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Costs and effectiveness of chiropractic care and physiotherapy in the treatment of chronic low back pain

Submission date
16/02/2017

Recruitment status
No longer recruiting

Registration date
20/02/2017

Overall study status
Completed

Last Edited
26/02/2025

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
Chronic low back pain (CLBP) is a global public health problem and a leading cause of disability all over the world. Besides its severe negative impact on health and quality of life, there are substantial societal costs within and outside the healthcare system. Both medical costs for the treatment and management of CLBP and costs for production losses due to absenteeism from work are sizable. Many different treatment options are available for CLBP and both drug and non-drug treatments like physical activity, manipulation and multidisciplinary rehabilitation interventions are widely used. However, the evidence to recommend the use of one treatment over another one is limited and therefore more research is needed to study the effects and cost-effectiveness of treatments for CLBP. The aim of this study is to assess the effects (functional limitation, pain intensity, health, health-related quality of life and working status), costs (medical costs and costs for production losses) and cost-effectiveness of chiropractic care and physiotherapy when added to information and advice for patients with CLBP in Sweden.

Who can participate?
Patients aged 18 to 60 with low back pain for at least 3 months

What does the study involve?
Participants are randomly allocated to one of four groups. In the first group participants are given oral and written information in a booklet on how to manage CLBP and advice about the importance of staying active and avoiding rest. Information and advice is given to all participants in the study (i.e. participants allocated to the other treatment groups are all given information and advice). In the second group participants are treated with physiotherapy, which involves training and exercise, and the duration, number and content of treatment is at the discretion of the physiotherapist. In the third group participants are treated with chiropractic care, which involves spinal manipulation, and the duration, number and content of treatment are at the discretion of the chiropractor. In the fourth group participants are treated with both chiropractic care and physiotherapy, which involves a combination of spinal manipulation, training and exercise, and the duration, number and content of treatment sessions are at the discretion of the chiropractor and physiotherapist who jointly make a treatment plan with the participant. A

web-based questionnaire is used to collect data at the start of the study and after 12, 26 and 52 weeks. Data collected include functional limitation, back pain intensity, general health, health-related quality-of-life, working status, direct costs (costs for pharmaceuticals, healthcare visits, clinical examinations, and hospital stay) and indirect costs (costs of changes in productivity).

What are the possible benefits and risks of participating?
The results from the study will increase knowledge of the effects, costs and cost-effectiveness of chiropractic care and physiotherapy for CLBP, which will improve clinical decision making. Potential risks of participating in the study are likely to be small, but minor pain and discomfort is usual after chiropractic care and physiotherapy. These mild symptoms should disappear after about 3 days.

Where is the study run from?
1. Haninge Rehab, Handens vårdcentral (Sweden)
2. Värmdö Rehab, Gustavsbergs vårdcentral (Sweden)
3. Sundbybergskliniken Primärvårdsrehab (Sweden)
4. Måbra hälsa Orminge (Sweden)
5. Måbra hälsa Saltsjöbaden (Sweden)
6. Rehab Nordost Täby (Sweden)
7. Nacka Rehabcentrum (Sweden)

When is the study starting and how long is it expected to run for?
March 2015 to December 2020

Who is funding the study?
1. Karolinska Institutet (Sweden)
2. Scandinavian of College of Chiropractic (Skandinaviska Kiropraktorhögskolan) (Sweden)

Who is the main contact?
Dr Niklas Zethraeus

Contact information

Type(s)
Scientific

Contact name
Dr Niklas Zethraeus

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Costs and effectiveness of chiropractic care and physiotherapy, compared with information and advice in the treatment of non-specific chronic low back pain: a pragmatic randomized study

Study objectives
Research questions:
1. Do chiropractic care and physiotherapy, chiropractic care, or physiotherapy improve outcomes (back pain-related functional limitation, back pain intensity, general health, health-related quality of life, and working status) when added to information and advice?
2. What are the effectiveness (quality adjusted life years) and costs (medical costs and costs for production losses) of chiropractic care and physiotherapy, chiropractic care, and physiotherapy, when added to information and advice?
3. From a societal perspective, which (if any) of chiropractic care and physiotherapy, chiropractic care, or physiotherapy is a cost-effective treatment strategy compared with information and advice?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala etikprövningsnämnden, Stockholm (the regional ethics board in Stockholm), 21/11 /2016, ref: 2016/1318-31-31

Study design
Multicentre pragmatic open randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Non-specific chronic low back pain

Interventions
Participants are randomised to one of four treatment groups:
1. Information and advice: Participants are given oral and written information in a booklet on how to manage non-specific chronic low back pain (CLBP) and advice about the importance of staying active and avoiding rest. Information and advice is given to all participants in the study (i. e. also participants allocated to the other treatment groups are given information and advice).
2. Physiotherapy: The treatment primarily involves training and exercise. The duration, number and content of treatment is at the discretion of the physiotherapist.
3. Chiropractic care: The treatment primarily involves spinal manipulation. The duration, number and content of treatment are at the discretion of the chiropractor.
4. Chiropractic care and physiotherapy: The treatment primarily involves a combination of spinal manipulation and training and exercise. The duration, number and content of treatment sessions are at the discretion of the chiropractor and physiotherapist who jointly with the patient make a treatment plan.

A computer generated block randomisation list will be produced to allocate participants to the treatment groups. The sequence will be concealed from the researchers involved in enrolling and assessing participants by using sequentially numbered, opaque, and sealed envelopes.

A patient self-reported web-based questionnaire is used to collect data on the outcome measures at baseline, 12, 26 and 52 weeks.

Intervention Type
Other

Primary outcome measure
Back pain-related functional limitation, measured using the Oswestry Disability Index (ODI) at baseline, 12, 26 and 52 weeks after baseline. The 26-week outcome measure is used as the primary endpoint and all other time-points are defined as secondary.

Secondary outcome measures
1. Back pain intensity, measured using the Numeric Rating Scale (NRS)
2. General health, measured using a self-rated health (SRH) question
3. Health-related quality-of-life, measured using the EQ-5D
4. Working status, defined as the percentage of full time work
Measured at baseline, 12, 26 and 52 weeks

Exploratory outcomes:
1. Costs: Direct (costs for pharmaceuticals, health care visits, clinical examinations, and hospital stay) and indirect costs (costs of changes in productivity) estimated during 12 months after randomization. The resource quantities collected at baseline, 12, 26 and 52 weeks after baseline
2. Effectiveness: Quality adjusted life years (QALYs) during 12 months after baseline, estimated using the quality of life weights based on EQ-5D (measured at baseline, 12, 26 and 52 weeks after baseline)

Overall study start date
10/03/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
The study includes individuals willing to participate in any of the included treatment groups; either in chiropractic care and physiotherapy, chiropractic care, physiotherapy or information and advice. The inclusion criteria are:
1. Pain below located costal margin and above the inferior gluteal folds
2. Reoccurring low back pain for at least 3 months
3. Age between 18 to 60 years
4. Can stand or walk independently
5. Swedish speaking and literate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

Total final enrolment
95

Key exclusion criteria
Current participant exclusion criteria (as of 22/12/2017):
1. Pain attributable to a known specific pathology
2. Lack of written informed consent
3. Pregnancy or less than 6 months postpartum or post weaning
4. Had any of the treatments defined in the chiropractic care and physiotherapy in the previous 1 month
5. Not showing up at baseline after randomisation

Previous participant exclusion criteria:
1. Pain attributable to a known specific pathology
2. Lack of written informed consent
3. Patient planning for surgery for low back pain during the study period or had surgery 3 month before

4. Pregnancy or less than 6 months postpartum or post weaning
5. Had any of the treatments defined in the chiropractic care and physiotherapy in the previous 1 month
6. Not showing up at baseline after randomisation

Date of first enrolment
27/02/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Haninge Rehab, Handens vårdcentral
Stockholm
Sweden
136 25

Study participating centre
Värmdö Rehab, Gustavsbergs vårdcentral
Stockholm
Sweden
134 40

Study participating centre
Sundbybergskliniken Primärvårdsrehab
Stockholm
Sweden
172 66

Study participating centre
Rehab Nordost Täby
Stockholm
Sweden
183 34

Study participating centre

Nacka Rehabcentrum
Stockholm
Sweden
131 45

Study participating centre
Vallentuna Rehab
Stockholm
Sweden
186 36

Study participating centre
AktivaRe Åkersberga Rehab
Stockholm
Sweden
184 35

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Tomtebodavägen 18A
Stockholm
Sweden
SE-17177

Sponsor type
University/education

Website
http://ki.se/mmc

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Government

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Scandinavian College of Chiropractics (Skandinaviska Kiropraktorhögskolan) (Sweden)

Results and Publications

Publication and dissemination plan
The plan is to publish in high impact peer review journals.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Filip Gedin (Filip.Gedin@ki.se).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/12/2017		Yes	No
Results article		25/02/2025	26/02/2025	Yes	No