



**ACUPUNCTURE FOR ACUTE NON-SPECIFIC LOW BACK PAIN:
A PROTOCOL FOR A RANDOMISED, CONTROLLED,
MULTICENTER INTERVENTION STUDY IN GENERAL
PRACTICE – THE ACUBACK STUDY.**

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ACUPUNCTURE FOR ACUTE NON-SPECIFIC LOW BACK PAIN: A PROTOCOL FOR A RANDOMISED, CONTROLLED, MULTICENTER INTERVENTION STUDY IN GENERAL PRACTICE – THE ACUBACK STUDY.

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ABSTRACT:

Introduction:

Some general practitioners (GPs) treat acute low back pain (LBP) with acupuncture, despite lacking evidence of its effectiveness for this condition.

The aim of this study is to evaluate whether a single treatment-session with acupuncture can reduce time to recovery when applied in addition to standard LBP-treatment according to the Norwegian national guidelines. Analyses of prognostic factors for recovery and cost-effectiveness will also be carried out.

Methods and analysis:

In this randomised, controlled, multicenter study in general practice in Southern Norway, 270 patients will be allocated into one of two treatment-groups, using a web-based application based on block randomisation. Outcome assessor will be blinded for group allocation of the patients.

The control group will receive standard treatment, while the intervention group will receive standard treatment plus acupuncture treatment. There will be different GPs treating the two groups, and both groups will just have one consultation. Adults who consult their GP because of acute LBP will be included. Patients with nerve root affection, "red flags", pregnancy, previous sick leave more than 14 days and disability pension will be excluded. The primary outcome of the study is the median time to recovery (days). The secondary outcomes are rated global improvement, back-specific functional status, sick leave, medication, GP visits and side effects. A pilot study will be conducted.

Ethics and dissemination:

Participation is based on informed written consent. We will apply for an ethical approval from the Regional Committee for Medical and Health Research Ethics (REC), when the study-protocol is completed. Results from this study, positive or negative, will be disseminated in scientific medical journals.

Discussion:

This study aims to explore whether acupuncture is a useful clinical tool for treating acute LBP in general practice.

Trial Registration:

ClinicalTrials.gov Identifier: NCT01439412.

INTRODUCTION:

Low back pain (LBP) is a very common disorder with consequences for the individual patient as well as for the society. Up to 80% of the population experiences back pain at least once in their lifetime, about 50% during the previous year. Point prevalence is 15%, and the condition relapses frequently, 40% within 6 months.¹ Back pain is the medical condition that ranks highest in terms of Norwegian socio-economic expenses.² Most people with acute LBP experience improvements in pain and disability within a month,³ but the median time to recovery recorded in studies on back pain varies widely, from 7 days to 58 days.^{4,5}

Acute LBP is treated primarily in the primary healthcare by general practitioners (GPs), physiotherapists, manual therapists and chiropractors. Recommended treatment according to clinical guidelines contains information about the condition, advice to stay active and, if possible, avoid bed rest, early and gradual mobilisation after the acute phase, pain treatment with paracetamol and/or non-steroidal anti-inflammatory drugs (NSAIDs) with time-contingent doses.^{2,6}

GPs educated and trained in acupuncture also use acupuncture for the treatment of both acute and chronic LBP cases.⁷ There is evidence that acupuncture is effective in chronic LBP, and such treatment is therefore recommended in the "National guidelines for LBP" in Norway.^{2,8-}

¹⁰ Reviews and meta-analyses conclude that the documentation of acupuncture treatment for acute LBP is limited by few and poorly conducted studies, however.^{10,11}

In 1997, He presented a Chinese study with 100 patients afflicted with LBP (5 days to 6 months duration) randomised to either manual acupuncture with moxibustion plus Chinese herbal medicine or Chinese herbal medicine alone.¹² A later Cochrane review concludes that this trial was of low methodological quality and showed limited evidence to back the fact that the combined treatment was more effective for a global measure of pain and function in the long-term follow-up.¹⁰

Araki et al have published an abstract of a trial where 40 patients with acute LBP (< 3 days) were randomised into two groups where the intervention group got acupuncture treatment in the acupuncture point SI3 bilaterally and then performed back exercises. The control group, however, received sham acupuncture treatment with mimicked needle insertion, after which they were asked to perform back exercises. Araki et al found no difference between the effects of acupuncture and that of the sham acupuncture.¹³

One of the studies referred to in the Cochrane review is a Norwegian study conducted by Kittang et al.¹⁴ They found that acupuncture was as effective as medical treatment with Naproxen per os in relation to pain and stiffness, but that the "Naproxen-group" had more side effects and greater recurrences in the observation period. While Kittang et al conclude that acupuncture is effective, this result is based on other studies showing the efficacy of NSAIDs for acute LBP.¹⁵

Kennedy et al published a pilot study in 2008, which demonstrated the feasibility of a randomised, controlled trial regarding the penetrating needle acupuncture when compared to non-penetrating sham acupuncture for the treatment of acute LBP in primary care. The study did not reveal any conclusions of the effects of acupuncture.¹⁶

Sham acupuncture involves inserting penetrating or non-penetrating needles in points that are not classical acupuncture points and/or are not located in the same segment. Several studies conclude, however, that sham acupuncture is not a valid placebo control, and this is explained

by neurophysiologic effects of the sham treatment.^{17 18} Trials with sham acupuncture need to be very comprehensive in order to demonstrate differences between the effects of real acupuncture and the sham treatment.¹⁹

In 2006, Vas et al published a study protocol of a four-branch randomised controlled trial, which intended to obtain further evidence on the effectiveness of acupuncture on acute LBP and isolate the specific and non-specific effects of the treatment.²⁰ The results have not yet been published.

Shin et al are planning to perform a randomised, controlled trial with two arms comparing a motion-style acupuncture with an NSAID injection.²¹

However, we have not yet found evidence favouring acupuncture as a treatment for acute LBP. Our clinical experience is that an acupuncture treatment of the distal and local acupuncture points combined with small mobilising movements means faster recovery of the pain. This treatment is according to textbooks on acupuncture.^{22 23} None of the mentioned protocols though examine this kind of acupuncture.

Strong stimulation of the distal acupuncture points is thought to act through activation of the extra-segmental pain inhibition, "Diffuse noxious inhibitory Controls" (DNIC) and the release of endorphins and possibly, other endogenous compounds in the central nervous system. Local acupuncture therapy immediately following the mobilisation movements may provide additional benefits through segmental pain-inhibition along with the inhibition of myofascial trigger points.²⁴

Clear prognostic factors for the efficacy of acupuncture for chronic LBP have, however, not been documented. In a large German study, the authors found that lower age, lower baseline spinal function and more than 10 years of education indicated a better response to acupuncture.²⁵ Some researchers still find that optimistic treatment expectations improve the effects of acupuncture,^{26 27} while others find the best treatment effects in patients who are neutral to acupuncture as a treatment method.²⁸ There are no similar studies for acute LBP.

In the present study, we aim at exploring whether a single treatment-session with acupuncture can reduce the time to recovery when applied in addition to the standard LBP-treatment in general practice according to Norwegian national guidelines. We will not use sham acupuncture as a control treatment. Further, we will not include a pure placebo group or a "waiting list group", because this will mean not giving treatment to patients with severe pain, which we consider unethical.

Secondary aims are pain intensity, disability, sick leave and drug use, and in addition we will evaluate the prognostic factors for recovery, and if possible, identify any factors that characterize those who have beneficial effects of the acupuncture treatment.

A systematic review found evidence supporting the cost-effectiveness of the guideline-endorsed treatments of acupuncture for sub-acute or chronic LBP.²⁹ Apart from the few trials of acupuncture treatment for acute LBP, there are no studies examining the cost-effectiveness of acupuncture for acute LBP. Therefore, we also aim at carrying out a cost-effectiveness analysis.

Our hypotheses are:

1. Acupuncture treatment contributes to faster pain-recovery in acute LBP compared to standard treatment in general practice provided in accordance with the Norwegian national guidelines.

2. Acupuncture treatment for acute LBP improves function, and reduces drug use and sick leave, compared to the standard treatment in general practice provided in accordance with national guidelines.
3. Acupuncture treatment for acute LBP is a cost-effective treatment in general practice.

METHODS AND ANALYSIS:

This is a randomised, controlled, multicenter study. The GPs administering the acupuncture have received their training through the education program of the Norwegian Society of Medical Acupuncture and are members of the Network Group of Medical Acupuncture, under the Norwegian College of General Practice. They are specialists in general practice and many of them are experienced participants in randomised clinical trials, given a parallel ongoing trial examining the effects of acupuncture on infantile colic.^{30 31} These GPs are located in different areas in southern Norway, both cities and rural municipalities. GPs in the same practices, but without training in acupuncture, however, need to be recruited to treat the control group.

A medical secretary at every doctor's office will carry out the telephonic interview in which, the patients will be informed about the study, the inclusion and exclusion criteria will be checked, the randomisation of the patients will be performed and the distributing and collecting questionnaires for the treatment day. A two-day workshop before the start of the main study will be arranged for the participating doctors and medical secretaries. The workshop will contribute to the standardization of information, reporting and patient management in general. A website with information about the study will be created.

We plan to recruit patients with acute LBP and randomly allocate them into two study-groups (A and C). Patients in both groups will receive standard treatment for LBP in accordance with the Norwegian national guidelines.² One group will receive *only* the standard treatment, while the other group also will receive additional acupuncture treatment as described below. To control for potential attention bias, we will measure the time spent on each patient in the intervention and control groups. Outcome assessor will be blinded for group allocation of the patients.

Inclusion criteria:

- Adults (20-55 years) who contact their GP's office because of acute nonspecific LBP (0-14 days).

Exclusion criteria:

- Nerve root affection and/or radiating pain below the knee.
- LBP with suspected "red flags", i.e. infections, tumours and metastatic disease, rheumatic disease, fractures and significant deformities of the spine.
- LBP which starts in pregnancy.
- Physician-reported sick leave of 14 days or more during the month before the commencement of the back pain, for any reason.
- Disability pension.

Control group C: Standard treatment in general practice is provided in accordance with the Norwegian national guidelines, i.e. general advice about activity, prescription of pain relievers (paracetamol), and sick leave, if needed.

Acupuncture group A: This group will receive standard treatment as the control group and in addition acupuncture treatment.

Acupuncture: The patient sits in a chair and the doctor stimulates the acupuncture points “the Lumbar Pain Points” on the right hand, with acupuncture needles of type Seirin B - 8a 0.30 x 30 mm. These are two points located between the second and third and the fourth and fifth metacarpal bones, immediately distal to the bases of the metacarpals. Insertion depth is 10-15 mm. The doctor stimulates the needles in a rotating up- and down movement to impart a powerful needle sensation (called “de Qi”), and this is repeated in short sequences to maintain the needle sensation for a total of 1 min. The needles shall stay in the hand during the rest of the treatment. The patient is then asked to rise and to perform slow rotating pelvic movements for 2 minutes, before lying down on a bench to be treated in the local points Huatuojiagi (“Jiaji”) with acupuncture needles of the type SEIRIN J-8 with sleeve 0.30 x 50 mm. These points are located 1.5 cm lateral to the depressions below the spinous processes, and we will acupuncture them bilaterally in the segments of the L2-L4 (6 needles) at a depth of 3-4 cm. They are stimulated manually until the patient experiences the needle sensation. Then, the patient lies quietly on the bench for another 5 minutes before all the needles are removed. The whole acupuncture session lasts for a total of 8 minutes. Thus part of the advice and prescription part is done while the patient is receiving acupuncture treatment, in order to let the consultation time for the two groups be as equal as possible. The consultation time will be measured and registered by the GPs.

Choice of treatment:

The described treatment with the specific distal and local acupuncture points has been chosen after a three-step process. We started with the treatment we used ourselves in clinical practice, compared it with the literature and standardized it for this trial. Then we asked several experienced acupuncture doctors how they treated acute LBP and what they thought about our suggestion of standardization.

Based on this feedback, we asked an expert group of physicians and physiotherapists experienced in administering acupuncture about which acupuncture points they preferred in the treatment of acute LBP. The end result was considered the treatment according to best practice for this study.

Patient flow:

When a patient with acute LBP contacts the GP’s office, the medical secretary provides information about the trial and asks whether the patient would want to participate in the study. If the patient consents, the medical secretary asks the patient questions regarding inclusion- and exclusion criteria. The inclusion and exclusion criteria are checked both in the telephone interview by the secretary and in the consultation by the GP. All contacts are counted and it is recorded at what level and for what reason exclusions are done. If the patient is eligible, the medical secretary randomises the patient to one of the two groups through the Web-based application at the Unit for Applied Clinical Research in Trondheim (<http://www.ntnu.no/dmf/akf>). This is used to register the patient in the appropriate doctor's timetable, but the patient does not know which group or which doctor he/she is going to meet. At the GP’s office, the patient is required to fill in the consent form and the first questionnaire (T0A). This is delivered to the medical secretary prior to the consultation.

Patients who are randomised to the control group will receive one standard treatment provided by a GP without acupuncture training. The consultation will include history, examination, information, prescription and advices, according to national guidelines for LBP. If the doctor discovers exclusion criteria, the patient will be excluded from the trial.

Patients who are randomised to the acupuncture group will receive one single acupuncture treatment in addition to the standard treatment as described for the control group. The consultation will be provided by a GP who is trained in acupuncture. If the patient's condition requires further consultations in the follow-up time, these will be recorded. These consultations, however, will not include additional acupuncture treatment.

When the patient has finished the consultation, they will fill in a post-treatment questionnaire (TOB) and submit it to the secretary in an enclosed envelope. The patient then will receive a back pain diary, which he/she will be required to fill in at home at the given times. The diary also contains information about how the patient can choose to give the answers in an electronic questionnaire (Figure 1).

Measurements:

For evaluation of the effects of treatment, we will use standardised instruments that have been validated, both internationally and nationally.^{32 33} The outcome measures will be filled in at baseline and after 1, 2, 4 and 12 weeks, and the following outcome measurements will be included:

The primary outcome is the median time in days to the recovery of pain, measured on the first day the patient scores 0 or 1 point on the Numerical Rating Scale (NRS). Clinically relevant differences between the groups are considered to be minimum 3 days.

Secondary outcome measures will be:

1. Pain intensity is assessed by the numerical rating scale (NRS) before and immediately after treatment and at the other follow-up times. The patient indicates his perceived pain intensity on an 11-point scale from 0 to 10 with endpoints indicating "no pain" and "worst imaginable pain". Based on other studies, the clinically relevant improvement is estimated as being minimum 2-3 points for individual patients and 1 point as the difference between the groups.
2. Back specific functional status by the Roland Morris Disability Questionnaire (RDQ). This measures patients' perceptions of function.³⁴ The patient answers yes or no concerning 24 allegations about the activities and conditions, depending on whether they feel that the statement describes them on this day.
3. Sick leaves, the number of days away from work due to back pain.
4. Global measure of improvement (Likert improvement assessment scale). This assesses the patients' perceptions of change, stated in whole numbers from 1 = much better to 5 = much worse.
5. Use of medication (paracetamol, eventually others), counting of daily consumption.
6. Number of new visits at the GP's office.
7. Side effects of treatment (acupuncture and medications).
8. Health-related quality-of-life by the EuroQoL (EQ-5D). This enumerates 5 questions that map the following areas: Walking, personal care, daily activities, pain/discomfort and anxiety/depression, as well as a 100 mm VAS scale (Visual Analogue Scale).³⁵

In addition the patients will be asked to fill in a Back pain diary. This refers to a small printed matter where the patient completes a daily questionnaire about the condition, as an aid to remember the results between each registration in the electronic questionnaire. It contains question about the pain level, function, use of medications, side effects and other comments every day for 2 weeks and 4 and 12 weeks after treatment.

The following questions will be included at the baseline for describing the baseline characteristics of the included sample and for the evaluation of potential prognostic factors for recovery:

Sociodemographic variables: This refers to age, gender, marital status, education, smoking status, use of alcohol, height, weight and serious life events during the 12 last months.

Örebro screening form for musculoskeletal pain: These are 25 questions that map all the main "yellow flags". This questionnaire about the pain and how it influences job-related activities shows prognostic factors for acute LBP.^{36 37}

Subjective Health Complaints (SHC): Here, the patient indicates in what degree he/she has had 29 different health complaints the last 30 days and how long the complaints have lasted.³⁸

Patients will fill in the questionnaire at baseline (before the first treatment) and then immediately after the first treatment at the GPs office. Patients will fill in the Back Pain Diary at home every day for 2 weeks and after 4 and 12 weeks. They may choose to fill in the results directly in the electronic questionnaire. If the results are not registered electronically, the patients may have to send the hard copy version of the diary to the project leader after 12 weeks, which is the maximum follow-up time.

Sample size:

We have calculated that a total of 270 patients will be needed for the study. Based on previous studies and clinical experience, we estimate that the 3 days' difference in median time to recovery between the acupuncture group and control group is clinically significant, with a median time to recovery of 7 days in the intervention group.^{4 39 40} The probability is 80 % that the study will detect a treatment difference at a two sided 5 % significance level, if the true hazard ratio is 1.429. This is based on the assumption that the accrual period will be 0 days, the follow-up period will be 84 days and the median survival is 7 days.⁴¹ In addition, we calculate with up to 10% dropout in the study.

Pilot study:

Prior to the main study, we plan to conduct a pilot study to test the study design, the assessment and reporting tools with a total of 8 patients, 4 in each group.

Randomisation

Randomisation will be performed by a web-based randomisation system developed and administered by the Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway, and it will use block randomisation with various sizes of the blocks.

Each patient is randomised after the inclusion and exclusion criteria are considered. It is the GP's medical secretary who checks the randomisation online, and the patient is then given an appointment with either the "control-GP" or the "acupuncture-GP". The patient is not told which group he/she is randomised to or the name of the GP before the consent form and the first questionnaire are filled in.

Analyses

Data will be analysed by an outcome assessor who is blinded to group status. The groups will be analysed only as group 1 and group 2, and the results presented in Tables and Figures will be worked out before the codes are broken. The primary analyses will be by intention-to-treat and we will restrict the number of analyses in order to reduce the possibility of Type I errors. For primary outcomes, a P value of <0.05 will be considered statistically significant. For the secondary outcomes a P value of <0.01 will be considered significant.

Primary Outcome Analyses:

We will assess the difference in survival curves (days to recovery) for the 2 groups using the log-rank statistic. The median days to recovery will be used to express the time to recovery for the two groups. Cox regression will be used to assess the effect of treatment group on hazard ratios after allowing for the days of pain duration as baseline covariate.

Secondary Outcome Analyses:

Differences between the groups will be presented as mean with 95% CI or in categories with odds ratio for categorical data. A mixed model with group as a fixed factor will be used for the other outcome measures. Post-hoc analyses will be conducted if there is a significant difference between treatment groups. We will also test for potential confounding factors in these models. Analyses of prognostic factors will be carried out by a multivariate regression models.

ETHICS AND DISSEMINATION:

When the patient contacts the GPs office, he/she will be informed about the objectives of the study and asked if he/she is willing to participate. The patients will be told that their participation is voluntary and that they will be granted full anonymity. Written consent will be required from the included patients.

All patients will receive the treatment they normally would receive from their GP, but half of them will undergo acupuncture treatment in addition to this. Given the randomisation, some patients will not meet their usual GP. Instead, another GP will consult the patient, though in the same office.

The risk of side effects of the acupuncture treatment has been found to be low.⁴²⁻⁴⁴ We will examine any side effects of the treatment during the trial.

The trial is registered in the ClinicalTrials.gov-register, NCT01439412.

We plan to apply to the Regional Ethics Committee of South-Eastern Norway when the protocol is completed and published.

Publication policy:

The results of the trial will be published in appropriate journals regardless of outcome. The trial will be implemented and reported in accordance with the recommendations of CONSORT and STRICTA.

DISCUSSION

This paper presents the design and rationale for a randomised, controlled multicenter study examining the effects of acupuncture on the recovery of patients with acute LBP. The project will increase the knowledge about the effects of acupuncture treatment for acute LBP, a common disorder seen by general practitioners entailing high costs for the patient and society. For the individual, a faster pain relief will aid an earlier return to normal, everyday activities. For the society, the effect may be that LBP patients will return earlier to their work. The primary outcome is the median time in days for recovery from pain. The secondary outcomes are rated global improvement, back specific functional status, sick leaves, medication, GP visits and side effects. A pilot study will be conducted. In the present study, we will also analyse possible prognostic factors for recovery and cost-effectiveness of acupuncture treatment for LBP.

Collaboration:

We have established an international collaboration agreement with Karolinska Institutet (Sweden) and Keele University (United Kingdom). Both institutions have extensive experience and knowledge within research in medical acupuncture and musculoskeletal disorders.

Funding:

TS has received research grants from the Norwegian College of General Practitioners to plan this trial.

Authors' contributions:

TS and HS initiated the project. TS, HS, MB, MG, IS and AF all contributed to conceptualisation and design of the study and all revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Competing interests:

None

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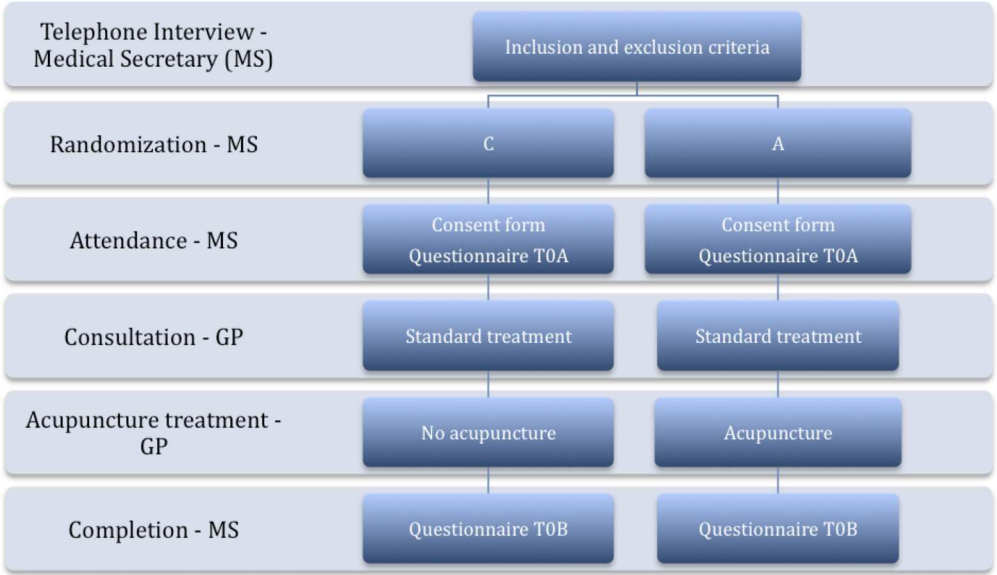
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Figure legends

Figure 1: Patient flow during inclusion, randomisation and treatment.

For peer review only



Patient flow during inclusion, randomisation and treatment.
159x92mm (300 x 300 DPI)



**ACUPUNCTURE FOR ACUTE NON-SPECIFIC LOW BACK PAIN:
A PROTOCOL FOR A RANDOMISED, CONTROLLED,
MULTICENTER INTERVENTION STUDY IN GENERAL
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ACUPUNCTURE FOR ACUTE NON-SPECIFIC LOW BACK PAIN: A PROTOCOL FOR A RANDOMISED, CONTROLLED, MULTICENTER INTERVENTION STUDY IN GENERAL PRACTICE – THE ACUBACK STUDY.

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Running title: Acupuncture for acute non-specific low back pain.

Key words: Acupuncture Therapy, Acute Pain, Clinical Research Protocol, General Practice, Low Back Pain

Word Count: 4120

ABSTRACT:**Introduction:**

Some general practitioners (GPs) treat acute low back pain (LBP) with acupuncture, despite lacking evidence of its effectiveness for this condition.

The aim of this study is to evaluate whether a single treatment-session with acupuncture can reduce time to recovery when applied in addition to standard LBP-treatment according to the Norwegian national guidelines. Analyses of prognostic factors for recovery and cost-effectiveness will also be carried out.

Methods and analysis:

In this randomised, controlled, multicenter study in general practice in Southern Norway, 270 patients will be allocated into one of two treatment-groups, using a web-based application based on block randomisation. Outcome assessor will be blinded for group allocation of the patients.

The control group will receive standard treatment, while the intervention group will receive standard treatment plus acupuncture treatment. There will be different GPs treating the two groups, and both groups will just have one consultation. Adults who consult their GP because of acute LBP will be included. Patients with nerve root affection, "red flags", pregnancy, previous sick leave more than 14 days and disability pension will be excluded. The primary outcome of the study is the median time to recovery (days). The secondary outcomes are rated global improvement, back-specific functional status, sick leave, medication, GP visits and side effects. A pilot study will be conducted.

Ethics and dissemination:

Participation is based on informed written consent. We will apply for an ethical approval from the Regional Committee for Medical and Health Research Ethics (REC), when the study-protocol is completed/published. Results from this study, positive or negative, will be disseminated in scientific medical journals.

Discussion:

~~This study aims to explore whether acupuncture is a useful clinical tool for treating acute LBP in general practice.~~

Trial Registration:

ClinicalTrials.gov Identifier: NCT01439412.

INTRODUCTION:

Low back pain (LBP) is a very common disorder with consequences for the individual patient as well as for the society. Up to 80% of the population experiences back pain at least once in their lifetime, about 50% during the previous year. Point prevalence is 15%, and the condition relapses frequently, 40% within 6 months.¹ Back pain is the medical condition that ranks highest in terms of Norwegian socio-economic expenses.² Most people with acute LBP experience improvements in pain and disability within a month,³ but the median time to recovery recorded in studies on back pain varies widely, from 7 days to 58 days.^{4 5} Acute LBP is treated primarily in the primary healthcare by general practitioners (GPs), physiotherapists, manual therapists and chiropractors. Recommended treatment according to clinical guidelines contains information about the condition, advice to stay active and, if possible, avoid bed rest, early and gradual mobilisation after the acute phase, pain treatment with paracetamol and/or non-steroidal anti-inflammatory drugs (NSAIDs) with time-contingent doses.^{2 6}

GPs educated and trained in acupuncture also use acupuncture for the treatment of both acute and chronic LBP cases.⁷ There is evidence that acupuncture is effective in chronic LBP, and such treatment is therefore recommended in the "National guidelines for LBP" in Norway.^{2 8-}

¹⁰ Reviews and meta-analyses conclude that the documentation of acupuncture treatment for acute LBP is limited by few and poorly conducted studies, however.^{10 11} In a systematic review conducted by Yuan et al, the authors concluded that for non-specific LBP, treatment regimens of acupuncture differ by the types of reference sources, in terms of treatment frequency, the points chosen, number of points needed per session, duration and sessions, and co-interventions.¹²

In 1997, He presented a Chinese study with 100 patients afflicted with LBP (5 days to 6 months duration) randomised to either manual acupuncture with moxibustion plus Chinese herbal medicine or Chinese herbal medicine alone.¹³ A later Cochrane review concludes that this trial was of low methodological quality and showed limited evidence to back the fact that the combined treatment was more effective for a global measure of pain and function in the long-term follow-up.¹⁰

Araki et al have published an abstract of a trial where 40 patients with acute LBP (< 3 days) were randomised into two groups where the intervention group got acupuncture treatment in the acupuncture point SI3 bilaterally and then performed back exercises. The control group, however, received sham acupuncture treatment with mimicked needle insertion, after which they were asked to perform back exercises. Araki et al found no difference between the effects of acupuncture and that of the sham acupuncture.¹⁴

One of the studies referred to in the Cochrane review is a Norwegian study conducted by Kittang et al.¹⁵ They found that acupuncture was as effective as medical treatment with Naproxen per os in relation to pain and stiffness, but that the "Naproxen-group" had more side effects and greater recurrences in the observation period. While Kittang et al conclude that acupuncture is effective, this result is based on other studies showing the efficacy of NSAIDs for acute LBP.¹⁶

Kennedy et al published a pilot study in 2008, which demonstrated the feasibility of a randomised, controlled trial regarding the penetrating needle acupuncture when compared to non-penetrating sham acupuncture for the treatment of acute LBP in primary care. However,

the study lacked sufficient power to draw any conclusion on treatment effects. The study did not reveal any conclusions of the effects of acupuncture.¹⁷

Sham acupuncture involves inserting penetrating or non-penetrating needles in points that are not classical acupuncture points and/or are not located in the same segment. Several studies conclude, however, that sham acupuncture is not a valid placebo control, and this is explained by neurophysiologic effects of the sham treatment.^{18 19} Trials with sham acupuncture need to be very comprehensive in order to demonstrate differences between the effects of real acupuncture and the sham treatment.²⁰

In 2006, Vas et al published a study protocol of a four-branch randomised controlled trial, which intended to obtain further evidence on the effectiveness of acupuncture on acute LBP and isolate the specific and non-specific effects of the treatment.²¹ The results have not yet been published.

Shin et al are planning to perform a randomised, controlled trial with two arms comparing a motion-style acupuncture with an NSAID injection.²²

However, we have not yet found evidence favouring acupuncture as a treatment for acute LBP. Our clinical experience is that an acupuncture treatment of the distal and local acupuncture points combined with small mobilising movements means faster recovery of the pain. This treatment is according to some textbooks on acupuncture.^{23 24} None of the mentioned protocols though examine this kind of acupuncture. All the points that we plan to use are mentioned among the common points used for LBP in the systematic review by Yuan et al, and mobilising movements are often used as a co-intervention for acute LBP.¹²

Strong stimulation of the distal acupuncture points is thought to act through activation of the extra-segmental pain inhibition, "Diffuse noxious inhibitory Controls" (DNIC) and the release of endorphins and possibly, other endogenous compounds in the central nervous system. Local acupuncture therapy immediately following the mobilisation movements may provide additional benefits through segmental pain-inhibition along with the inhibition of myofascial trigger points.²⁵

Clear prognostic factors for the efficacy of acupuncture for chronic LBP have, however, not been documented. In a large German study, the authors found that lower age, lower baseline spinal function and more than 10 years of education indicated a better response to acupuncture.²⁶ Some researchers still find that optimistic treatment expectations improve the effects of acupuncture,^{27 28} while others find the best treatment effects in patients who are neutral to acupuncture as a treatment method.²⁹ There are no similar studies for acute LBP.

A systematic review found evidence supporting the cost-effectiveness of the guideline-endorsed treatments of acupuncture for sub-acute or chronic LBP.³⁰ Apart from the few trials of acupuncture treatment for acute LBP, there are no studies examining the cost-effectiveness of acupuncture for acute LBP.

In the present study, we aim at exploring whether a single treatment-session with acupuncture can reduce the time to recovery when applied in addition to the standard LBP-treatment in general practice according to Norwegian national guidelines. We will not use sham acupuncture as a control treatment. Further, we will not include a pure placebo group or a "waiting list group", because this will mean not giving treatment to patients with severe pain, which we consider unethical.

Secondary aims are pain intensity, disability, sick leave and drug use, and in addition we will evaluate the prognostic factors for recovery, and if possible, identify any factors that characterize those who have beneficial effects of the acupuncture treatment.

~~A systematic review found evidence supporting the cost-effectiveness of the guideline-endorsed treatments of acupuncture for sub-acute or chronic LBP.³⁰ Apart from the few trials of acupuncture treatment for acute LBP, there are no studies examining the cost-effectiveness of acupuncture for acute LBP. Therefore~~Finally, we also aim at carrying out a cost-effectiveness analysis.

Our hypotheses are:

1. Acupuncture treatment contributes to faster pain-recovery in acute LBP compared to standard treatment in general practice provided in accordance with the Norwegian national guidelines.
2. Acupuncture treatment for acute LBP improves function, and reduces drug use and sick leave, compared to the standard treatment in general practice provided in accordance with national guidelines.
3. Acupuncture treatment for acute LBP is a cost-effective treatment in general practice.

METHODS AND ANALYSIS:

This is a randomised, controlled, multicenter study, which will involve 15 GP group practices located in different areas in southern Norway, both cities and rural municipalities. The 15 GPs administering the acupuncture have received their training through the education program of the Norwegian Society of Medical Acupuncture and are members of the Network Group of Medical Acupuncture, under the Norwegian College of General Practice. They are specialists in general practice and many of them are experienced participants in randomised clinical trials, given a parallel ongoing trial examining the effects of acupuncture on infantile colic.³¹

~~15 These GPs are located in different areas in southern Norway, both cities and rural municipalities.~~ GPs in the same practices, but without training in acupuncture, ~~however, need to be~~will be recruited to treat the control group.

A medical secretary at every doctor's office will carry out the telephonic interview in which, the patients will be informed about the study, the inclusion and exclusion criteria will be checked, the randomisation of the patients will be performed and the distributing and collecting questionnaires for the treatment day. A two-day workshop before the start of the main study will be arranged for all the participating doctors and medical secretaries. The workshop will contribute to the standardization of information, reporting and patient management in general. A website with information about the study will be created.

We plan to recruit patients with acute LBP and randomly allocate them into two parallel study-groups (A and C) of equal sizes. Patients in both groups will receive standard treatment for LBP in accordance with the Norwegian national guidelines.² One group will receive *only* the standard treatment, while the other group also will receive additional acupuncture treatment as described below. To control for potential attention bias, we will measure the time spent on each patient in the intervention and control groups. Outcome assessor will be blinded for group allocation of the patients.

Inclusion criteria:

- Adults (20-55 years) who contact their GP's office because of acute nonspecific LBP (0-14 days).

Exclusion criteria:

- Nerve root affection and/or radiating pain below the knee.
- LBP with suspected “red flags”, i.e. infections, tumours and metastatic disease, rheumatic disease, fractures and significant deformities of the spine.
- LBP which starts in pregnancy.
- Physician-reported sick leave of 14 days or more during the month before the commencement of the back pain, for any reason.
- Disability pension.

Control group C: Standard treatment in general practice is provided in accordance with the Norwegian national guidelines, i.e. general advice about activity, prescription of pain relievers (paracetamol), and sick leave, if needed.

Acupuncture group A: This group will receive standard treatment as the control group and in addition acupuncture treatment.

Acupuncture: The patient sits in a chair and the doctor stimulates the acupuncture points “the Lumbar Pain Points” ([Yaotongxue/Yaotongdian](#)) on the right hand, with acupuncture needles of type Seirin B - 8a 0.30 x 30 mm. These are two points located between the second and third and the fourth and fifth metacarpal bones, immediately distal to the bases of the metacarpals. Insertion depth is 10–15 mm. The doctor stimulates the needles in a rotating up-and down movement to impart a powerful needle sensation (called “de Qi”), and this is repeated in short sequences to maintain the needle sensation for a total of 1 min. The needles shall stay in the hand during the rest of the treatment. The patient is then asked to rise and to perform slow rotating pelvic movements for 2 minutes, before lying down on a bench to be treated in the local points Huatuoji (Jiaji) with acupuncture needles of the type SEIRIN J-8 with sleeve 0.30 x 50 mm. These points are located 1.5 cm lateral to the depressions below the spinous processes, and we will acupuncture them bilaterally in the segments of the L2-L4 (6 needles) at a depth of 3–4 cm. They are stimulated manually until the patient experiences the needle sensation. Then, the patient lies quietly on the bench for another 5 minutes before all the needles are removed.

The whole acupuncture session lasts for a total of 8 minutes. Thus part of the advice and prescription part is done while the patient is receiving acupuncture treatment, in order to let the consultation time for the two groups be as equal as possible. The consultation time will be measured and registered by the GPs. The duration of the acupuncture treatment in this trial is shorter than in earlier trials, and we will only have one treatment session.¹² This is to reduce potential attention bias.

Choice of treatment:

The described treatment with the specific distal and local acupuncture points has been chosen after a three-step process. We started with the treatment we used ourselves in clinical practice, compared it with the literature and standardized it for this trial. Then we asked several experienced acupuncture doctors how they treated acute LBP and what they thought about our suggestion of standardization.

Based on this feedback, we asked an expert group of physicians and physiotherapists experienced in administering acupuncture about which acupuncture points they preferred in the treatment of acute LBP. The end result was considered the treatment according to best practice for this study.

Patient flow:

When a patient with acute LBP contacts the GP’s office, the medical secretary provides information about the trial and asks whether the patient would want to participate in the study.

The patient will be informed that he/she will meet a GP and get the usual treatment for LBP, and may or may not get acupuncture in addition to the usual treatment. During the observation period of 12 months, patients are asked for not to receive any additional acupuncture treatments.

If the patient consents, the medical secretary asks the patient questions regarding inclusion- and exclusion criteria. The inclusion and exclusion criteria are checked both in the telephone interview by the secretary and in the consultation by the GP. All contacts are counted and it is recorded at what level and for what reason exclusions are done. If the patient is eligible, the medical secretary randomises the patient to one of the two groups through the Web-based application at the Unit for Applied Clinical Research in Trondheim (<http://www.ntnu.no/dmf/akf>). This is used to register the patient in the appropriate doctor's timetable, but the patient does not know which group or which doctor he/she is going to meet. At the GP's office, the patient is required to fill in the consent form and the first questionnaire (T0A). This is delivered to the medical secretary prior to the consultation.

Patients who are randomised to the control group will receive one standard treatment provided by a GP without acupuncture training. The consultation will include history, examination, information, prescription and advices, according to national guidelines for LBP. If the doctor discovers exclusion criteria, the patient will be excluded from the trial.

Patients who are randomised to the acupuncture group will receive one single acupuncture treatment in addition to the standard treatment as described for the control group. The consultation will be provided by a GP who is trained in acupuncture. If the patient's condition requires further consultations in the follow-up time, these will be recorded. These consultations, however, will not include additional acupuncture treatment.

When the patient has finished the consultation, they will fill in a post-treatment questionnaire (T0B) and submit it to the secretary in an enclosed envelope. The patient then will receive a back pain diary, which he/she will be required to fill in at home at the given times. The diary also contains information about how the patient can choose to give the answers in an electronic questionnaire (Figure 1).

Measurements:

For evaluation of the effects of treatment, we will use standardised instruments that have been validated, both internationally and nationally.^{33 34} The outcome measures will be filled in at baseline and after 1, 2, 4, ~~and~~ 12 weeks and 12 months, and the following outcome measurements will be included:

The primary outcome is the median time in days to the recovery of pain, measured on the first day the patient scores 0 or 1 point on the Numerical Rating Scale (NRS). Clinically relevant differences between the groups are considered to be minimum 3 days.

Secondary outcome measures will be:

1. Pain intensity is assessed by the numerical rating scale (NRS) before and immediately after treatment and at the other follow-up times. The patient indicates his perceived pain intensity on an 11-point scale from 0 to 10 with endpoints indicating "no pain" and "worst imaginable pain". Based on other studies, ~~the clinically~~ relevant improvement is estimated to as being minimum 2-31.5 points in a previous Norwegian study on patients with acute LBP for individual patients and 1 point as the difference between the groups.³⁵

2. Back specific functional status by the Roland Morris Disability Questionnaire (RDQ). This measures patients' perceptions of function.³⁶ The patient answers yes or no concerning 24 allegations about the activities and conditions, depending on whether they feel that the statement describes them on this day.
3. Sick leaves, the number of days away from work due to back pain.
4. Global measure of improvement (Likert improvement assessment scale). This assesses the patients' perceptions of change, stated in whole numbers from 1 = much better to 5 = much worse.
5. Use of medication (paracetamol, eventually others), counting of daily consumption.
6. Number of new visits at the GP's office.
7. Side effects of treatment (acupuncture and medications).
8. Health-related quality-of-life by the EuroQoL (EQ-5D). This enumerates 5 questions that map the following areas: Walking, personal care, daily activities, pain/discomfort and anxiety/depression, as well as a 100 mm VAS scale (Visual Analogue Scale).³⁷

In addition the patients will be asked to fill in a Back pain diary. This refers to a small printed matter where the patient completes a daily questionnaire about the condition, as an aid to remember the results between each registration in the electronic questionnaire. It contains question about the pain level, function, use of medications, side effects and other comments every day for 2 weeks and 4, ~~and~~ 12 weeks and 12 months after treatment.

The following questions will be included at the baseline for describing the baseline characteristics of the included sample and for the evaluation of potential prognostic factors for recovery:

Sociodemographic variables: This refers to age, gender, marital status, education, smoking status, use of alcohol, height, weight and serious life events during the 12 last months.

In addition we will ask the patients about their preferences for the two treatment options for LBP and if they believe that acupuncture will contribute to faster recovery than the usual treatment.

Örebro screening form for musculoskeletal pain: These are 25 questions that map all the main "yellow flags". This questionnaire about the pain and how it influences job-related activities shows prognostic factors for acute LBP.^{38 39}

Subjective Health Complaints (SHC): Here, the patient indicates in what degree he/she has had 29 different health complaints the last 30 days and how long the complaints have lasted.⁴⁰

Patients will fill in the questionnaire at baseline (before the first treatment) and then immediately after the first treatment at the GPs office. Patients will fill in the Back Pain Diary at home every day for 2 weeks, ~~and~~ after 4 and 12 weeks and after 12 months. They may choose to fill in the results directly in the electronic questionnaire. If the results are not registered electronically, the patients may have to send the hard copy version of the diary to the project leader after 12 weeks. The last questionnaire has to be sent after 12 months, which is the maximum follow-up time.

Patients will receive a SMS reminder about the registration. If the patient does not respond to the electronic questionnaire or the Back pain diary, he/she will be reminded by SMS or telephone twice. Those who withdraw will be asked for the reason for doing so.

Sample size:

We have calculated that a total of 270 patients will be needed for the study. Based on previous studies and clinical experience, we estimate that the 3 days' difference in median time to recovery between the acupuncture group and control group is clinically significant, with a

median time to recovery of 7 days in the intervention group.^{441 42} The probability is 80 % that the study will detect a treatment difference at a two sided 5 % significance level, if the true hazard ratio is 1.429. This is based on the assumption that the accrual period will be 0 days, the follow-up period will be 84-365 days and the median survival is 7 days.⁴³ In addition, we calculate with up to 10% dropout in the study.

Pilot study:

Prior to the main study, we plan to conduct a pilot study to test the study design, the assessment and reporting tools with a total of 8 patients, 4 in each group.

Randomisation

Randomisation will be performed by a web-based randomisation system developed and administered by the Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway, and it will use block randomisation with various sizes of the blocks.

Each patient is randomised after the inclusion and exclusion criteria are considered. It is the GP's medical secretary who checks the randomisation online, and the patient is then given an appointment with either the "control-GP" or the "acupuncture-GP". The patient is not told which group he/she is randomised to or the name of the GP before the consent form and the first questionnaire are filled in.

Analyses

Data will be analysed by an outcome assessor who is blinded to group status. The groups will be analysed only as group 1 and group 2, and the results presented in Tables and Figures will be worked out before the codes are broken. The primary analyses will be by intention-to-treat and we will restrict the number of analyses in order to reduce the possibility of Type I errors. For primary outcomes, a P value of <0.05 will be considered statistically significant. For the secondary outcomes a P value of <0.01 will be considered significant.

Primary Outcome Analyses:

We will assess the difference in survival curves (days to recovery) for the 2 groups using the log-rank statistic. The median days to recovery will be used to express the time to recovery for the two groups. Cox regression will be used to assess the effect of treatment group on hazard ratios after allowing for the days of pain duration as baseline covariate.

Secondary Outcome Analyses:

Differences between the groups will be presented as mean with 95% CI or in categories with odds ratio for categorical data. A mixed model with group as a fixed factor will be used for the other outcome measures. Post-hoc analyses will be conducted if there is a significant difference between treatment groups. We will also test for potential confounding factors in these models. Analyses of prognostic factors will be carried out by a multivariate regression models.

ETHICS AND DISSEMINATION:

When the patient contacts the GPs office, he/she will be informed about the objectives of the study and asked if he/she is willing to participate. The patients will be told that their participation is voluntary and that they will be granted full anonymity. Informed wWritten consent will be required from the included patients.

All patients will receive the treatment they normally would receive from their GP, but half of them will undergo acupuncture treatment in addition to this. Given the randomisation, some

patients will not meet their usual GP. Instead, another GP will consult the patient, though in the same office.

The risk of side effects of the acupuncture treatment has been found to be low.⁴⁴⁻⁴⁶ We will examine any side effects of the treatment during the trial.

The trial is registered in the ClinicalTrials.gov-register, NCT01439412.

We plan to apply to the Regional Ethics Committee of South-Eastern Norway when the protocol is ~~completed and~~ published.

Publication policy:

The results of the trial will be published in appropriate journals regardless of outcome. The trial will be implemented and reported in accordance with the recommendations of CONSORT and STRICTA.

DISCUSSION

This paper presents the design and rationale for a randomised, controlled multicenter study examining the effects of acupuncture on the recovery of patients with acute LBP. The project will increase the knowledge about the effects of acupuncture treatment for acute LBP, a common disorder seen by general practitioners entailing high costs for the patient and society. For the individual, a faster pain relief will aid an earlier return to normal, everyday activities. For the society, the effect may be that LBP patients will return earlier to their work. The primary outcome is the median time in days for recovery from pain. The secondary outcomes are rated global improvement, back specific functional status, sick leaves, medication, GP visits and side effects. A pilot study will be conducted. In the present study, we will also analyse possible prognostic factors for recovery and cost-effectiveness of acupuncture treatment for LBP.

Collaboration:

We have established an international collaboration agreement with Karolinska Institutet (Sweden) and Keele University (United Kingdom). Both institutions have extensive experience and knowledge within research in medical acupuncture and musculoskeletal disorders.

Funding:

TS has received research grants from the Norwegian College of General Practitioners to plan this trial. The study funder will not have any impact on the trial and the publication of the results.

Authors' contributions:

TS and HS initiated the project. TS, HS, MB, MG, IS and AF all contributed to conceptualisation and design of the study and all revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Competing interests:

None

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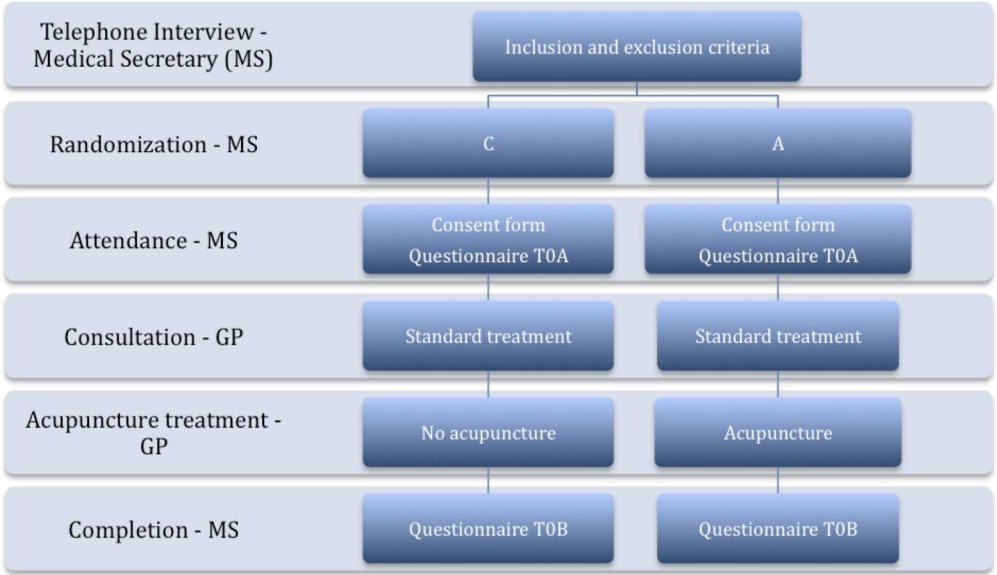
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Figure legends

Figure 1: Patient flow during inclusion, randomisation and treatment.

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Patient flow during inclusion, randomisation and treatment.
159x92mm (300 x 300 DPI)