

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	<input type="checkbox"/> Prospectively registered
Registration date 30/10/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/05/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Lars Alfredsson

Contact details

Karolinska Institutet
Institute of Environmental Medicine
Box 210
Stockholm
Sweden
SE-171 77

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lars.alfredsson@ki.se

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

Nobels väg 5
Solna
Stockholm
Sweden
SE-171 77
+46 8 524 800 00
info@ki.se

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?
Results article	results	01/06/2007		Yes	No
Results article	results	05/02/2010		Yes	No
Results article		08/10/2021	11/10/2021	Yes	No
Results article		16/05/2022	18/05/2022	Yes	No