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The STONE-Trial (STOckholm NEck Trial): The effect of massage and/or physical exercise on sub-acute or long lasting neck pain

Submission date
19/05/2014

Recruitment status
No longer recruiting

Registration date
03/07/2014

Overall study status
Completed

Last Edited
17/02/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Neck pain is very common, especially among women, and it can have a big impact on health and quality of life. However, not enough is known about what causes it and what effects commonly used treatments have on the condition. Massage and physical exercise are often recommended, at considerable cost to both the individual and society at large, but there is little scientific evidence on whether these treatments are beneficial or not. In this study, we will explore the short and long-term effect of massage and physical exercise on sub-acute and chronic neck pain.

Who can participate?
Adults between 18-70 years of age with sub-acute or chronic neck pain.

What does the study involve?
Participants are randomly allocated into one of four groups:
1. Massage only: Participants in this group receive individually tailored massage therapy for up to six sessions, over a six week period.
2. Physical exercise only: Participants receive individually tailored instruction and support on physical exercises for up to six, 30 minute, sessions over a six week period.
3. Massage and physical exercise: Participants will receive both the massage and physical exercise treatments over a six week period.
4. Advice on staying active: Participants receive help and support on how to keep active and on pain coping strategies. General advice on exercise and a booklet containing examples of exercises and general information on back and neck pain is provided. Up to two follow up consultations are offered.
The effectiveness of each of these treatments are measured by a series of web-based questionnaires that the participants complete at 7, 12, 26 and, finally, 52 weeks from when they start the treatment.

What are the possible benefits and risks of participating?
The risk of serious adverse events of massage treatments are minimal as well as for physical exercise and advice. Each group of participants receive treatments that are recommended for

neck pain. Furthermore, both massage and physical exercise are considered to have preventive and rehabilitative effect on overall wellbeing.

Where is the study run from?
Scandinavian College of Naprapathic Medicine, Stockholm (Sweden)

When is the study starting and how long is it expected to run for?
August 2014 to December 2020

Who is funding the study?
Swedish Research Council (Vetenskapsrådet) (Sweden) and Swedish Research Council for Health, Working life and Welfare (FORTE) (Sweden).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Eva Skillgate

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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 massage and/or physical exercise on sub-acute or long lasting neck pain: a randomized controlled trial

Acronym

STONE-Trial

Study objectives
Specific primary research questions:
1. Is massage more effective than physical exercise a combination of massage and physical exercise or advice to stay active regarding pain, disability and perceived recovery for persons with sub-acute or chronic neck pain?
2. Is physical exercise or a combination of massage and physical exercise more effective than advice to stay active regarding pain, disability and recovery for persons with sub-acute/chronic neck pain?

Specific secondary research questions:
1. Is there a difference between massage and/or physical exercise and advice to stay active respectively regarding the risk of adverse events?
2. What is the course of neck pain over one year in the four treatment arms?
3. What is the cost effectiveness of the treatments of neck pain with massage and/or physical activity?
4. Is the prognosis and the risk of adverse events the same in subgroups of participants as young /old, men/women etc?
5. What is the prognostic effect of comorbidity, expectations of recovery, sleep disturbances, job strain, lifestyle etc on sub-acute or chronic neck pain?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethical Review Board (Etikprövningsnämnden Stockholm) (www.epn.se), 15/08/2014, ref. 2014/755-31/3

Study design
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 pain

Interventions
Participants are randomised to 4 treatment arms:
1. Massage: Up to six treatment sessions within six weeks, with massage therapy (first effleurage and then deeper techniques) applied to the neck, thoracic spine area and chest for a session of 30 minutes (total visit time 45 minutes). Myofascial trigger points will be treated with pressure and deep muscle/fascia massage techniques. The treatment will be adapted to the patient's condition.
2. Physical exercise: Instruction and support on physical exercises in up to six 30-minutes sessions within six weeks, at the clinic. The primary focus will be on self-mobilization exercise (gentle controlled movement) of the neck and shoulder joints, including neck retraction, extension, flexion, rotation, lateral bending motions, and scapular retraction) and strengthen exercises. The delivery method was 1-on-1, and the program will be individualized and adapted to the patient's condition with 5 to 10 repetitions of each exercise every second day at home. A booklet prescribing the exercises and basic anatomy of the neck area will be provided.
3. Massage and physical exercise: Up to six massage treatments (30 minutes) followed by physical exercise (30 minutes) as described above within six weeks. The exact number of visits will be based on the clinical progress of each participant as determined by the massage therapist, based on their findings and discussion with the participant. The treatment will be adapted to the patient's condition.
4. Advice on staying active: The advice, which is evidence bases and known to be effective for back and neck pain, is defined as support and advice on staying active and on pain coping strategies, according to guidelines and evidence-based reviews. This will be given in direct conjunction to the medical examination (an additional 15 minutes) at the clinic. The aim is to empower the patient with the understanding of the importance of staying active and living as normal a life as possible, including work and physical activities, and to improve pain coping strategies. Advice on exercises will be general and adapted to the patient's condition. A booklet with examples of exercises and general information on back and neck pain will also be provided. Up to two return visits will be offered.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The outcomes will be measured by web-based self-report questionnaires 7, 12, 26 and 52 weeks after inclusion in the trial. Up to three reminders will be sent out, and a personal phone call if necessary aiming to reach a high participating rate.
The primary outcomes will be pain and disability, measured by a slightly modified Chronic Pain Questionnaire (4 weeks recall period instead of 6 months) with 6 items on a numerical 11-point rating scale and 1 item on the number of disability days of pain and disability. Three items rates pain (the current pain, the worst pain experienced during the preceding 4 weeks, and an average of the pain during the preceding 4 weeks). A pain score will be constructed from the mean of these 3 items. Three items rates disability and concerned to what degree pain 'interfered with your daily activities', 'changed your ability to take part in recreational, social, and family activities', and 'changed your ability to work (including housework)' in the past 4 weeks. The disability score will be the mean of these 3 items. On the basis of these scores, 2 dichotomized outcomes will be defined based on what is considered to correspond to a clinical important improvement when the baseline and the follow-up value is compared.

Secondary outcome measures
Global improvement, health (EQ-5D), satisfaction with care, sick leave, drug consumption, health care utilization
2. Adverse events within 24 hours post treatment will be measured at each return visit (duration and severity), with a questionnaire used in one of our previous trials
3. Patients will be followed with automated text messages (SMSes) every week to survey the course of neck pain over one year. They will receive two questions every week:
3.1. How would you rate your neck pain intensity, on average, the previous week? Please answer with a number between 0 and 10, where 0 is 'No pain' and 10 is 'Worst imaginable pain'
3.2. How much has your neck pain in average hindered your ability to work or perform other daily activities during the last week? Answer by selecting a number on a scale from 0-10, where 0 is 'Not at all' and 10 is 'Impossible to perform these activities'

Overall study start date
15/08/2014

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Age 18-70 years
2. Ongoing neck pain (including whiplash associated pain WAD and neck pain with headache and /or radiating findings in the upper limbs) of sub-acute (30-90 days duration) or long lasting (>90days duration) duration with pain intensity of at least 2 on a numerical rating scale (0-10), as an average the preceding 4 weeks and at present. The neck pain shall be such that it is disturbing daily activities at work and/ or leisure
3. Participants are required to have a mobile phone and access to internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
600

Total final enrolment
619

Key exclusion criteria
1. Pregnancy
2. Inability to understand Swedish
3. Manual therapy or physical therapy for the neck pain in the preceding months
4. Problems with the skin that makes it difficult to give massage in the area
5. Have or have had cancer
6. Too mild symptoms
7. Surgery in the painful area
8. Acute prolapsed disc
9. Spondylolisthesis, stenosis
10. Red flags (older than 55 when the pain debut for the first time, recent trauma in the area, constant pain or pain getting worse in the night, cancer in the past or at present, consumption steroids now or recently, drug abuser, HIV)

Date of first enrolment
15/08/2014

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet (Karolinska Institute)
Stockholm
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Box 210

Sponsor information

Organisation
Scandinavian College of Naprapathic Manual Medicine (Naprapathögskolan) (Sweden)

Sponsor details
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Sponsor type

Hospital/treatment centre

Website
http://www.nph.se

Funder(s)

Funder type
Research council

Funder Name
Swedish Research Council (Sweden)

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan

The trialists plan to publish the main paper within 6 months.

Intention to publish date
01/07/2019

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?
Protocol article	protocol	16/09/2015		Yes	No
Results article	results	01/02/2020	14/01/2020	Yes	No
Other publications	cost-effectiveness analysis	01/04/2020	27/01/2020	Yes	No