ISRCTN56954776 https://doi.org/10.1186/ISRCTN56954776

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

Registration date
30/10/2006

Overall study status
Completed

Last Edited
18/05/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
409

Key exclusion criteria

1. Pregnancy
2. Specific diagnose as acute slipped disc or spinal stenos
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 Instituet
Stockholm
Sweden
SE-171 77

Sponsor information

Organisation
Karolinska Institutet (Sweden)

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

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