

The effect of various combinations of naprapathic manual therapy for patients with neck pain and/or back pain

Submission date 04/02/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/10/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Eva Skillgate

Contact details

Karolinska Institutet
Institute of Environmental Medicine
Box 210
Stockholm
Sweden
17177

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eva.skillgate@ki.se

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The effect of various combinations of naprapathic manual therapy: a randomised controlled trial

Acronym

The MInT Trial

Study objectives

The main purpose of this study is to:

Examine the difference in treatment effect between different combinations of Naprapathic manual therapy including massage techniques, stretching (both as a treatment technique and a home exercise), spinal mobilisation and spinal manipulation, for patients with neck pain and/or back pain.

Secondary objectives are to provide answers to the following questions.

1. What is the prevalence of adverse reactions to treatment in the different combinations of naprapathic manual therapy, and what is the severity and duration of such symptoms post treatment?
2. Are there specific subgroups of patients who have greater benefit from the respectively treatment?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The regional Ethic Board in Stockholm (Regionala etikprövningsnämnden i Stockholm), 11/01 /2010, Ref: 2009/1848-31/2

Study design

Single-centre three-arm open-label randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-specific neck and/or back pain

Interventions

The treatment arms being evaluated are:

1. Naprapathic manual therapy (which includes a combination of various massage techniques, stretching (both as a treatment technique and a home exercise), spinal mobilisation and spinal manipulation.
2. Naprapathic manual therapy, except spinal manipulation.
3. Naprapathic manual therapy, except stretching (both as a treatment technique and as a advice for home exercise)

All patients in each arm will receive up to 6 treatment sessions within 6 weeks from inclusion in the trial. The total duration of follow up will be 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Self rated pain and function with the use of Chronic Pain Questionnaire (CPQ) will be assessed at baseline, 7 weeks, 3, 6 and 12 months.
2. Prevalence, duration and intensity of adverse treatment reactions. This is measured with the use of a questionnaire including eight numerical rating scales (NRS 0-10) seven of which concern symptoms that has been reported in other studies after naprapathic treatment sessions or other manual therapy. The last question is other in case of other symptoms experienced by the patient. Patients will answer this questionnaire when coming back to the clinic for a new treatment session.

Key secondary outcome(s)

1. Health related quality of life (Short-Form [SF-12])
 2. Perceived recovery (A 6-point Likert scale including Complete pain free and have no complaints from neck/back to Is much worse)
- Outcomes will be measured at baseline, 7 weeks, 3, 6 and 12 months.

Completion date

31/12/2012

Eligibility**Key inclusion criteria**

Patients 18-65 years of age who seek naprapathic therapy for a new episode of non-specific episode of neck and/or back pain with a duration of at least one week, at the student clinic at The Scandinavian College of Naprapathic Manual Medicine

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Pain level < 2 on a 10 point numerical rating scale
2. Pregnancy
3. Not fluent in the Swedish language
4. Contraindication for spinal manipulation according to SOSFS 1996:16 (The regulations and general recommendations from the Swedish National Board of Health and Welfare), such as pain caused by trauma.
5. Treatment by a naprapath, chiropractor, osteopath or a physiotherapist in the past month.
6. Specific diagnoses such as
 - 6.1. Spondylitis
 - 6.2. Ankylosing spondylitis (Morbus Bechterew's disease)
 - 6.3. Disc herniation
 - 6.4. Red flags not included in the SOSFS, above
7. Other primary pain diagnosis according to the judgment made by the therapist at the time of inclusion

Date of first enrolment

15/03/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Institutet

Stockholm

Sweden

17177

Sponsor information

Organisation

The Scandinavian College of Naprapathic Manual Medicine (Sweden)

Funder(s)

Funder type

University/education

Funder Name

The Scandinavian College of Naprapathic Manual Medicine (Sweden)

Funder Name

Swedish Association of Naprapaths (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan**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	12/03/2014		Yes	No
Results article	results	23/04/2016		Yes	No
Results article	results	12/06/2019	23/01/2020	Yes	No
Results article		08/10/2021	11/10/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes