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

Submission date	Recruitment status	[X] Prospectively registered
04/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/03/2010

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
1,050

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)

Sponsor details
Kräftriket 23A
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11419
+46 (0)8 160120
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Sponsor type
Hospital/treatment centre

Website
http://www.nph.se

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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