientific Title

Naprapathy or evidence-based care provided by a physician for patients with non-specific low back and/or neck/shoulder pain: a randomised controlled trial

## Acronym

The BJÖRN-study

## Study objectives

The hypothesis tested was: naprapathic treatment is more effective for patients with non-specific pain and disability in low back and/or neck/shoulder, than evidence-based advices provided by a physician.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics committee approval was received on the 29th of December 2003 from the Karolinska Institutet (dnr: 03-657)

## 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

Neck, shoulder or low back pain

## Interventions

Naprapathy (index group): One out of eight naprapaths gave a maximum of six treatments within six weeks in his/her own clinic. The naprapath decided how the treatment sequences should be performed and precise notes about the treatment, advises, progress and possible adverse reactions, were kept. Each appointment lasted for about 45 minutes. Naprapathy, founded by Dr Oakley Smith in the beginning of the 20th century, is a manual therapy for soft

tissues and joints aimed at decreasing pain and re-establishing musculoskeletal function. Treatment with Naprapathy means that every patient is given an individual combination of manual naprapathic techniques as manipulation and mobilisation of joints as well as stretching and massage for the muscles. In addition to the manual treatments, preventive and rehabilitating physical activity and ergonomic advices often are given.

Evidence Based Care provided by a physician (control group): One out of four physicians gave evidence based care in direct conjunction with the physical examination all participating patients got prior to the randomisation (an additional 15 minutes). The evidence-based care (gold standard) involved evidence-based advice and support by the physician according to guidelines that aimed to empower the patient in the understanding of the fact that the best prognosis for recovery is received by living as normal a life as possible, including work and physical activities. The aim of the consultation was empowerment of the patients belief in and faith in his/her own capacity to handle and cope with the pain. A booklet and exercises conformed to the patients conditions were given. Precise notes were kept and a second consultation (approximately 15 minutes) after three weeks was scheduled. The patient was told that additional consultation could be offered if necessary.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Pain and disability, measured by the Chronic Pain Questionnaire (CPQ)

### **Secondary outcome measures**

Health status, , measured by the Medical Outcomes Study Short Form-36 Health Survey (SF-36) at 26 and 52 weeks, incorporating

1. Recovery
2. Quality of life
3. General health
4. Sick leave
5. Economical aspects in short and long term

### **Overall study start date**

07/03/2005

### **Completion date**

30/09/2006

## **Eligibility**

### **Key inclusion criteria**

Participants were assembled mainly among employees at two big companies in Stockholm, Sweden (in total around 40,000 persons) during the period March to September 2005.

The inclusion criteria was a present non-specific pain in back or neck/shoulder of the kind that brought about marked disability at work and/or in leisure time, for at least two weeks.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

400

**Total final enrolment**

409

**Key exclusion criteria**

1. Pregnancy
2. Specific diagnose as acute slipped disc or spinal stenosis
3. Recently have been exposed to naprapathic treatment or evidence based physician consultation (the preceding two months) or other manual therapy with the exception of massage (the preceding month)
4. Surgery in the painful area
5. Red flags (e.g. serious disease in back or neck and recent trauma in the area)
6. Not able to understand Swedish

**Date of first enrolment**

07/03/2005

**Date of final enrolment**

30/09/2006

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

Karolinska Institutet

Stockholm

Sweden

SE-171 77

**Sponsor information****Organisation**

Karolinska Institutet (Sweden)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.ki.se>

**ROR**

<https://ror.org/056d84691>

**Funder(s)**

**Funder type**

Government

**Funder Name**

Swedish Research Council (Sweden) (ref: K2005-27VK-15355-01A)

**Alternative Name(s)**

Swedish Research Council, VR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

Stockholm County Council (Sweden) (ref: 20050585)

**Alternative Name(s)**

Stockholm County Council

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

**Funder Name**

Uppsala County Council (Sweden)

**Funder Name**

Capio (Sweden) (ref: 626)

**Funder Name**

Swedish Naprapathic Association (Sweden)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2007		Yes	No
<a href="#">Results article</a>	results	05/02/2010		Yes	No
<a href="#">Results article</a>		08/10/2021	11/10/2021	Yes	No
<a href="#">Results article</a>		16/05/2022	18/05/2022	Yes	No