BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034157
Article Type:	Original research
Date Submitted by the Author:	07-Sep-2019
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Keywords:	COMPLEMENTARY MEDICINE, Back pain < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS, PAIN MANAGEMENT

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Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

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Word count:

3999

Key words

Acupuncture Therapy, Low Back Pain, Randomised Controlled Trial, General Practice

ABSTRACT

Objectives

The aim of this study was to evaluate whether a single treatment session of acupuncture, when applied in addition to standard treatment for acute low back pain (ALBP), reduces the time to recovery compared with standard treatment alone.

Design

A multicentre, randomised, controlled trial.

Setting

Conducted at 11 Norwegian general practitioners' (GPs') offices.

Participants

171 adults aged 20–55 years seeking their GP for ALBP (≤ 14 days) between March 2014–2017. Patients with secondary back pain and previous sick leave and acupuncture treatment were excluded.

Interventions

The participants were randomised to either the control group (CG) or the acupuncture group (AG) by online software. The CG received standard treatment according to the Norwegian guidelines, while the AG received one session of acupuncture treatment in addition to standard treatment. The statistician was blinded to group status.

Primary and secondary outcome measures

The primary outcome was median days to recovery. Secondary outcomes were pain intensity, global improvement, back-specific functional status, sick leave, medication, and adverse effects. We also performed a cost-effectiveness analysis.

Results

185 participants were randomised, 95 in the CG, 90 in the AG. 14 participants did not receive the allocated intervention, and four were excluded from analysis. Thus, 167 participants were included in the analysis, 86 in the CG, 81 in the AG. The groups were similar according to baseline characteristics. The recovery period was 14 days for the control group and 9 days for the acupuncture group (p = 0.089). There was a nonsignificant difference of 4 days for the return-to-work period. The cost-effectiveness analysis indicated that acupuncture treatment was likely to be cost-effective.

Conclusions

We found clinically relevant reduction in time-to-recovery and return-to-work after a single session of acupuncture for ALBP compared with standard care, but the results were not statistically significant.

Trial registration

NCT01439412

Strengths and limitations of this study

- The adherence to the protocol and uniformity of patient handling lead to similar groups, leading to reduced attention bias.
- The performance of a pilot study and development of software lead to improved logistics and increased response rate.
- This is the first trial evaluating cost-effectiveness of acupuncture for acute low back pain.
- The lower inclusion rates than expected reduced the power, leading to weaker conclusions about the effectiveness of the treatment.

INTRODUCTION

Low back pain (LBP) is a common symptom and an important cause of disability globally.[1 2] The causes of LBP are multifactorial, and most episodes of LBP are categorized as nonspecific.[1 3] The majority of patients affected by acute LBP (ALBP) experience a decrease in pain and disability within a month, but a significant number will experience recurrences or develop chronic pain.[1 4]

Most cases of ALBP are treated in primary health care. Clinical guidelines for treatment of ALBP recommend information and education, advise to stay active and avoid bed rest.[5] The Norwegian guidelines of 2007 still include pain treatment with paracetamol and/or nonsteroidal anti-inflammatory drugs (NSAIDs),[6] which is nowadays internationally less emphasized.[5 7-9] In the 2017 US guideline pharmacological treatment is recommended only if nonpharmacological treatment does not succeed.[7] Some guidelines recommend acupuncture as first-line treatment, despite lack of high-quality evidence.[7 10]

In 2013, Lee et al. published a systematic review of acupuncture for ALBP and found that evidence is sparse.[11] They concluded that acupuncture might be more effective than medication for symptom improvement and pain relief than sham acupuncture (SA). However, the authors suggested new trials with better design and reporting of results.

In another study, Vas et al. compared different acupuncture types with conventional therapy (CT), and found that the intervention groups fared significantly better than the CT groups.[12] However, there was no difference between valid acupuncture according to Traditional Chinese Medicine (TCM), SA, or placebo acupuncture.

Another trial using nonpenetrating SA was described by Hasegawa et al., in which the intervention was a Japanese type of acupuncture, Yamanoto's new scalp acupuncture (YNSA).[13] Although their intervention did not reach the predefined values for the primary

outcome, the authors concluded that YNSA was more effective than sham treatment in ALBP for both pain relief and other outcomes.

In 2013, Shin et al. reported that one session of motion-style acupuncture treatment (MSAT), consisting of walking with the needles inserted, was superior to one intramuscular injection of diclofenac with respect to pain reduction and function.[14]

Our study aimed to evaluate if a single treatment session with acupuncture could result in a faster recovery when applied in addition to standard treatment for ALBP compared with standard treatment alone. Our aim was also to describe pain intensity, disability, work absence, adverse effects, use of medication, and cost-effectiveness.

METHODS

Study design and randomization

The study was a multicentre, randomised, controlled trial (RCT) undertaken in 11 Norwegian GPs' offices. The study period was from March 2014 to March 2017 with a last follow-up in March 2018, after an extension of 1 year due to slow patient enrolment. The participants were randomised by a health secretary into an acupuncture group (AG) or a control group (CG) in a ratio of 1:1, using a web-based randomization system developed and administered by the Unit of Applied Clinical Research, Norwegian University of Science and Technology,[15] which performs block randomization with various block sizes.

Data collection was performed by electronic surveys at 19 different time points; before and after treatment on the day of treatment, and each day for 2 weeks; then, after 4 weeks, 12 weeks, and 1 year. To administer the logistics of the surveys, we developed software, SESAMe, which is described in a previous publication.[16]

In a pre-study power calculation, we estimated the sufficient sample size to be 135 in each group.[17] Each patient was blinded to the group allocation when reporting baseline data, but from the time of consultation neither the patient nor the GP was blinded.

The protocol of the present study was published in 2012 and includes further details.[17] Prior to the main study, we conducted a pilot study that included eight participants during October 2013 to January 2014. The results from the pilot study led to the web-based version of SESAMe,[16] an exclusion criterion of previous acupuncture, and advices to the participating GP offices about medication standardization, study logistics, and efforts to minimize differences in placebo effects.

The study is registered in ClinicalTrials.gov (NCT01439412). Ethical approval was given by the Regional Ethics Committee of South-Eastern Norway (reference 2013/611/REK sør-øst A). The reporting of the study follows the CONSORT statement[18] and the STRICTA recommendations.[19]

Participants and recruitment procedure

Patients with ALBP lasting 14 days or less who contacted their GP office were asked to participate in the trial. We included adults aged 20–55 years with nonspecific ALBP who gave informed consent. Exclusion criteria were nerve root affection, "red flags", pregnancy, disability pension, sick leave of more than 14 days, and acupuncture during the last month.

The inclusion/exclusion process was performed by the health secretary at the GP's office and in an initial online survey with information and the consent. She also administered the emails in SESAMe and asked the patient to answer the baseline survey before the consultation. If the GP discovered any exclusion criteria during the consultation, the patient was excluded. This, as well as the time spent in the consultation, was recorded by the GPs.

At each GP office, one GP was trained in acupuncture and treated the AG, and from one to four other GPs treated the CG. All acupuncture GPs were specialists in family medicine, and the mean time of acupuncture experience was 7.4 years (range 1–19 years). Nine of the GPs had at least 320 hours of education in acupuncture.

Most treating GPs in the CG were experienced specialists in family medicine, but some of them were working in the internship program; thus, the overall experience of the treating GPs varied more than for the AG.

Study interventions

Standard treatment (CG) consisted of advice about activity, prescription of analgesic medication (paracetamol and/or ibuprofen), and sick leave, if needed, according to the Norwegian national guidelines.[6]

The AG received the same standard treatment as the CG and, in addition, one session of acupuncture treatment. This session consisted of 1 minute with two needles of Seirin® type B-8a 0.30 × 30 mm in the acupuncture points, Lumbar Pain Points (Yaotongxue/Yaotongdian) on the right hand, stimulated to a powerful needle sensation, called "de Qi" in TCM. With the needles in the hand, the patient was asked to rise and perform mobilization movements (slow rotating pelvic movements) for 2 minutes, followed by 5 minutes on a bench while the patient received six needles of the SEIRIN® type J-8 0.30 × 50 mm in the local points Huatuojiaji ("Jiaji") in the L2–L4-segments, stimulated until needle sensation. The needles remained in place until all the needles were removed after a total treatment time of 8–9 minutes. The short treatment and the choice of only one session of acupuncture were an attempt to reduce potential attention bias. The details of the procedure and the process of choosing the specific and standardized treatment are briefly described in the published protocol.[17]

Before the study, the health secretaries and many GPs (including all acupuncture doctors) were gathered at a workshop to ensure they understood the study logistics, the standard ALBP treatment, and the standardization of the acupuncture treatment. During the trial, we arranged two workshops to remind the GP offices of the need of inclusion and update about the study logistics.

Outcome measurements and data collection

The primary outcome in the study was days to recovery, defined as the first day the patient scored 0 or 1 on the Numerical Rating Scale (NRS).[20 21] This definition is in line with the definition of "sustained recovery" with an NRS of 0 or 1 for seven consecutive days.[21 22] We defined a minimum of a 3-day faster recovery as a clinically relevant difference between the groups.

The secondary outcome measurements were pain intensity,[20] disability by Roland Morris Disability Questionnaire (RMDQ),[23] sick leave, 5-point global improvement (Likert scale), use of medication, adverse effects, and health-related quality of life by the EuroQol (EQ-5D-3L), using UK tariff for time trade-off.[24] RMDQ and EQ-5D-3L were collected at baseline, 1, 2, 4, 12 weeks, and 1 year, while the other secondary outcomes were collected at all time points. In addition, at baseline, we asked for sociodemographic variables, patient preferences for treatment options, expectations with respect to the effect of acupuncture and psychosocial risk profile according to the Örebro screening form for musculoskeletal pain.[25 26] We also asked the participants in the 1-year survey about the number of new LBP episodes, work absence, and if they had received any other kind of treatment for LBP the last 9 months.

For the cost-effectiveness analysis, we estimated costs at day 28 and day 365. Both time points included direct costs for the study treatment (one consultation with the GP), estimation

of extra consultations with the GP, reported use of medication, and absence from work. Day 365 also included costs of physiotherapy, chiropractic, osteopathy, naprapathy, acupuncture and surgery, estimated by reported types of therapy and number of new LBP episodes.

For the estimation of the health care costs we used the following assumptions of moderate use of health care services: one consultation with the GP for one new episode of LBP, two consultations for two episodes, three for three to four episodes, and four consultations for five or more new episodes. For the other therapies, we estimated four treatments per new episode. We also performed sensitivity analysis with a lower and a higher use of health care services.

In Norway, 58.9% of the GPs are specialists in family medicine with higher charges per consultation. Therefore, GP charges were weighted according to this.[27] Moreover, the GP costs were adjusted for per capita subsidy and differentiated by consultation time (≤20 or >20 minutes). Costs for absence from work were based on official statistics of average wages by sex and age groups, adjusted for the proportion of part-time positions (women 35.2, men 13.3), with respectively working per cent (women 59 and men 56). Information on costs per unit is given in Supplementary file 1. We used costs in NOK for 2018, converted to US dollars, USD 1 = NOK 7.7186.

The cost-effectiveness analysis used quality-adjusted life-years (QALYs) to express health gains. The cost-effectiveness threshold for LBP was based on the Norwegian governmental report No. 34 to the parliament with a value of NOK 275,000 (USD 35,628) per QALY.[28] This number is used in the estimation of net monetary benefit (NMB).

Statistical analysis

Details of the protocol for randomization, allocation procedures, and power calculation were published previously.[17] Statistical analyses were performed using the programs IBM SPSS Statistics® 25 and StataSE® 15. Data were analysed by a statistician who was blinded to group status, and the results presented in tables and figures were finalized before codes were revealed. The primary intention-to-treat (ITT) analyses were done. We calculated the difference in days to recovery for the two groups using the log-rank test, and missing answers were censored, leaving the last specified value for analysis.

The time to recovery was expressed by the median days to recovery for the two groups, and Cox proportional hazard regression models were used to assess the effect of treatment on pain duration (in days). We checked the Cox proportionality assumption and concluded that our model satisfied the assumption of proportionality.

Numeric secondary outcomes such as NRS were analysed using linear multilevel models with patient random effects, while binary outcomes such as medication use were analysed using binary multilevel logistic regression models. With numeric outcomes, mean changes over time in the groups were obtained, while predicted probabilities over time for each group were obtained for binary outcomes.

For primary outcomes, a p-value of <0.05 was considered statistically significant. For the secondary outcomes, a p-value of <0.01 was considered significant, and 99% confidence intervals (CIs) given.

Cost-effectiveness was estimated by the incremental cost-effectiveness ratio (ICER), defined by the incremental costs relative to QALYs gained. To find the QALYs gained, the trapezoidal method was used to estimate the area under the curve by combining utility indexes and time. To avoid ambiguous interpretation of the ICER, the NMB defined by incremental QALYs times the threshold minus the incremental costs was calculated. When the NMB is

equal to or higher than zero, acupuncture is considered cost-effective. Uncertainty was analysed by the bootstrap method with 1,000 replicated datasets.

RESULTS

The study flow chart shows that of a total of 185 participants that were randomised into the two groups, 167 were included in the analysis (Figure 1). Recruitment of participants at the 11 GP offices varied considerably (Supplementary file 2).

The overall response rate in the trial was 87.4%, but varied in each survey and decreased over time. One year into the observation period, 66 participants in the AG and 61 in the CG had answered the survey, resulting in a response rate of 76.0%. Supplementary file 3 shows the numbers of missing answers per survey for the primary outcome and Supplementary file 4 for the secondary outcomes. One participant in the AG underwent an operation for sciatica during the follow-up period.

Table 1 shows the baseline characteristics with sociodemographic data and clinical features of the participants.

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Characteristic	Control (n = 86)	Acupuncture (n = 81)
Age (year), mean (SD)	39.3 (9.4)	39.8 (11.4)
Female, n (%)	44 (51.2)	41 (50.6)
Living with a partner, n (%)	57 (67.9)	65 (83.3)
Born in Norway, n (%)	78 (92.9)	69 (88.5)
Level of education >13 years, n (%)	28 (33.3)	30 (38.5)
Work status		
Employed, n (%)	77 (91.7)	70 (87.5)
Student, n (%)	7 (8.3)	6 (7.5)
Unpaid work, n (%)	1 (1.2)	1 (1.3)
Unemployed, n (%)	2 (2.4)	3 (3.8)
Sick leave, n (%)	3 (3.6)	3 (3.8)
BMI		
<25 (normal), n (%)	28 (33.3)	30 (38.5)
25.00–29.99 (overweight), n (%)	29 (34.5)	29 (37.2)
>30 (obese), n (%)	27 (32.1)	19 (24.4)
Smoking, n (%)	20 (23.8)	14 (17.9)
Alcohol several times a week, n (%)	10 (11.9)	8 (10.3)
Serious life events last 12 months, n (%)	15 (17.9)	17 (21.3)
Previous LBP, n (%)	63 (73.3)	58 (71.6)
Treatment preference: acupuncture, n (%)	66 (78.6)	58 (74.4)
Belief in acupuncture treatment (0–10), mean (SD)	6.6 (2.6)	6.6 (2.5)
Back pain intensity (0–10), mean (SD)	6.3 (1.8)	6.2 (1.9)
Leg pain intensity (0–10), mean (SD)	2.7 (2.6)	2.4 (2.7)
RMDQ (0–24), mean (SD)	14.8 (4.4)	15.0 (4.2)
EQ-5D, mean (SD)	0.40 (0.33)	0.41 (0.31)
DDD non-opioid medication, mean (SD)	0.66 (0.85)	0.93 (0.97)
DDD opioid medication, mean (SD)	0.09 (0.27)	0.09 (0.31)
Örebro		
Low risk, n (%)	41 (48.8)	47 (60.3)
Medium risk, n (%)	25 (29.8)	19 (24.4)
High risk, n (%)	18 (21.4)	12 (15.4)
SHC, mean (SD)	11.25 (7.44)	9.12 (5.36)
Missing	2	3

Data in n (%) or mean (SD). SD indicates standard deviation; BMI, body mass index; LBP, low back pain; RMDQ (0–24), Roland Morris Disability Questionnaire, higher score represents greater overall disability; DDD, defined daily dose; SHC, subjective health complaints, higher score means more reported health complaints. EQ-5D, higher score represents better health state; NRS (0–10), higher score represents more pain. There were no significant differences between the groups in any of the variables.

Primary outcome

Median time to recovery was 14 days for the CG (IQR 6-84) and 9 days for AG (IQR 4-84) The difference of 5 days was not statistically significant (p=0.089) despite it reached the a priori threshold for clinical relevance. Time to recovery for 365 days and the first 28 days are shown in Figure 2. The log-rank test for 365 days is based on 56 observed and 65.3 expected events in the CG and 64 observed and 54.7 expected events in the AG, which was not statistically significant (p = 0.072). We also performed a sensitivity analysis on the four excluded participants with the same result.

Mean time to recovery was 67.2 days for the CG and 62.8 days for the AG, with mean difference of 4.4 days (95% CI -33.1, 41.9).

9.6 (95% CI: 9.5, 9.7) people are needed to be treated (NNT) for one person to recover by 7 days.

Secondary outcomes

The pain intensity assessed by NRS during the study period showed neither clinically relevant nor statistically significant differences (Supplementary file 5).

The mean difference in pain between the two groups during the whole study was 0.43 in favour of the AG. This equals a standardized mean difference (SMD) of 0.12, which is a small effect size. The mean difference at days 0–4 is 0.94, which results in a SMD of 0.44, which is close to a moderate effect size.

Disability by RMDQ showed no statistically significant difference during the study (Supplementary file 6).

There was a difference of 4 days in the median time of return to work, with 5 days (IQR 1-12) for the CG versus 1 day (IQR 1-7) for the AG (p = 0.13). However, the predicted probability curve for the time to return to work showed statistically significant differences just for days 5 and 6 (Supplementary file 7).

The predicted probability of the participants' perception of global improvement (feeling better or much better) showed a significant difference between the groups from day 0 after treatment through day 8 (Figure 3).

The predicted probability of using non-opioid medication given group as a fixed factor, showed significant differences for days 3 to 8 in favour of the AG (Supplementary file 8). There were no differences between the groups for opioids.

No serious adverse events were reported in the study. Sixteen participants (18.6%) in the CG reported some adverse effects compared with 11 (13.6%) in the AG (p = 0.38). Two participants reported pain/soreness in their hand because of the needles the day after the treatment. Twenty-two participants reported gastrointestinal symptoms, 14 of them in the CG. Other less frequent symptoms were tiredness, headache, dyspnoea, and muscle pain.

The duration of the consultations in the AG were 20.2 minutes, merely 3.2 minutes longer than in the CG. In the study 22% of the patients in the CG were treated by their regular GP versus 40% in the AG (p = 0.043). The difference between the groups in terms of new visits to the GP through the study period was 0.13 (99% CI -0.72, 0.98). There were nonsignificantly more LBP episodes in the CG after 1 year, 0.7 (99% CI -0.29, 1.76).

Cost-effectiveness analysis

The mean health care costs at day 28 were USD 101 (SD 54) in the AG, USD 94 (SD 50) in the CG, and USD 686 (SD 1,462) and USD 709 (SD 920), respectively, at 1-year follow-up. Total societal costs, including absence from work, were estimated to be USD

1,997 (SD 2,980) for the AG and USD 2,759 (SD 3,253) for the CG at day 28, and after 1 year the total costs were USD 6,544 (SD 12,153) and USD 9,208 (SD 17,734), respectively.

Health-related quality of life measured by EQ-5D-3L did not show significant differences at any time (Supplementary file 9). At day 28 the observed difference between the groups was 0.0005 QALYs (99% CI -0.0060, 0.0049), and at day 365 the difference was 0.0487 (99% CI -0.1073, 0.0099), both in favour of the AG.

From a health care perspective, the ICER at day 28 was USD 14,000 per QALY gained and USD -472 per QALY gained at day 365, while from a societal perspective, the ICER was USD -1,524,000 per QALY gained and USD -54,702 per QALY gained, at day 28 and 365, respectively. Three out of four calculations were showing a negative ICER, indicating that acupuncture was cost saving (Supplementary file 10).

The NMB was positive in all calculations. With regard to the health care costs at day 28, the NMB was USD 11 and at day 365, the NMB was USD 1,758; NMB for societal costs were USD 780 and USD 4,399, respectively.

The uncertainty analysis of total societal costs at 1 year is shown in Figure 4. The ICERs were estimated with the assumption of a moderate use of health services, and sensitivity analysis with low or high use of health services did not change the result substantially. From the bootstrapped results the majority of the replicated dataset indicate that acupuncture was cost-saving and provided a QALY gain. Given the threshold of NOK 275,000, the probability for acupuncture being cost-effective was 93.1%.

DISCUSSION

This study showed that adding one single session of 8–9 minutes of acupuncture treatment to standard guideline-based care to patients with ALBP resulted in a reduced median recovery

period of 5 days, a difference that was not statistically different despite our a priori predefined clinically relevant difference of 3 days or more. Similarly, adding acupuncture to standard guideline-based primary care did not show any stiatistically significant effect in the secondary outcome measures of pain and disability, but for reduced time until return to work, self-reported global improvement, medication and cost-effectiveness. Finally, the acupuncture treatment was safe, with no significant differences of major symptoms or serious adverse events.

The main strength of this study was the adherence to the protocol with standardised intervention procedures and uniformity of patient handling, leading to similar groups, also regarding the consultation time. The performance of a pilot study lead to logistic changes that contributed to both an equality of the groups and an improved response rate. The innovative process of developing our own logistic software (SESAMe) was central in this quality improvement.[16]

The main limitation of this study was the low power due to lower inclusion rates than expected, even after we extended the inclusion period with 1 year. This led to weaker conclusions about the effectiveness of the treatment. The results of the primary outcome could well be a type II error. However, low power in a trial reduces the likelihood that the observed effect represents a true effect.[29] Despite a generally high response rate, the study was also limited by relatively few observations for the health economic analysis.

Acupuncture treatment provided in this trial consisted of both shorter treatment time and fewer treatment sessions than usual.[30 31] Our results support Vas et al. showing the effectiveness of acupuncture versus conventional therapy.[12] The effect of only one acupuncture treatment session for LBP was previously shown by Shin et al. and Araki et al.[14 32] However, MacPherson et al. showed that pain outcomes were influenced by increased numbers of needles and more sessions, and thus the dose was important.[31] After the trials of

Vickers and MacPherson,[31 33] the US National Center for Complementary and Integrative Health (NCCIH) announced a need for pragmatic acupuncture trials for pain management, testing the effectiveness in "real world" conditions.[34] This was what we aimed to do in the present study. Because this was a pragmatic trial in accordance with the NCCIH recommendations, the participants and GPs were not blinded. Some may argue that this is a problem in acupuncture trials, but a large systematic review with individual patient data meta-analysis by Vickers et al. in 2012[33] showed that acupuncture has a small, specific effect on pain. The difference between true acupuncture and sham or placebo acupuncture is small, and trials will need large sample sizes to emphasize these differences, which Vas et al. demonstrated to be also true for ALBP.[12]

The two study groups scored equal for treatment preferences and belief in acupuncture. For the AG, this might represent a positive expectation bias when receiving the treatment, while those in the CG might have had a negative expectation bias when not receiving the acupuncture they had wanted. This would be in accordance with other research demonstrating an effect of treatment preferences and belief in the treatment in pain studies.[35 36]

The highly significant difference in the likelihood of global improvement could also be a result of the positive expectations, but it could also be due to the experience of a faster recovery with less pain and a faster return to work. The findings are in accordance with the systematic review by Lee et al. in which acupuncture is compared with the use of NSAIDs.[11] However, subjective outcomes have been shown to exaggerate effect estimates in trials that were not blinded.[37]

The observed improvements can be due to specific and nonspecific needle effects, the contribution of the mobilization movements, the extra consultation time, or the attention bias provided by the overall extra treatment ritual. Short consultation times are a key challenge to

implementing best practices for LBP,[5] but in our study, we cannot conclude whether the extra time for acupuncture compensated for possibly less time for giving advice.

More participants in the AG than in the CG met with their regular GP during the consultation. Continuity in the doctor–patient relationship, including previous knowledge about the patient, is associated with improved patient outcomes.[38 39]

There is a need for more research exploring the cost-effectiveness of acupuncture and other treatments of LBP.[5 11] Our study indicates the potential of acupuncture for clinically relevant effects, which makes it an actual nonpharmacological therapy for ALBP. Despite the lack of statistical significance of the main outcomes, this trial adds new knowledge about the cost-effectiveness of acupuncture for ALBP as it is the only trial hitherto with this outcome. The difference in costs between the groups was mainly driven by production gain. However, the difference in the sum of health care costs as well as the total societal costs at day 365, combined with the difference in QALY, leads to highly positive NMBs. Our findings are similar to those in a newly published trial of acupuncture for pelvic pain and LBP in pregnancy.[40]

Conclusion

This trial evaluated the additional effect of one treatment session of acupuncture in combination with mobilization movements on ALBP and showed a clinically relevant reduction in recovery time of 5 days, and a 4-day faster return to work compared with standard care by GPs. The difference was not statistically significant even though we reached the pre-study-defined goals for clinical relevance. This was probably due to the lack of

statistical power. Still, the null-hypothesis cannot be rejected. The cost-effectiveness analysis indicated that acupuncture treatment was likely to be cost-effective.

There is a need for larger trials in order to replicate the effect of faster recovery and return to work. Future acupuncture trials would benefit from including cost-effectiveness analysis.

Acknowledgements

The authors would like to thank the participating GPs and health secretaries, and Finn Steen whose contribution to the data collection was essential through the development of SESAMe.

Competing Interests

The authors report no conflict of interest.

Funding

This study was funded by Institute of Health and Society, University of Oslo. The study received also some funding for logistic expenses by private endowments, the "Gidske and Peter Jacob Sørensens fund" and the "Trygve Gythfeldts fund".

Author Contributions

TS and HS had the idea of the project. TS, HS, MB, MG and AF contributed to conceptualization and design of the study. TS, AK and Finn Steen developed the software for data collection. TS and IM performed the statistical analyses. TS and EA performed the health-economic analyses. TS drafted the article. All authors have discussed the results and revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Data sharing statement

The additional unpublished data are available from the corresponding author on request.

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LEGENDS

Figure 1 CONSORT flow diagram in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Figure 2 Time to recovery for acute low back pain with acupuncture and standard treatment compared with standard treatment alone. One-year follow-up and first 28 days (n = 167).

Figure 3 Predicted probability of the participants' perception of global improvement during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Figure 4 Scatter plot of total incremental costs and incremental QALYs at day 365; societal perspective in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 1 Cost categories, units, valuation, and unit price used in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Supplementary file 2 Number of participants at each general practitioner's (GP's) office in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone, by treatment group.

Supplementary file 3 Numbers of missing answers per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — primary outcome.

Supplementary file 4 Numbers of missing answers per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — secondary outcomes.

Supplementary file 5 Pain intensity during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Supplementary file 6 Disability by Roland Morris Disability Questionnaire (RMDQ) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

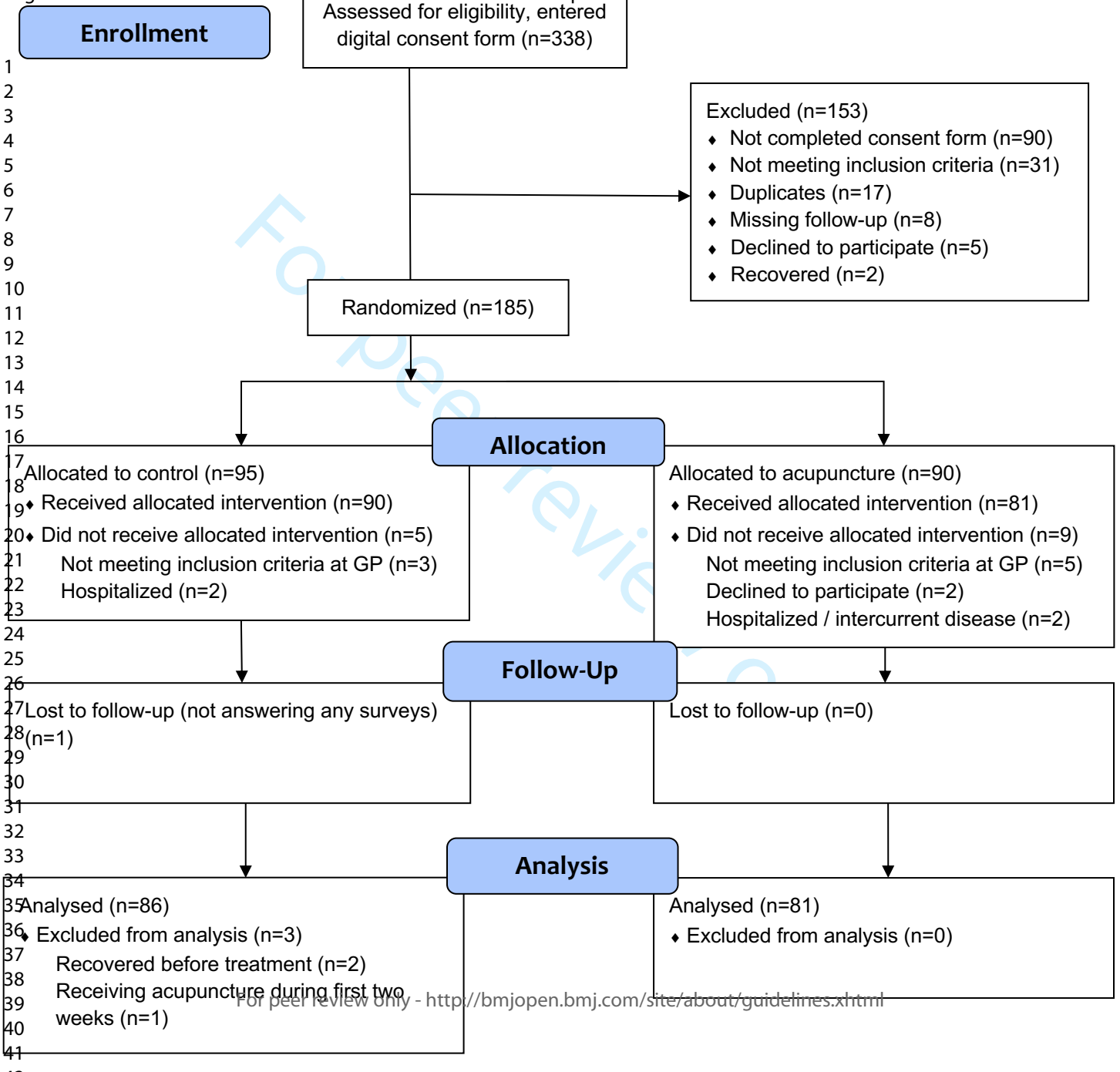
Supplementary file 7 Predicted probability for return to work during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

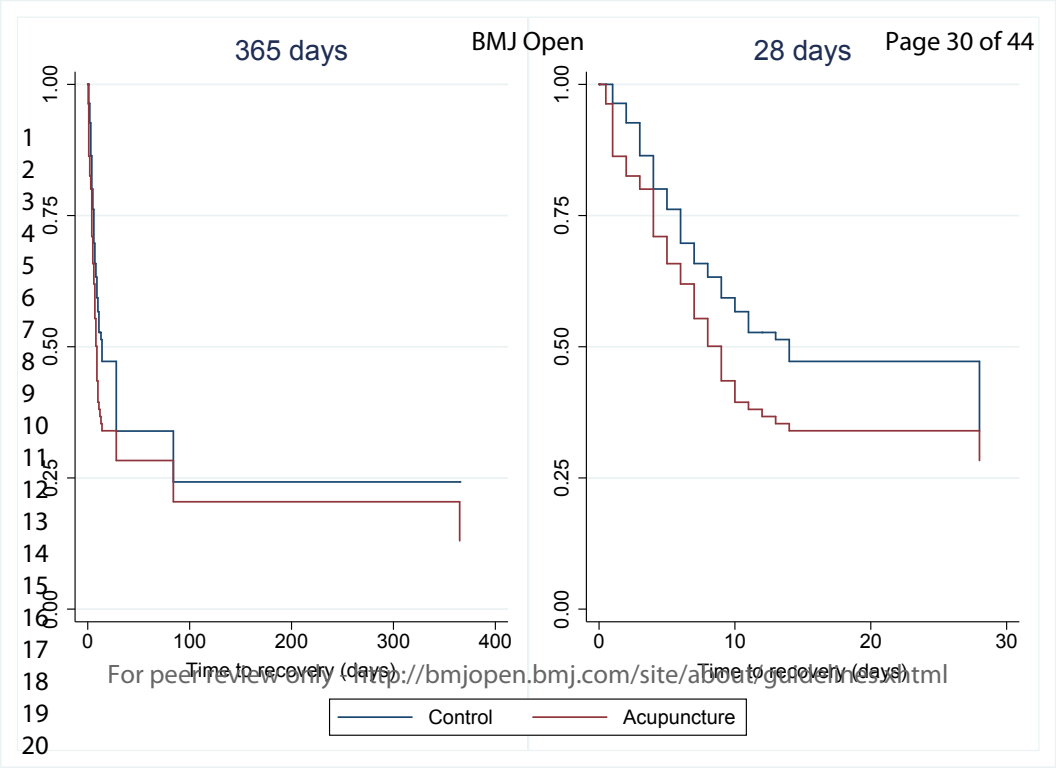
Supplementary file 8 Predicted probability for use of non-opioid medication during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

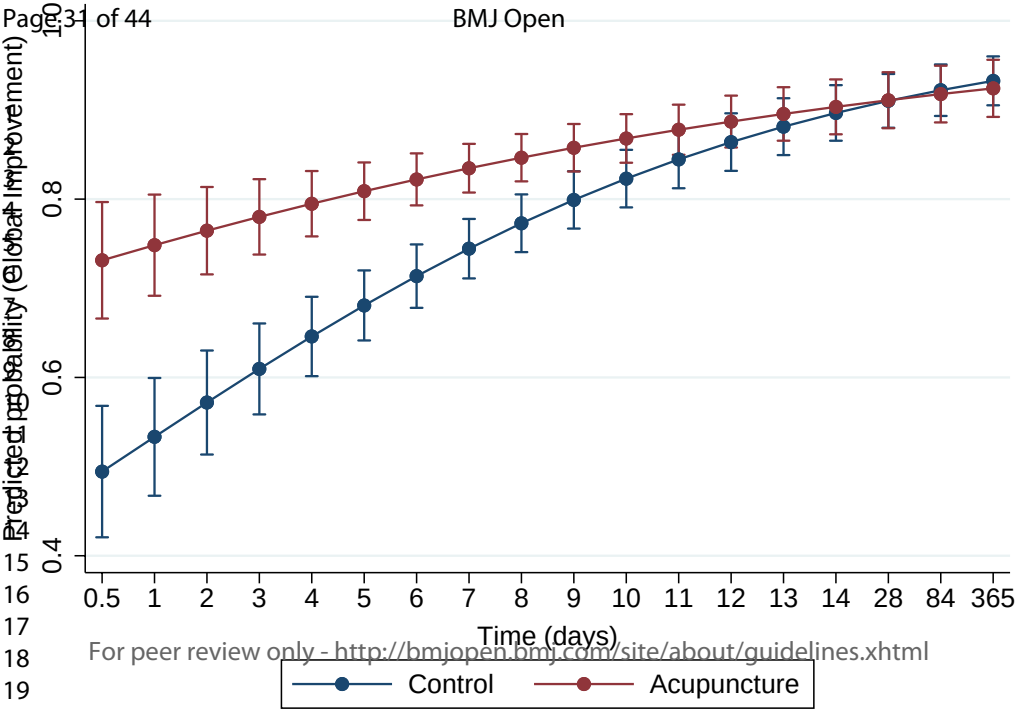
Supplementary file 9 Health-related quality-of-life by the EuroQoL (EQ-5D)

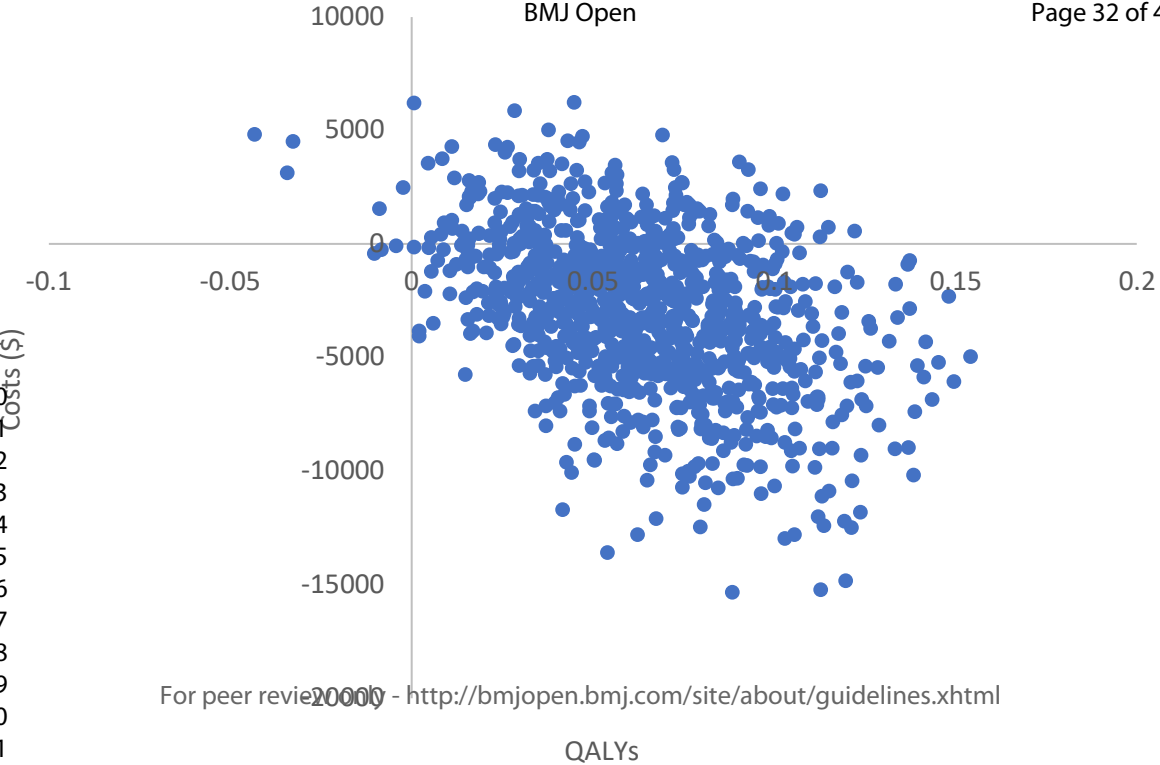
during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Supplementary file 10 Incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) at different time points in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.









Cost Categories	Unit	Valuation	Unit Price	
			USD	NOK
General Practitioner	Per treatment	Charge [a]	58	450
	Per phone prescription	Charge	14	110
Physiotherapist	Per treatment	Charge	73	560
Other therapists	First treatment	Charge	97	750
	Later treatments	Charge	58	450
Back surgery (day surgery)	Per surgery	Charge	6024	46500
Acupuncture equipment	Per treatment	Cost	13	100
Non-opioid medication	Per Defined Daily Doses	Cost [b]	0.5	3.9
Opioid medication	Per Defined Daily Doses	Cost [b]	1.7	13.2
Production loss (away from work)	Per day	Wage rate [c]	319	2463

[a] GP charge: Mean, calculations used different charges for ≤20 min and >20 min.

[b] Medication cost: Estimated price weighted by different medication types and packages.

[c] Wage rate: Mean, calculation used differentiated salaries by sex and age in Norway.

GP Office	Control (n=86)	Acupuncture (n=81)	Total (n=167)
1	20	16	36
2	10	11	21
3	3	3	6
4	1	1	2
5	11	14	25
6	1	2	3
7	10	10	20
8	10	5	15
9	2	1	3
10	0	1	1
11	18	17	35

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127

Pain intensity + medication

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127

Global improvement

	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																		
Missing	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Acupuncture group (n=81)																		
Missing	6	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	75	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Total (n=167)																		
Missing	19	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	148	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127

Return to work

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																	
Missing	14	11	15	12	14	11	14	15	15	15	19	19	19	19	24	21	27
Answers	72	75	71	74	72	75	72	71	71	71	67	67	67	67	62	65	59
Acupuncture group (n=81)																	
Missing	8	6	10	11	12	9	8	11	14	13	13	12	16	12	15	13	17
Answers	73	75	71	70	69	72	73	70	67	68	68	69	65	69	66	68	64
Total (n=167)																	
Missing	22	17	25	23	26	20	22	26	29	28	32	31	35	31	39	34	44
Answers	145	150	142	144	141	147	145	141	138	139	135	136	132	136	128	133	123

RMDQ

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Acupuncture group (n=81)						
Missing	3	8	10	12	14	15
Answers	78	73	71	69	67	66
Total (n=167)						
Missing	5	19	26	32	36	41
Answers	162	148	141	135	131	126

EQ5D

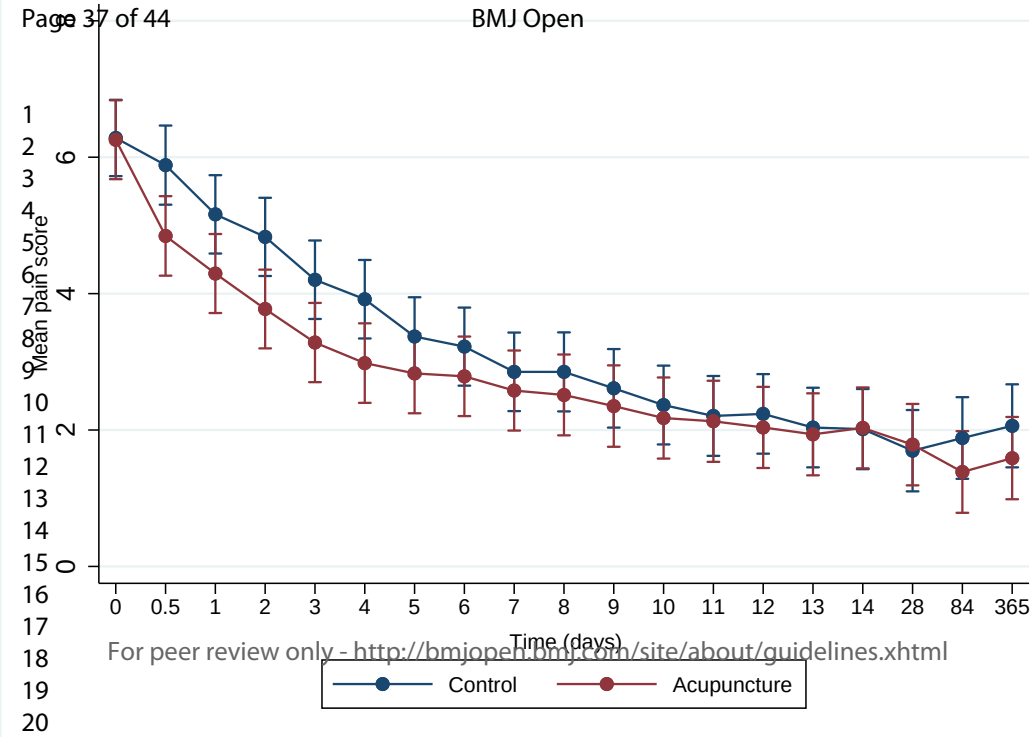
	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Acupuncture group (n=81)						
Missing	3	8	10	14	14	15
Answers	78	73	71	67	67	66
Total (n=167)						
Missing	5	19	26	34	36	41
Answers	162	148	141	133	131	126

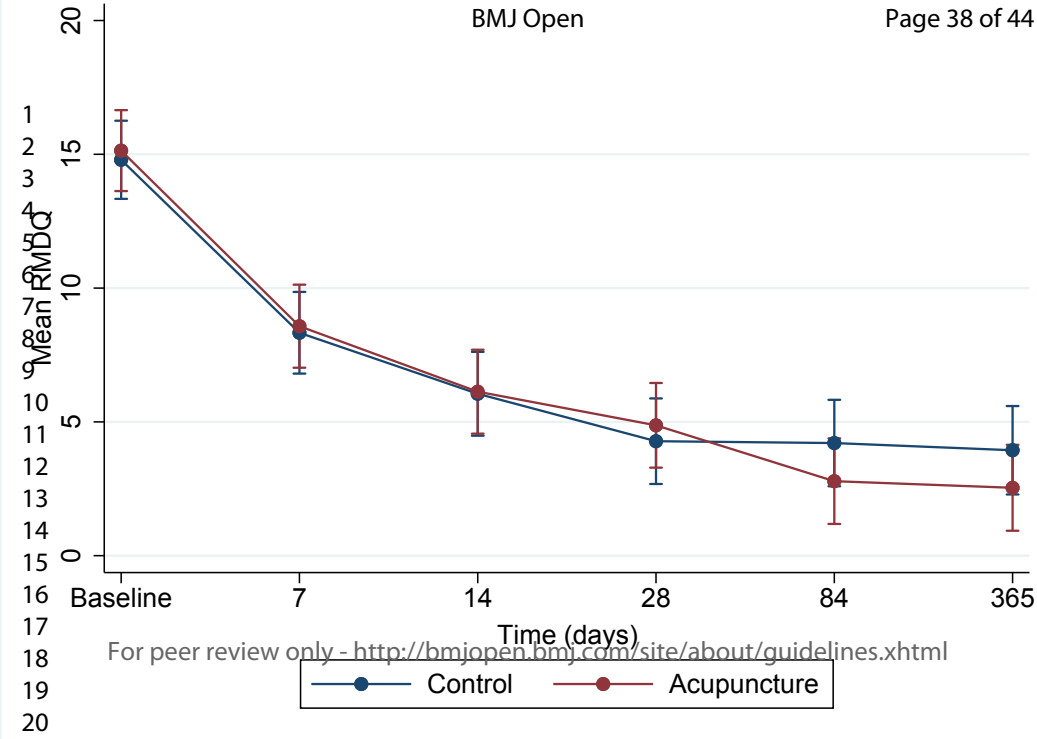
Costs

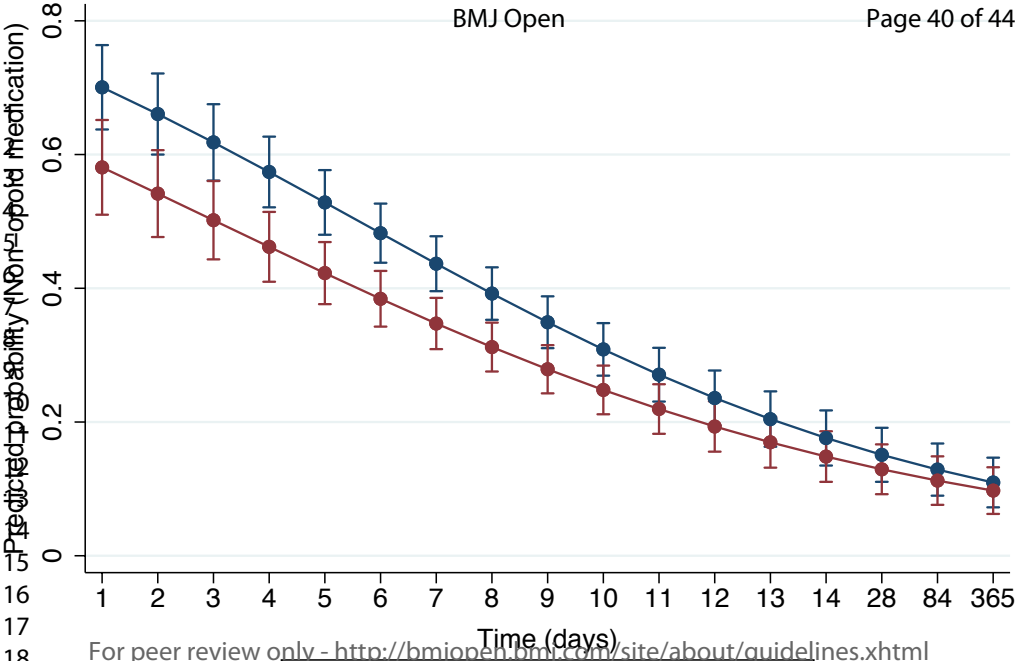
	Tot28	Tot365	Health28	Health365
Control group (n=86)				
Missing	44	52	38	44
Answers	42	34	48	42
Acupuncture group (n=81)				
Missing	34	36	31	32
Answers	47	45	50	49
Total (n=167)				
Missing	78	88	69	76
Answers	89	79	98	91

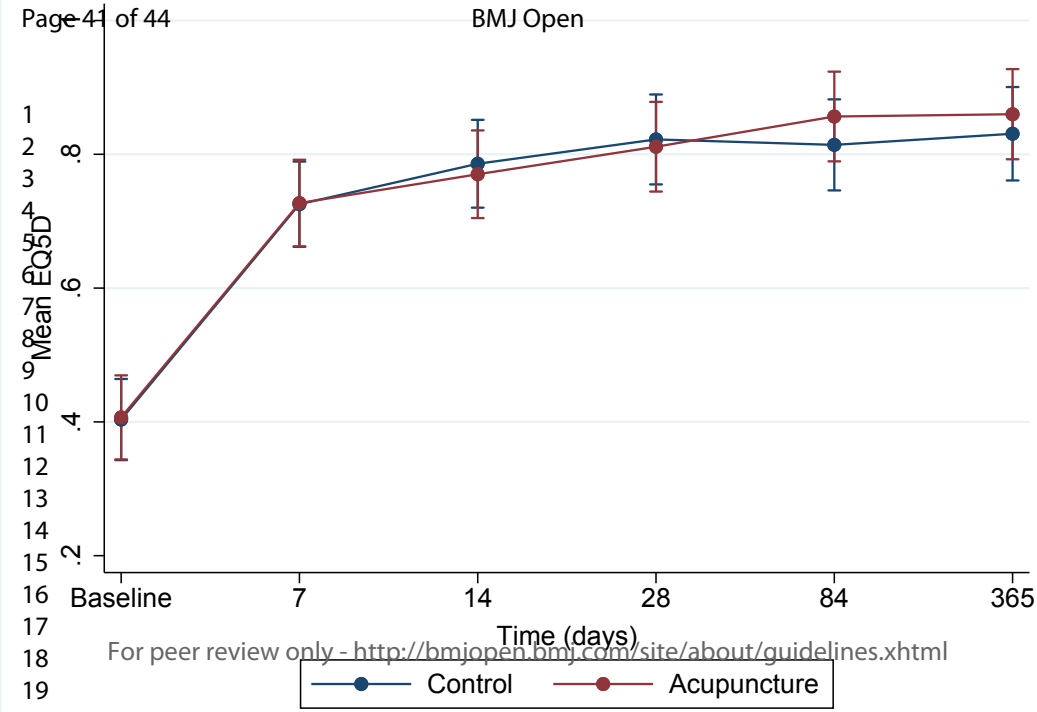
QALY

	Day 28	Day 365
Control group (n=86)		
Missing	25	37
Answers	61	49
Acupuncture group (n=81)		
Missing	19	25
Answers	62	56
Total (n=167)		
Missing	44	62
Answers	123	105









	Health costs Day 28	Health costs Day 365	Health costs (ex opr) Day 365	QALYs Day 28	QALYs Day 365	ICER Day 28[a]	ICER Day 365[a]	ICER (ex opr) Day 365[a]	NMB Health Costs Day 28[b]	NMB Health Costs Day 365[b]	NMB Health Costs (ex opr) Day 365[b]
Control	94	709	709	0.0562	0.8049						
Acupuncture	101	686	564	0.0567	0.8536	14000	-472	-2977	11	1758	1880

	Total costs Day 28	Total costs Day 365	Total costs (ex opr) Day 365	QALYs Day 28	QALYs Day 365	ICER Day 28[a]	ICER Day 365[a]	ICER (ex opr) Day 365[a]	NMB Total Costs Day 28[b]	NMB Total Costs Day 365[b]	NMB Total Costs (ex opr) Day 365[b]
Control	2759	9208	9208	0.0562	0.8049						
Acupuncture	1997	6544	6410	0.0567	0.8536	-1524000	-54702	-57454	780	4399	4533

All numbers in US dollars (USD), except QALYs.

[a] Incremental cost-effectiveness ratio (ICER) = (Costs Acup – Costs Control) / (QALY Acup – QALY Control)

[b] Net Monetary Benefit (NMB) = ((QALY Acup – QALY Control) * WTP) – (Costs Acup – Costs Control)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6-7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6-8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7,11

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12+Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	12+Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13 (Table 1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12 + Suppl. file 3+4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-16
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16-20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-20
Other information			
Registration	23	Registration number and name of trial registry	7
Protocol	24	Where the full trial protocol can be accessed, if available	7 + Ref. 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of the study as randomized	Title page
Authors *	Contact details for the corresponding author	Title page
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	8
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	10, 12-14
Interventions	Interventions intended for each group	16-19
Objective	Specific objective or hypothesis	4-6
Outcome	Clearly defined primary outcome for this report	21
Randomization	How participants were allocated to interventions	16-17
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	19
Results		
Numbers randomized	Number of participants randomized to each group	25
Recruitment	Trial status	25-27
Numbers analysed	Number of participants analysed in each group	27
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	28-29
Harms	Important adverse events or side effects	NA
Conclusions	General interpretation of the results	33-35
Trial registration	Registration number and name of trial register	37
Funding	Source of funding	-

**this item is specific to conference abstracts*

BMJ Open

Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034157.R1
Article Type:	Original research
Date Submitted by the Author:	06-Jan-2020
Complete List of Authors:	Skonnord, Trygve; University of Oslo, Department of General Practice, Institute of Health and Society Skjeie, Holgeir; University of Oslo, Department of General Practice, Institute of Health and Society Brekke, Mette; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Klovning, Atle; University of Oslo, Department of General Practice, Institute of Health and Society Grotle, Margreth; Oslo Metropolitan University, Department of Physiotherapy; Oslo universitetssykehus Ulleval, Research and Communication Unit for Musculoskeletal Health Aas, Eline; University of Oslo, Department of Health Management and Health Economics, Institute of Health and Society; Akershus University Hospital, Health Services Research Unit Mdala, Ibrahimu; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Fetveit, Arne; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	General practice / Family practice, Rehabilitation medicine
Keywords:	COMPLEMENTARY MEDICINE, Back pain < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS, PAIN MANAGEMENT

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Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

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Word count:

3870

Key words

Acupuncture Therapy, Low Back Pain, Randomised Controlled Trial, General Practice

ABSTRACT

Objectives

The aim of this study was to evaluate whether a single treatment session of acupuncture, when applied in addition to standard treatment for acute low back pain (ALBP), reduces the time to recovery compared with standard treatment alone.

Design

A multicentre, randomised, controlled trial.

Setting

Conducted at 11 Norwegian general practitioners' (GPs') offices.

Participants

171 adults aged 20–55 years seeking their GP for ALBP (≤ 14 days) between March 2014–2017. Patients with secondary back pain and previous sick leave and acupuncture treatment were excluded.

Interventions

The participants were randomised to either the control group (CG) or the acupuncture group (AG) by online software. The CG received standard treatment according to the Norwegian guidelines, while the AG received one session of Western medical acupuncture treatment in addition to standard treatment. The statistician was blinded to group status.

Primary and secondary outcome measures

The primary outcome was median days to recovery. Secondary outcomes were pain intensity, global improvement, back-specific functional status, sick leave, medication, and adverse effects.

Results

185 participants were randomised, 95 in the CG, 90 in the AG. 14 participants did not receive the allocated intervention, and four were excluded from analysis. Thus, 167 participants were included in the analysis, 86 in the CG, 81 in the AG. The groups were similar according to baseline characteristics. The recovery period was 14 days for the control group and 9 days for the acupuncture group, HR 1.37 (95% CI 0.95, 1.96), (p = 0.089). There was also a nonsignificant difference of 4 days for the return-to-work period.

Conclusions

We did not find any statistically significant reduction in time-to-recovery after a single session of acupuncture for ALBP compared with standard care.

Trial registration

NCT01439412

Strengths and limitations of this study

- The standardised intervention procedures.
- The performance of a pilot study and the development of software led to improved logistics and increased response rate.
- Lower inclusion rates than expected reduced the power, leading to weaker conclusions about the effectiveness of the treatment.
- Trial logistic reasons led to per protocol analysis instead of intention-to-treat analysis.

INTRODUCTION

Low back pain (LBP) is a common symptom and an important cause of disability globally.[1 2] The causes of LBP are multifactorial, and most episodes of LBP are categorized as nonspecific.[1 3] The majority of patients affected by acute LBP (ALBP) experience a decrease in pain and disability within a month, but a significant number will experience recurrences or develop chronic pain.[1 4]

Most cases of ALBP are treated in primary health care. Clinical guidelines for treatment of ALBP recommend information and education, advice to stay active and to avoid bed rest.[5] The Norwegian guidelines of 2007 still include pain treatment with paracetamol and/or nonsteroidal anti-inflammatory drugs (NSAIDs),[6] which is nowadays internationally less emphasized.[5 7-9] In the 2017 US guideline pharmacological treatment is recommended only if nonpharmacological treatment does not succeed.[7] Some guidelines recommend acupuncture as first-line treatment, despite lack of high-quality evidence.[7 10]

In 2013, Lee et al. published a systematic review of acupuncture for ALBP and found that evidence is sparse.[11] They concluded that acupuncture might be more effective than medication for symptom improvement and pain relief than sham acupuncture (SA). However, the authors suggested new trials with better design and reporting of results.

After this systematic review, there has been published four RCTs of acupuncture for ALBP. [12-15] Vas et al. compared different acupuncture types with conventional therapy (CT), and found that the intervention groups fared significantly better than the CT groups.[12] However, there was no difference between valid acupuncture according to Traditional Chinese Medicine (TCM), SA, or placebo acupuncture. Hasegawa et al. concluded that Yamanoto's new scalp acupuncture (YNSA) was more effective than sham treatment in ALBP for both pain relief and other outcomes, although their intervention did not reach the

predefined values for the primary outcome.[14] In 2013, Shin et al. reported that one session of motion-style acupuncture treatment (MSAT), consisting of walking with the needles inserted, was superior to one intramuscular injection of diclofenac with respect to pain reduction and function.[13] In the latest publication for this topic, Fox et al. performed a pilot study with 30 participants evaluating a type of ear acupuncture, "Battlefield acupuncture" (BFA).[15] The authors concluded that BFA was feasible as a non-pharmacological treatment in addition to standard care for LBP in a civilian emergency departments.[15]

The idea for the present study was based on clinical experience from GPs, who experienced faster recovery in patients receiving acupuncture for ALBP, often after the first treatment session. We found no other studies with time-to-recovery as primary outcome, but the single treatment session was supported by two previous studies.[13 16 17] The treatment was also in accordance with textbooks on acupuncture.[18 19]

Our study aimed to evaluate if a single treatment session with acupuncture could result in a faster recovery when applied in addition to standard treatment for ALBP compared with standard treatment alone. Our aim was also to describe pain intensity, disability, work absence, adverse effects and use of medication.

METHODS

Study design and randomization

The study was a multicentre, randomised, controlled trial (RCT) undertaken in 11 Norwegian GPs' offices. The study period was from March 2014 to March 2017 with the last follow-up in March 2018, after an extension of 1 year due to slow patient recruitment. The participants were randomised by a health secretary into an acupuncture group (AG) or a control group

(CG) in a ratio of 1:1, using a web-based randomization system developed and administered by the Unit of Applied Clinical Research, Norwegian University of Science and Technology,[20] which performs block randomisation with various block sizes.

Data collection was performed by electronic surveys at 19 different time points; before and after treatment on the day of treatment, and each day for the following 2 weeks; then, after 4 weeks, 12 weeks, and 1 year. To administer the logistics of the surveys, we developed software, SESAMe, which is described in a previous publication.[21]

In a pre-study power calculation, we estimated the sufficient sample size to be 135 in each group.[22] Each patient was blinded to the group allocation when reporting baseline data, but from the time of consultation neither the patient nor the GP was blinded.

The protocol of the present study was published in 2012 and includes further details.[22] Prior to the main study, we conducted a pilot study that included eight participants during October 2013 to January 2014. The results from the pilot study led to the web-based version of SESAMe,[21] an exclusion criterion of previous acupuncture, and advices to the participating GP offices about medication standardization, study logistics, and efforts to minimize differences in placebo effects.

The study is registered in ClinicalTrials.gov (NCT01439412). Ethical approval was given by the Regional Ethics Committee of South-Eastern Norway (reference 2013/611/REK sør-øst A). The reporting of the study follows the CONSORT statement[23] and the STRICTA recommendations.[24]

Participants and recruitment procedure

Patients with ALBP lasting 14 days or less who contacted their GP office were asked to participate in the trial. We included adults aged 20–55 years with nonspecific ALBP who

gave informed consent. Exclusion criteria were nerve root affection, “red flags”, pregnancy, disability pension, sick leave of more than 14 days, and acupuncture during the last month.

The inclusion/exclusion process was performed by the health secretary at the GP’s office and in an initial online survey with information and the consent. She also administered the emails in SESAMe and asked the patient to answer the baseline survey before the consultation. If the GP revealed any exclusion criteria during the consultation, the patient was excluded. This, as well as the time spent in the consultation, was recorded by the GPs.

At each GP office, one GP was trained in acupuncture and treated the AG, and from one to four other GPs treated the CG. All acupuncture GPs were specialists in family medicine, and the mean time of acupuncture experience was 7.4 years (range 1–19 years). Nine of the GPs had at least 320 hours of education in acupuncture.

Most treating GPs in the CG were experienced specialists in family medicine, but some of them were working in the internship program; thus, the overall experience of the treating GPs varied more than for the AG.

Study interventions

Standard treatment (CG) consisted of advice about activity, prescription of analgesic medication (paracetamol and/or ibuprofen), and sick leave, if needed, according to the Norwegian national guidelines.[6]

The AG received the same standard treatment as the CG and, in addition, one session of acupuncture treatment with Western medical acupuncture style. This session consisted of 1 minute with two needles of Seirin® type B-8a 0.30 × 30 mm in the acupuncture points, Lumbar Pain Points (Yaotongxue/Yaotongdian) on the right hand, stimulated to a powerful needle sensation, called “de Qi” in TCM. With the needles in the hand, the patient was asked

to rise and perform mobilization movements (slow rotating pelvic movements) for 2 minutes, followed by 5 minutes on a bench while the patient received six needles of the SEIRIN® type J-8 0.30 × 50 mm in the local points Huatuojiaji ("Jiaji") in the L2–L4-segments, stimulated until needle sensation. The needles remained in place until all the needles were removed after a total treatment time of 8–9 minutes. The short treatment and the choice of only one session of acupuncture were an attempt to reduce potential attention bias. The details of the procedure and the process of choosing the specific and standardized treatment are briefly described in the published protocol, based on clinical experience, literature and feedback from a medical acupuncture expert group.[22]

Prior to the study, the health secretaries and many GPs (including all acupuncture doctors) were gathered at a workshop to ensure they understood the study logistics, the standard ALBP treatment, and the standardization of the acupuncture treatment. During the trial, we arranged two workshops to remind the GP offices of the need of inclusion and update about the study logistics.

Outcome measurements and data collection

The primary outcome in the study was days to recovery, defined as the first day the patient scored 0 or 1 on the Numerical Rating Scale (NRS).[25 26] This definition is in line with the definition of "sustained recovery" with an NRS of 0 or 1 for seven consecutive days.[26 27] We defined a minimum of a 3-day faster recovery as a clinically relevant difference between the groups, based on clinical experience and previous studies.[28 29]

The secondary outcome measurements were pain intensity,[25] disability by Roland Morris Disability Questionnaire (RMDQ),[30] sick leave, 5-point global improvement (Likert scale), use of medication, new visits at the GP's office, health-related quality of life by the

EuroQol (EQ-5D-3L), using UK tariff for time trade-off,[31] and adverse effects. RMDQ and EQ-5D-3L were collected at baseline, 1, 2, 4, 12 weeks, and 1 year, while the other secondary outcomes were collected at all time points. In addition, at baseline, we asked for sociodemographic variables, patient preferences for treatment options, expectations with respect to the effect of acupuncture and psychosocial risk profile according to the Örebro screening form for musculoskeletal pain.[32 33]

We also asked the participants in the 1-year survey about the number of new LBP episodes, work absence, and if they had received any other kind of treatment for LBP the last 9 months.

Patient and public involvement

No patients were involved in the planning of the study or in the recruitment and the conduct of the study. The study participants were informed that the results of the study would be presented at the study Facebook page. The burden of the intervention could be reported by the patients through the questionnaires of global improvement and adverse events.

Statistical analysis

Study sample size was calculated to be 270 participants, with 80% power to detect a 3 days' difference in median time to recovery with an α level of 0.05 and a true hazard ratio (HR) of 1.429. This was based on the assumption of a 365 days follow-up period, an accrual period of 0 days and a median survival of 7 days.[34] The study allowed for a dropout rate of up to 10%.

Details of the protocol for randomization and allocation procedures were published previously.[22] Statistical analyses were performed using the programs IBM SPSS Statistics® 25 and StataSE® 15. Data were analysed by a statistician who was blinded to group status, and the results presented in tables and figures were finalized before codes were revealed. The

analyses were performed per protocol. The NRS data were transformed to the first day of recovery, independent of any intermittent missing answers. We calculated the difference in days to recovery for the two groups using the log-rank test, and late missing answers were censored, leaving the last specified value for analysis.

The time to recovery was expressed by the median days to recovery for the two groups, and Cox proportional hazard regression models were used to assess the effect of treatment on pain duration (in days). We checked the Cox proportionality assumption and concluded that our model satisfied the assumption of proportionality. The same method was also used for the secondary outcome Time to return to work.

Numeric secondary outcomes such as NRS were analysed using linear multilevel models with patient random effects, while binary outcomes such as medication use were analysed using binary multilevel logistic regression models. With numeric outcomes, mean changes over time in the groups were obtained, while estimates of odds ratios with their 99% confidence intervals were obtained for binary outcomes.

For primary outcomes, a p-value of <0.05 was considered statistically significant. For the secondary outcomes, a p-value of <0.01 was considered significant, and 99% confidence intervals (CIs) given.

RESULTS

The study flow chart shows that of a total of 185 participants that were randomised into the two groups, 167 were included in the analysis, 86 in the CG and 81 in the AG (Figure 1). Recruitment of participants at the 11 GP offices varied considerably, and there were also differences in exclusions at each site (Supplementary file 1). The overall recruitment was poorer than expected, and even if the inclusion period was extended with one year, the

planned sample size was not met. Possible causes can be less LBP patients seeking the GPs due to previous public campaigns, patients seeking other therapists, and the circumstances of the trial taking place in busy GP practices with voluntary work by both GPs and health secretaries with no professional research network to help.

The overall response rate in the trial was 87.4%, but varied in each survey and decreased over time. One year into the observation period, 66 participants in the AG and 61 in the CG had answered the survey, resulting in a response rate of 76.0%. Supplementary file 2 shows the numbers of missing answers per survey for the primary outcome and Supplementary file 3 for the secondary outcomes. There were no statistically significant differences between the groups in response rate, except for primary outcome at day 2 ($p = 0.037$). One participant in the AG underwent an operation for sciatica during the follow-up period.

Table 1 shows the baseline characteristics with sociodemographic data and clinical features of the participants. There were no statistically significant differences between the groups in any of the variables.

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Characteristic	Control (n = 86)	Acupuncture (n = 81)
Age (year), mean (SD)	39.3 (9.4)	39.8 (11.4)
Female, n (%)	44 (51.2)	41 (50.6)
Living with a partner, n (%)	57 (67.9)	65 (83.3)
Born in Norway, n (%)	78 (92.9)	69 (88.5)
Level of education >13 years, n (%)	28 (33.3)	30 (38.5)
Work status		
Employed, n (%)	77 (91.7)	70 (87.5)
Student, n (%)	7 (8.3)	6 (7.5)
Unpaid work, n (%)	1 (1.2)	1 (1.3)
Unemployed, n (%)	2 (2.4)	3 (3.8)
Sick leave, n (%)	3 (3.6)	3 (3.8)
BMI		
<25 (normal), n (%)	28 (33.3)	30 (38.5)
25.00–29.99 (overweight), n (%)	29 (34.5)	29 (37.2)
>30 (obese), n (%)	27 (32.1)	19 (24.4)
Smoking, n (%)	20 (23.8)	14 (17.9)
Alcohol several times a week, n (%)	10 (11.9)	8 (10.3)
Serious life events last 12 months, n (%)	15 (17.9)	17 (21.3)
Previous LBP, n (%)	63 (73.3)	58 (71.6)
Treatment preference: acupuncture, n (%)	66 (78.6)	58 (74.4)
Belief in acupuncture treatment (0–10), mean (SD)	6.6 (2.6)	6.6 (2.5)
Back pain intensity (0–10), mean (SD)	6.3 (1.8)	6.2 (1.9)
Leg pain intensity (0–10), mean (SD)	2.7 (2.6)	2.4 (2.7)
RMDQ (0–24), mean (SD)	14.8 (4.4)	15.0 (4.2)
EQ-5D, mean (SD)	0.40 (0.33)	0.41 (0.31)
DDD non-opioid medication, mean (SD)	0.66 (0.85)	0.93 (0.97)
DDD opioid medication, mean (SD)	0.09 (0.27)	0.09 (0.31)
Days from randomisation to treatment, mean (SD)	0.59 (1.84)	0.53 (1.09)
Örebro		
Low risk, n (%)	41 (48.8)	47 (60.3)
Medium risk, n (%)	25 (29.8)	19 (24.4)
High risk, n (%)	18 (21.4)	12 (15.4)
SHC, mean (SD)	11.25 (7.44)	9.12 (5.36)
Missing	2	3

Data in n (%) or mean (SD). SD indicates standard deviation; BMI, body mass index; LBP, low back pain; RMDQ (0–24), Roland Morris Disability Questionnaire, higher score represents greater overall disability; DDD, defined daily dose; SHC, subjective health complaints, higher score means more reported health complaints. EQ-5D, higher score represents better health state; NRS (0–10), higher score represents more pain. There were no significant differences between the groups in any of the variables.

The duration of the consultations in the AG were 20.2 minutes (99% CI 19.0, 21.5), versus 17.0 minutes (99% CI 15.4, 18.5) in the CG, and the difference of 3.2 minutes were statistically significant ($p \leq 0.001$). In the study 21.9% (99% CI 10.4, 33.4) of the patients in the CG were treated by their regular GP versus 40.0% (99% CI 26.0, 54.0) in the AG ($p = 0.011$). There were more, but statistically nonsignificant, LBP episodes in the CG after 1 year, 3.2 (99% CI 2.4, 3.9) versus 2.4 (99% CI 1.7, 3.2) in the AG ($p = 0.06$).

Primary outcome

Median time to recovery was 14 days for the CG (IQR 6-84) and 9 days for AG (IQR 4-84). Based on the Cox regression model, the difference of 5 days was not statistically significant, despite achieving the a priori threshold for clinical relevance of 3 days, with a HR 1.37 (95% CI 0.95, 1.96), ($p = 0.089$).

Time to recovery for 365 days and the first 28 days are shown in Figure 2. The log-rank test for 365 days is based on 56 observed and 65.3 expected events in the CG and 64 observed and 54.7 expected events in the AG, which was not statistically significant ($p = 0.072$). We also performed a sensitivity analysis on the four excluded participants with the same result.

8.5 (95% CI: 8.1, 8.8) people are needed to be treated (NNT) for one extra person to recover by 7 days, and for the whole study period, the NNT was 7.2 (95% CI 7.0, 7.4).

Secondary outcomes

Pain intensity during the study period reduced in both groups with no clinically relevant nor statistically significant differences between the two groups (Figure 3). The mean difference in pain between the two groups during the whole study was 0.48 (95% CI 0.25, 0.71) in favour

of the AG. This equals a standardized mean difference (SMD) of 0.13, which is a small effect size.

The same pattern was seen for back-related disability by RMDQ, which showed an improvement during the year for both groups but with no statistically significant difference between the two groups (Supplementary file 4).

There was a nonsignificant difference of 4 days in the median time of return to work, with 5 days (IQR 1-12) for the CG versus 1 day (IQR 1-7) for the AG (p = 0.13) (Figure 4).

The participants' perception of global improvement (feeling better or much better), was highly significantly better in the AG group on day 0 after treatment (OR 8.00, 99% CI 2.88, 22.05), but later the difference became gradually smaller, with statistically significance on just one other day (day 4) (Supplementary file 5).

There were no statistically significant differences in the use of medication, unless for day 3 when fewer participants in the AG used non-opioid medication than in the CG (Supplementary file 6).

The estimated number of new visits to the GP through the study period was 2.7 (99% CI 2.0, 3.5) in the CG and 2.6 (99% CI 1.9, 3.3) in the AG (p = 0.76). Health-related quality of life measured by EQ-5D-3L did not show statistically significant differences between the two groups at any time point during the study (Supplementary file 7).

No serious adverse events were reported in the study. Sixteen participants (18.6%, 99% CI 7.8, 29.4) in the CG reported some adverse effects compared with 11 (13.6%, 99% CI 3.8, 23.4) in the AG (p = 0.38). Two participants reported pain/soreness in their hand because of the needles the day after the treatment. Twenty-two participants reported gastrointestinal symptoms, 14 of them in the CG. Other less frequent symptoms were tiredness, headache, dyspnoea, and muscle pain.

DISCUSSION

This study showed that adding one single session of 8–9 minutes of acupuncture treatment to standard guideline-based care to patients with ALBP resulted in a 5 days faster recovery of pain, but the result was not statistically significant. Similarly, adding acupuncture to standard guideline-based primary care did not show any statistically significant effect in the secondary outcome measures of pain, disability, time until return to work and quality of life. For the secondary outcomes of self-reported global improvement and medication, we found small differences. Finally, the acupuncture treatment was safe, with no significant differences of major symptoms or serious adverse events.

The main strength of this study was the standardised intervention procedures, leading to no attention bias between the two groups. Another strength was the performance of a pilot study which led to logistic changes that contributed to both an equality of the groups and an improved response rate. The innovative process of developing our own logistic software (SESAMe) was central in this quality improvement.[21]

The main limitation of this study was the low power due to lower inclusion rates than expected, even after we extended the inclusion period with 1 year. This led to weaker conclusions about the effectiveness of the treatment. The results of the primary outcome could well be due to a type II error. However, low power in a trial reduces the likelihood that the observed effect represents a true effect.[35] The wider standard deviations in an underpowered study make it more likely to reach clinical relevant values.[35] The lacking effect on pain and disability can imply that the 5 days faster time to recovery can be a spurious finding. Another limitation is that we were not able to perform the intended intention-to-treat analysis. Of logistic reasons, we had to perform the last eligibility-evaluation by the GP in the consultation. That is why 14 participants were randomised, but excluded before intervention

was given. In addition, 4 participants were excluded from analysis, three of them because of statistical challenges (left censoring) and one because of exclusion criteria. However, a sensitivity analysis did not change the results. On the other hand, the exclusion after randomisation may have caused bias. Lack of fidelity check list to measure the fidelity of the interventions is another limitation.

The acupuncture treatment provided in this trial consisted of both shorter treatment time and fewer treatment sessions than usual.[36 37] This may have caused less chances to detect a real difference in effectiveness. On the other side, a longer treatment time and more sessions could have caused more attention bias. Our results could not support Vas et al. showing the effectiveness of acupuncture compared to conventional therapy.[12] The short-term effect of only one acupuncture treatment session for LBP was previously shown by Shin et al.,[13] but MacPherson et al. showed that pain outcomes were influenced by increased numbers of needles and more sessions, and thus the dose was important.[37] After the trials of Vickers and MacPherson,[37 38] the US National Center for Complementary and Integrative Health (NCCIH) announced a need for pragmatic acupuncture trials for pain management, testing the effectiveness in "real world" conditions, while efficacy studies seek effect under ideal conditions.[39 40] Because this was a pragmatic trial in accordance with the NCCIH recommendations, the participants and GPs were not blinded. Some may argue that this is a problem in acupuncture trials, and it would be a limitation in an efficacy study. However, a large systematic review with individual patient data meta-analysis by Vickers et al. in 2012 has evaluated the efficacy of acupuncture for pain, and the authors showed that acupuncture has a small, specific effect on pain.[38] The difference between true acupuncture and sham or placebo acupuncture is small, and trials will need large sample sizes to emphasize these differences, which Vas et al. demonstrated to be also true for ALBP.[12]

The highly significant difference in the early perception of global improvement could be a result of the positive expectations, but it could also be due to the experience of a faster recovery with less pain and a faster return to work. The findings are in accordance with the systematic review by Lee et al. in which acupuncture is compared with the use of NSAIDs.[11] However, subjective outcomes have been shown to exaggerate effect estimates in trials that were not blinded.[41]

The two study groups scored equal for treatment preferences and belief in acupuncture prior to the treatment. For the AG, this might represent a positive expectation bias when receiving the treatment, while those in the CG might have had a negative expectation bias when not receiving the acupuncture they had wanted. This would be in accordance with other research demonstrating an effect of treatment preferences and belief in the treatment in pain studies.[42 43]

There are not many trials of non-pharmacological treatments reporting NNT. Despite the lack of effect between the two groups in the present study, the NNT from our trial was comparable to both other LBP trials[44 45] and acupuncture trials.[46 47]

The few observed differences between the two groups can be due to specific and nonspecific needle effects, the contribution of the mobilization movements, the extra consultation time, or the attention bias provided by the overall extra treatment ritual. There could also be an operator effect of a less or more enthusiastic behaviour in the consultation. The patient-practitioner relationship is shown to influence the placebo effect, even in standardised intervention procedures.[48] However, this could be a phenomenon in both groups, and also influenced by the prescribing of medication, performing a physical examination or not, empathic behaviour and time spent. Short consultation times are a key challenge to implementing best practices for LBP,[5] but in our study, we cannot conclude whether the extra time for acupuncture compensated for possibly less time for giving advice.

More participants in the AG than in the CG met with their regular GP during the consultation. Continuity in the doctor–patient relationship, including previous knowledge about the patient, is associated with improved patient outcomes.[49 50]

Conclusion

This trial showed that adding one treatment session of acupuncture in combination with mobilization movements had similar effect as usual care for patients with ALBP during one year of follow-up. The observed difference of 5 days earlier recovery in the acupuncture group was not statistically significant due to low power. Furthermore, there was no statistically significant differences in self-reported outcome measures of pain, disability, and health-related quality-of-life.

Acknowledgements

The authors would like to thank the participating GPs and health secretaries, and Finn Steen whose contribution to the data collection was essential through the development of SESAMe.

Competing Interests

The authors report no conflict of interest.

Funding

This study was funded by Institute of Health and Society, University of Oslo. The study received also some funding for logistic expenses by private endowments, the "Gidske and Peter Jacob Sørensens fund" and the "Trygve Gythfeldts fund".

Author Contributions

TS and HS had the idea for the project. TS, HS, MB, MG and AF contributed to conceptualization and design of the study. TS, AK and Finn Steen developed the software for data collection. TS and IM performed the statistical analyses. TS and EA performed the health-economic analyses. TS drafted the article. All authors have discussed the results and revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Data sharing statement

The additional unpublished data are available from the corresponding author on request.

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LEGENDS

Figure 1 CONSORT flow diagram in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Figure 2 Time to recovery for acute low back pain with acupuncture and standard treatment compared with standard treatment alone. One-year follow-up and first 28 days (n = 167).

Figure 3 Pain intensity during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Figure 4 Time to return to work in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone. First 14 days (n = 147).

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 1 Number of participants included and excluded at each general practitioner's (GP's) office in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone, by treatment group.

Supplementary file 2 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — primary outcome.

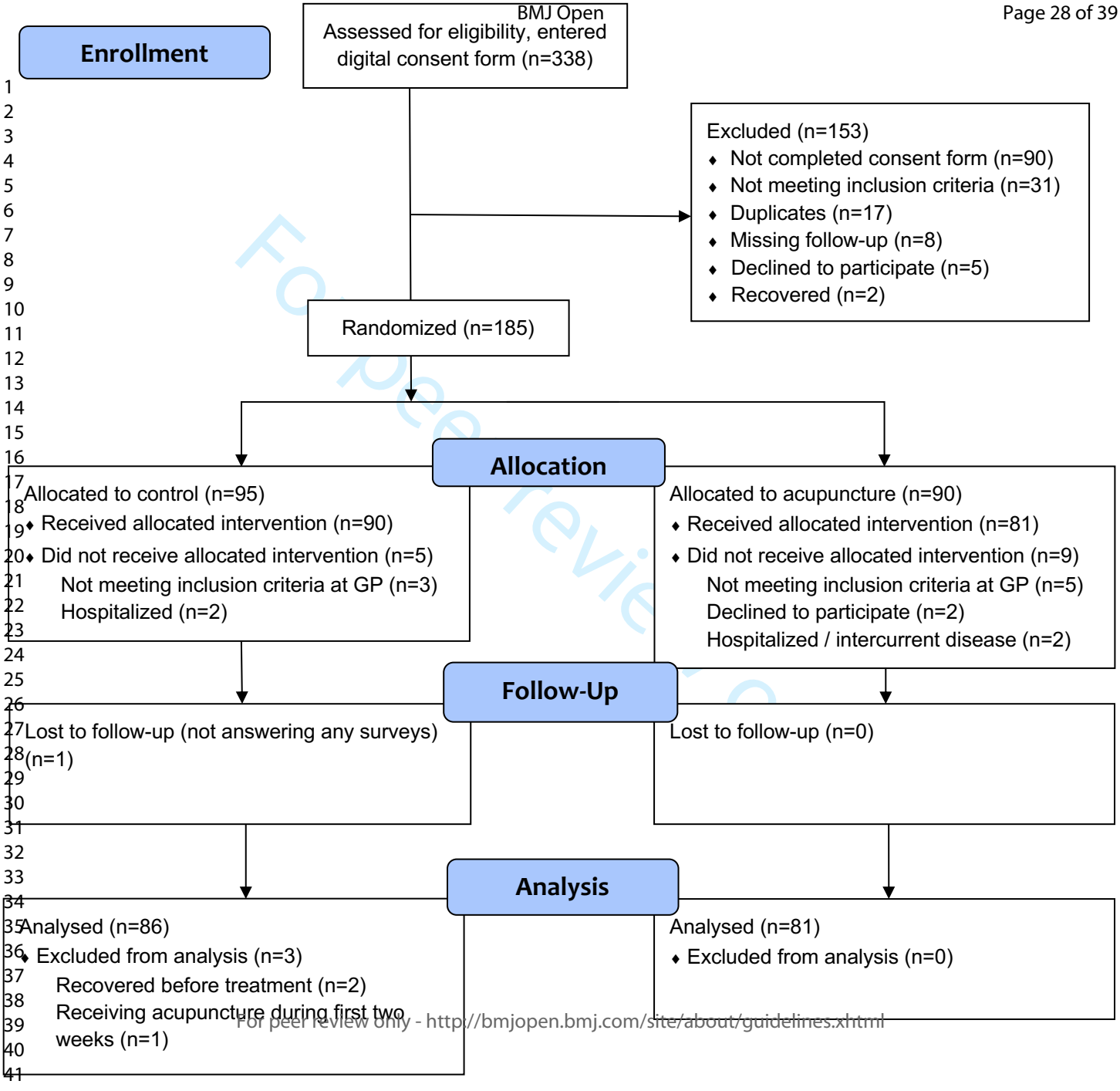
Supplementary file 3 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — secondary outcomes.

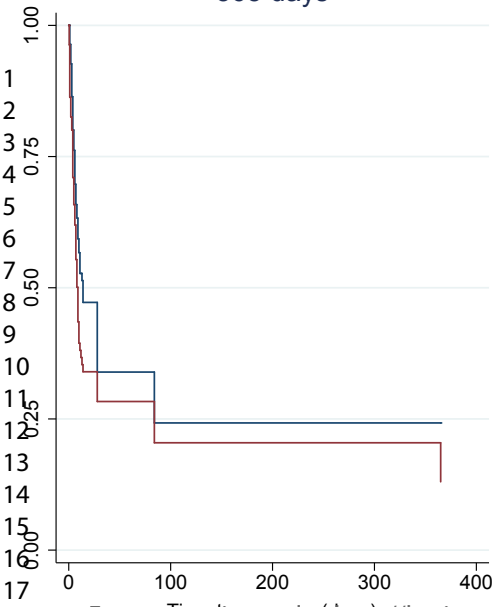
Supplementary file 4 Disability by Roland Morris Disability Questionnaire (RMDQ) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

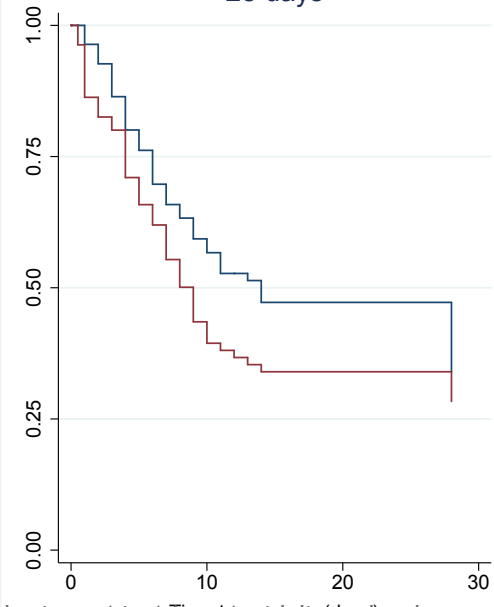
Supplementary file 5 Participants' perception of global improvement during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 6 Use of medication during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

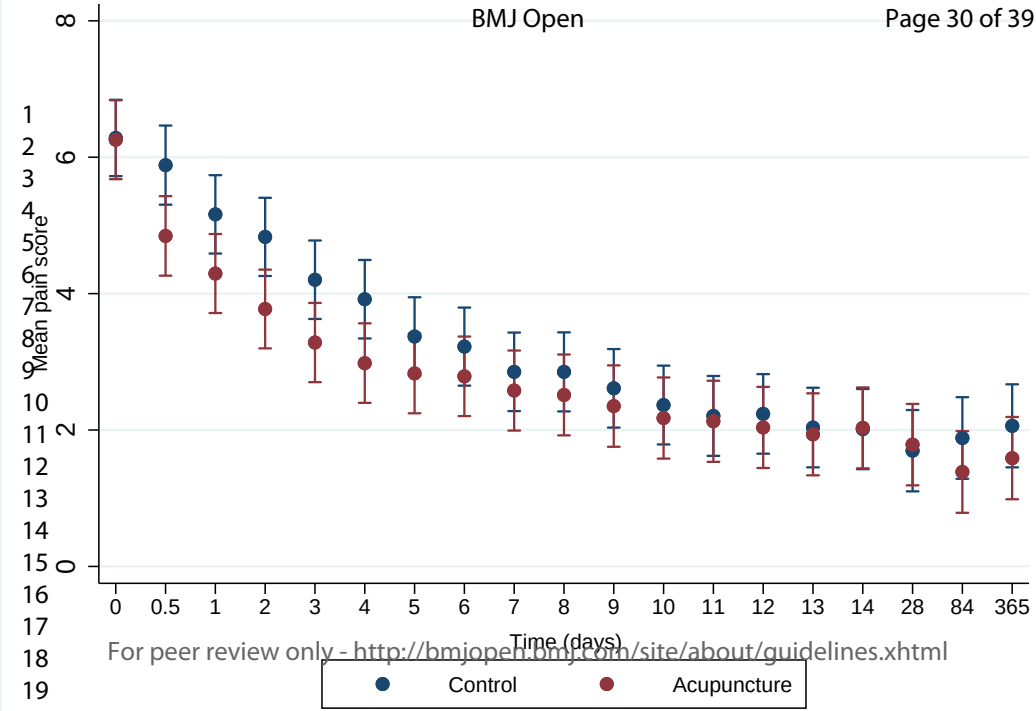
Supplementary file 7 Health-related quality-of-life by the EuroQoL (EQ-5D) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

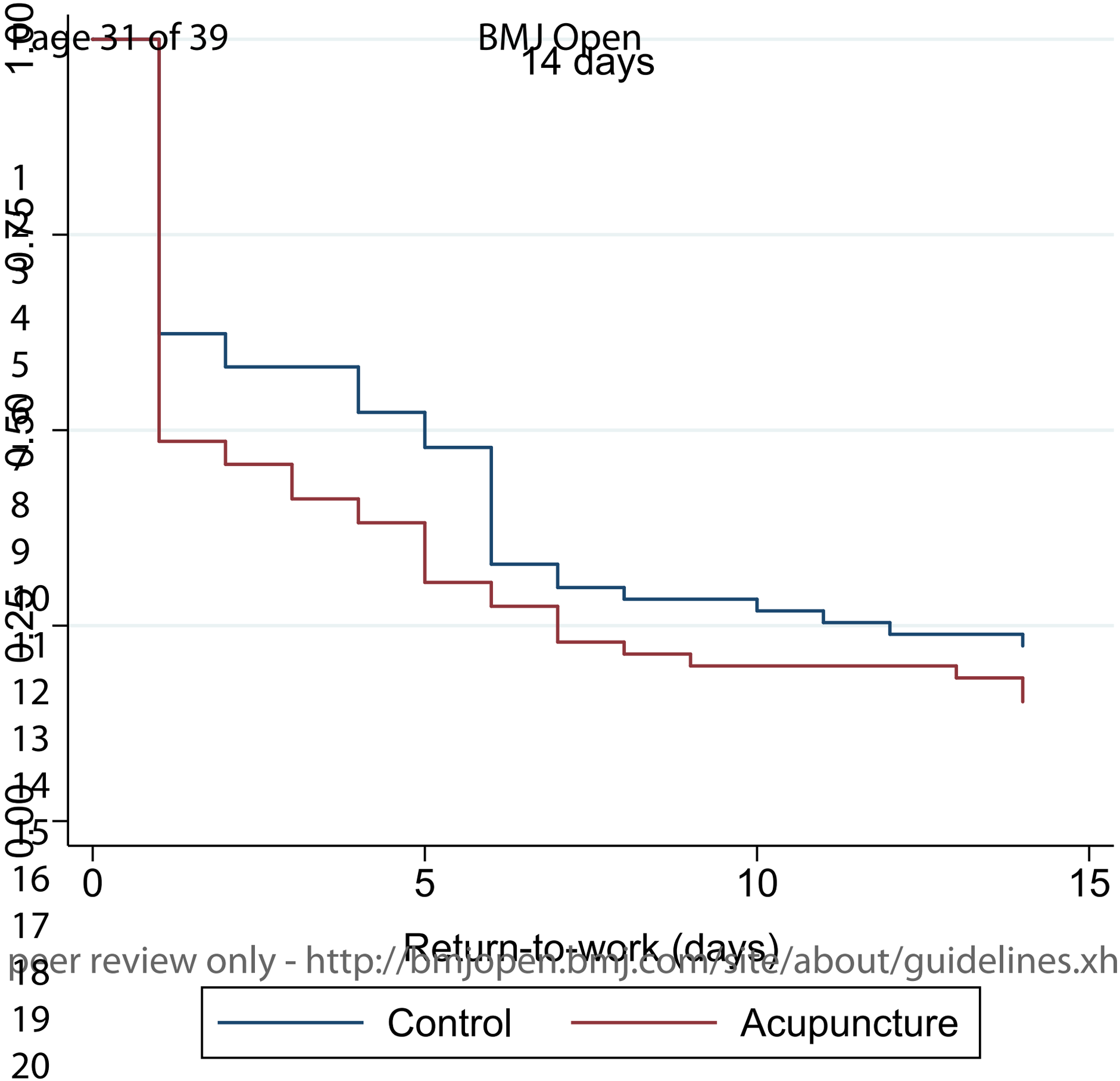






Control Acupuncture





GP Office	Inclusion Control (n=86)	Inclusion Acupuncture (n=81)	Inclusion Total (n=167)	Exclusion Control (n=8)	Exclusion Acupuncture (n=10)	Exclusion Total (n=18)
1	20	16	36	1	1	2
2	10	11	21	1	0	1
3	3	3	6	0	0	0
4	1	1	2	0	0	0
5	11	14	25	4	0	4
6	1	2	3	0	0	0
7	10	10	20	0	0	0
8	10	5	15	1	2	3
9	2	1	3	0	0	0
10	0	1	1	0	0	0
11	18	17	35	1	7	8

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Pain intensity + medication

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Global improvement

	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																		
Missing	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																		
Missing	6	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	75	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	93	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																		
Missing	19	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	148	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Return to work

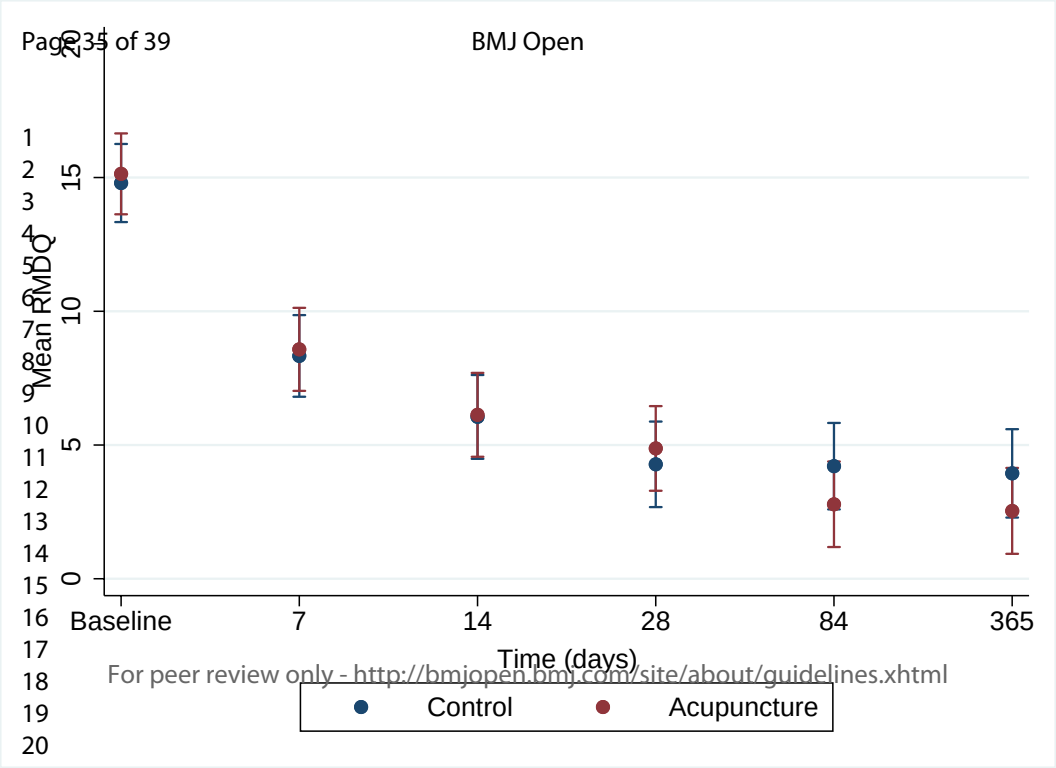
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																	
Missing	14	11	15	12	14	11	14	15	15	15	19	19	19	19	24	21	27
Answers	72	75	71	74	72	75	72	71	71	71	67	67	67	67	62	65	59
Response rate (%)	84	87	83	86	84	87	84	83	83	83	78	78	78	78	72	76	69
Acupuncture group (n=81)																	
Missing	8	6	10	11	12	9	8	11	14	13	13	12	16	12	15	13	17
Answers	73	75	71	70	69	72	73	70	67	68	68	69	65	69	66	68	64
Response rate (%)	90	93	88	86	85	89	90	86	83	84	84	85	80	85	81	84	79
Total (n=167)																	
Missing	22	17	25	23	26	20	22	26	29	28	32	31	35	31	39	34	44
Answers	145	150	142	144	141	147	145	141	138	139	135	136	132	136	128	133	123
Response rate (%)	87	90	85	86	84	88	87	84	83	83	81	81	79	81	77	80	74

RMDQ

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	12	14	15
Answers	78	73	71	69	67	66
Response rate (%)	96	90	88	85	83	81
Total (n=167)						
Missing	5	19	26	32	36	41
Answers	162	148	141	135	131	126
Response rate (%)	97	89	84	81	78	75

EQ5D

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	14	14	15
Answers	78	73	71	67	67	66
Response rate (%)	96	90	88	83	83	81
Total (n=167)						
Missing	5	19	26	34	36	41
Answers	162	148	141	133	131	126
Response rate (%)	97	89	84	80	78	75



Global improvement

	Better or Not after treatment?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 0 (after treatment)	62	11	31	44	8.00	2.88, 22.05
Day 1	37	39	25	53	2.01	0.86, 4.72
Day 2	30	47	17	62	2.33	0.93, 5.80
Day 3	25	51	13	64	2.41	0.90, 6.44
Day 4	22	54	9	67	3.03	1.02, 8.97
Day 5	17	59	11	64	1.68	0.57, 4.87
Day 6	21	57	13	63	1.79	0.65, 4.85
Day 7	11	65	9	65	1.22	0.37, 4.02
Day 8	15	59	12	59	1.25	0.43, 3.66
Day 9	11	65	6	63	1.78	0.48, 6.57
Day 10	11	64	7	63	1.55	0.44, 5.46
Day 11	6	65	9	61	0.63	0.16, 2.43
Day 12	8	64	7	63	1.13	0.30, 4.26
Day 13	9	63	7	60	1.22	0.33, 4.52
Day 14	9	61	12	59	0.73	0.22, 2.37
Day 28	7	59	4	65	1.93	0.41, 9.01
Day 84	10	55	5	63	2.29	0.56, 9.22
Day 365	14	47	11	55	1.49	0.48, 4.58

Non-opioid medication

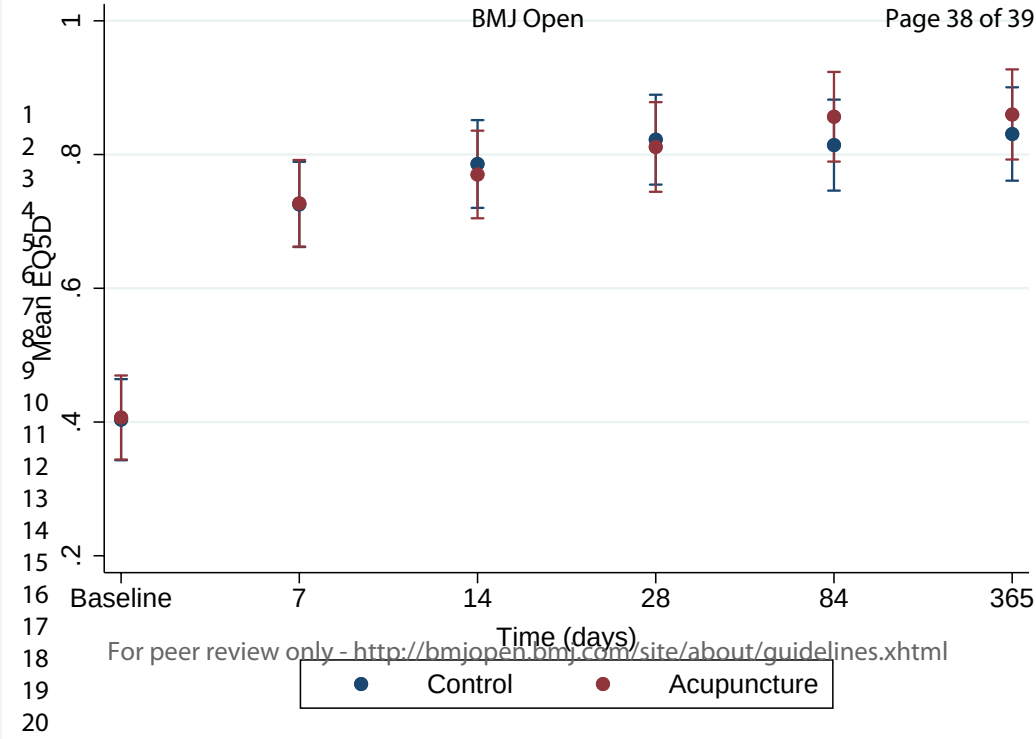
	Using non-opioid medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	21	54	28	50	0.69	0.29, 1.69
Day 2	22	54	33	46	0.57	0.24, 1.35
Day 3	24	51	41	36	0.41	0.17, 0.98
Day 4	34	41	45	31	0.57	0.25, 1.33
Day 5	38	37	46	29	0.64	0.28, 1.51
Day 6	44	33	50	26	0.69	0.30, 1.63
Day 7	45	30	48	26	0.81	0.34, 1.93
Day 8	44	29	49	22	0.68	0.28, 1.67
Day 9	51	24	46	23	1.06	0.43, 2.63
Day 10	54	20	52	18	0.93	0.36, 2.44
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	55	16	60	10	0.57	0.19, 1.74
Day 13	55	16	56	11	0.68	0.23, 2.01
Day 14	53	16	56	15	0.89	0.32, 2.48
Day 28	55	11	59	10	0.85	0.26, 2.76
Day 84	57	8	62	6	0.69	0.17, 2.76
Day 365	54	7	60	6	0.77	0.19, 3.19

Opioid medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	57	18	65	13	0.48	0.18, 1.33
Day 2	63	13	66	13	0.95	0.33, 2.80
Day 3	57	18	67	10	0.47	0.16, 1.40
Day 4	62	13	65	11	0.81	0.27, 2.46
Day 5	63	12	67	8	0.63	0.19, 2.10
Day 6	67	10	68	8	0.79	0.23, 2.73
Day 7	64	11	65	9	0.81	0.24, 2.66
Day 8	65	8	66	5	0.62	0.15, 2.60
Day 9	69	6	62	7	1.30	0.32, 5.30
Day 10	66	8	63	7	0.92	0.24, 3.48
Day 11	66	5	66	4	0.80	0.16, 4.08
Day 12	65	6	67	3	0.49	0.00, 2.66
Day 13	66	5	62	5	1.06	0.22, 5.05
Day 14	65	4	65	6	1.50	0.31, 7.25
Day 28	63	3	65	4	1.29	0.21, -
Day 84	63	2	66	2	0.95	-
Day 365	61	0	65	1	-	-

Medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	19	56	23	55	0.81	0.32, 2.04
Day 2	21	55	27	52	0.74	0.30, 1.79
Day 3	22	53	36	41	0.47	0.20, 1.13
Day 4	33	42	40	36	0.71	0.31, 1.63
Day 5	35	40	43	32	0.65	0.28, 1.51
Day 6	42	35	48	28	0.70	0.30, 1.63
Day 7	43	32	46	28	0.82	0.35, 1.92
Day 8	43	30	49	22	0.64	0.26, 1.57
Day 9	50	25	44	25	1.14	0.47, 2.78
Day 10	53	21	51	19	0.94	0.37, 2.42
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	54	17	59	11	0.59	0.20, 1.74
Day 13	55	16	53	14	0.91	0.32, 2.57
Day 14	52	17	53	15	1.00	0.36, 2.79
Day 28	53	13	58	11	0.77	0.25, 2.39
Day 84	55	10	62	6	0.53	0.14, 2.04
Day 365	54	7	59	7	0.92	0.23, 3.63



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1/1-2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3/1-4/9
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5/1-6/16
	2b	Specific objectives or hypotheses	6/13-16
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6/20-7/3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7/11-16
Participants	4a	Eligibility criteria for participants	7/24 – 8/2
	4b	Settings and locations where the data were collected	6/22-8/14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/16-9/14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9/16-10/9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10/18-21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6/24-7/3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6/24-7/3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6/24-7/10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6/20-8/14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7/9-10,

		assessing outcomes) and how	10/24-25
	11b	If relevant, description of the similarity of interventions	8/16-9/14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10/17-11/17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10/17-11/17
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11/21-22 +Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6/23-24
	14b	Why the trial ended or was stopped	6/23-24
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12/13-18 + Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12/5-12 + Suppl. file 2+3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14/8-16/24 + Fig2-4+SF4-7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	(SF 5+6)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14/1-6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15/19-24
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16/16-18/6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16/1-19/11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16/1-19/11
Other information			
Registration	23	Registration number and name of trial registry	4/12 + 7/17
Protocol	24	Where the full trial protocol can be accessed, if available	7/11 + Ref. 22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20/7-10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034157.R2
Article Type:	Original research
Date Submitted by the Author:	01-May-2020
Complete List of Authors:	Skonnord, Trygve; University of Oslo, Department of General Practice, Institute of Health and Society Skjeie, Holgeir; University of Oslo, Department of General Practice, Institute of Health and Society Brekke, Mette; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Klovning, Atle; University of Oslo, Department of General Practice, Institute of Health and Society Grotle, Margreth; Oslo Metropolitan University, Department of Physiotherapy; Oslo universitetssykehus Ulleval, Research and Communication Unit for Musculoskeletal Health Aas, Eline; University of Oslo, Department of Health Management and Health Economics, Institute of Health and Society; Akershus University Hospital, Health Services Research Unit Mdala, Ibrahimu; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Fetveit, Arne; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	General practice / Family practice, Rehabilitation medicine
Keywords:	COMPLEMENTARY MEDICINE, Back pain < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS, PAIN MANAGEMENT

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Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

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Word count:

4051

Key words

Acupuncture Therapy, Low Back Pain, Randomised Controlled Trial, General Practice

ABSTRACT

Objectives

The aim of this study was to evaluate whether a single treatment session of acupuncture, when applied in addition to standard treatment for acute low back pain (ALBP), reduces the time to recovery compared with standard treatment alone.

Design

A multicentre, randomised, controlled trial.

Setting

Conducted at 11 Norwegian general practitioners' (GPs') offices.

Participants

171 adults aged 20–55 years seeking their GP for ALBP (≤ 14 days) between March 2014–2017. Patients with secondary back pain and previous sick leave and acupuncture treatment were excluded.

Interventions

The participants were randomised to either the control group (CG) or the acupuncture group (AG) by online software. The CG received standard treatment according to the Norwegian guidelines, while the AG received one session of Western medical acupuncture treatment in addition to standard treatment. The statistician was blinded to group status.

Primary and secondary outcome measures

The primary outcome was median days to recovery. Secondary outcomes were pain intensity, global improvement, back-specific functional status, sick leave, medication, and adverse effects.

Results

185 participants were randomised, 95 in the CG, 90 in the AG. 14 participants did not receive the allocated intervention, and four were excluded from analysis. Thus, 167 participants were included in the analysis, 86 in the CG, 81 in the AG. The groups were similar according to baseline characteristics. The recovery period was 14 days for the control group and 9 days for the acupuncture group, HR 1.37 (95% CI 0.95, 1.96), (p = 0.089). No serious adverse effects were reported.

Conclusions

We did not find any statistically significant reduction in time-to-recovery after a single session of acupuncture for ALBP compared with standard care.

Trial registration

NCT01439412

Strengths and limitations of this study

- The standardised intervention procedures.
- The performance of a pilot study and the development of software led to improved logistics and increased response rate.
- Lower inclusion rates than expected reduced the power, leading to weaker conclusions about the effectiveness of the treatment.
- Trial logistic reasons led to per protocol analysis instead of intention-to-treat analysis.

INTRODUCTION

Low back pain (LBP) is a common symptom and an important cause of disability globally.[1 2] The causes of LBP are multifactorial, and most episodes of LBP are categorized as nonspecific.[1 3] The majority of patients affected by acute LBP (ALBP) experience a decrease in pain and disability within a month, but a significant number will experience recurrences or develop chronic pain.[1 4]

Most cases of ALBP are treated in primary health care. Clinical guidelines for treatment of ALBP recommend information and education, advice to stay active and to avoid bed rest.[5] The Norwegian guidelines of 2007 still include pain treatment with paracetamol and/or nonsteroidal anti-inflammatory drugs (NSAIDs),[6] which is nowadays internationally less emphasized.[5 7-9] In the 2017 US guideline pharmacological treatment is recommended only if nonpharmacological treatment does not succeed.[7] Some guidelines recommend acupuncture as first-line treatment, despite lack of high-quality evidence.[7 10]

In 2013, Lee et al. published a systematic review of acupuncture for ALBP and found that evidence is sparse.[11] They concluded that acupuncture might be more effective than medication for symptom improvement and pain relief than sham acupuncture (SA). However, the authors suggested new trials with better design and reporting of results.

After this systematic review, there has been published four RCTs of acupuncture for ALBP. [12-15] Vas et al. compared different acupuncture types with conventional therapy (CT), and found that the intervention groups fared significantly better than the CT groups.[12] However, there was no difference between valid acupuncture according to Traditional Chinese Medicine (TCM), SA, or placebo acupuncture. Hasegawa et al. concluded that Yamanoto's new scalp acupuncture (YNSA) was more effective than sham treatment in ALBP for both pain relief and other outcomes, although their intervention did not reach the

predefined values for the primary outcome.[14] In 2013, Shin et al. reported that one session of motion-style acupuncture treatment (MSAT), consisting of walking with the needles inserted, was superior to one intramuscular injection of diclofenac with respect to pain reduction and function.[13] In the latest publication for this topic, Fox et al. performed a pilot study with 30 participants evaluating a type of ear acupuncture, "Battlefield acupuncture" (BFA).[15] The authors concluded that BFA was feasible as a non-pharmacological treatment in addition to standard care for LBP in a civilian emergency department.[15]

The idea for the present study was based on clinical experience from GPs, who experienced faster recovery in patients receiving acupuncture for ALBP, often after the first treatment session. We found no other studies with time-to-recovery as primary outcome, but the single treatment session was supported by two previous studies.[13 16 17] The treatment was also in accordance with textbooks on acupuncture.[18 19]

Our study aimed to evaluate if a single treatment session with acupuncture could result in a faster recovery when applied in addition to standard treatment for ALBP compared with standard treatment alone. Our aim was also to describe pain intensity, disability, work absence, adverse effects and use of medication.

METHODS

Study design and randomization

The study was a multicentre, randomised, controlled trial (RCT) undertaken in 11 Norwegian GPs' offices. The study period was from March 2014 to March 2017 with the last follow-up in March 2018, after an extension of 1 year due to slow patient recruitment. The participants were randomised by a health secretary into an acupuncture group (AG) or a control group

(CG) in a ratio of 1:1, using a web-based randomization system developed and administered by the Unit of Applied Clinical Research, Norwegian University of Science and Technology,[20] which performs block randomisation with various block sizes.

Data collection was performed by electronic surveys at 19 different time points; before and after treatment on the day of treatment, and each day for the following 2 weeks; then, after 4 weeks, 12 weeks, and 1 year. To administer the logistics of the surveys, we developed software, SESAMe, which is described in a previous publication.[21]

In a pre-study power calculation, we estimated the sufficient sample size to be 135 in each group.[22] Each patient was blinded to the group allocation when reporting baseline data, but from the time of consultation neither the patient nor the GP was blinded.

The protocol of the present study was published in 2012 and includes further details.[22] Prior to the main study, we conducted a pilot study that included eight participants during October 2013 to January 2014. The results from the pilot study led to the web-based version of SESAMe,[21] an exclusion criterion of previous acupuncture, and advices to the participating GP offices about medication standardization, study logistics, and efforts to minimize differences in placebo effects.

The study is registered in ClinicalTrials.gov (NCT01439412). Ethical approval was given by the Regional Ethics Committee of South-Eastern Norway (reference 2013/611/REK sør-øst A). The reporting of the study follows the CONSORT statement[23] and the STRICTA recommendations.[24]

Participants and recruitment procedure

Patients with ALBP lasting 14 days or less who contacted their GP office were asked to participate in the trial. We included adults aged 20–55 years with nonspecific ALBP who

gave informed consent. Exclusion criteria were nerve root affection, “red flags”, pregnancy, disability pension, sick leave of more than 14 days, and acupuncture during the last month.

The inclusion/exclusion process was performed by the health secretary at the GP’s office and in an initial online survey with information and the consent. She also administered the emails in SESAMe and asked the patient to answer the baseline survey before the consultation. If the GP revealed any exclusion criteria during the consultation, the patient was excluded. This, as well as the time spent in the consultation, was recorded by the GPs.

At each GP office, one GP was trained in acupuncture and treated the AG, and from one to four other GPs treated the CG. All acupuncture GPs were specialists in family medicine, and the mean time of acupuncture experience was 7.4 years (range 1–19 years). Nine of the GPs had at least 320 hours of education in acupuncture.

Most treating GPs in the CG were experienced specialists in family medicine, but some of them were working in the internship program; thus, the overall experience of the treating GPs varied more than for the AG.

Study interventions

Standard treatment (CG) consisted of advice about activity, prescription of analgesic medication (paracetamol and/or ibuprofen), and sick leave, if needed, according to the Norwegian national guidelines.[6]

The AG received the same standard treatment as the CG and, in addition, one session of acupuncture treatment with Western medical acupuncture style. This session consisted of 1 minute with two needles of Seirin® type B-8a 0.30 × 30 mm in the acupuncture points, Lumbar Pain Points (Yaotongxue/Yaotongdian) on the right hand, stimulated to a powerful needle sensation, called “de Qi” in TCM. With the needles in the hand, the patient was asked

to rise and perform mobilization movements (slow rotating pelvic movements) for 2 minutes, followed by 5 minutes on a bench while the patient received six needles of the SEIRIN® type J-8 0.30 × 50 mm in the local points Huatuojiaji ("Jiaji") in the L2–L4-segments, stimulated until needle sensation. The needles remained in place until all the needles were removed after a total treatment time of 8–9 minutes. The short treatment and the choice of only one session of acupuncture were an attempt to reduce potential attention bias. The details of the procedure and the process of choosing the specific and standardized treatment are briefly described in the published protocol, based on clinical experience, literature and feedback from a medical acupuncture expert group.[22]

Prior to the study, the health secretaries and many GPs (including all acupuncture doctors) were gathered at a workshop to ensure they understood the study logistics, the standard ALBP treatment, and the standardization of the acupuncture treatment. During the trial, we arranged two workshops to remind the GP offices of the need of inclusion and update about the study logistics.

Outcome measurements and data collection

The primary outcome in the study was days to recovery, defined as the first day the patient scored 0 or 1 on the Numerical Rating Scale (NRS).[25 26] This definition is in line with the definition of "sustained recovery" with an NRS of 0 or 1 for seven consecutive days.[26 27] We defined a minimum of a 3-day faster recovery as a clinically relevant difference between the groups, based on clinical experience and previous studies.[28 29]

The secondary outcome measurements were pain intensity,[25] disability by Roland Morris Disability Questionnaire (RMDQ),[30] sick leave, 5-point global improvement (Likert scale), use of medication, new visits at the GP's office, health-related quality of life by the

EuroQol (EQ-5D-3L), using UK tariff for time trade-off,[31] and adverse effects. RMDQ and EQ-5D-3L were collected at baseline, 1, 2, 4, 12 weeks, and 1 year, while the other secondary outcomes were collected at all time points. In addition, at baseline, we asked for sociodemographic variables, patient preferences for treatment options, expectations with respect to the effect of acupuncture and psychosocial risk profile according to the Örebro screening form for musculoskeletal pain.[32 33]

We also asked the participants in the 1-year survey about the number of new LBP episodes, work absence, and if they had received any other kind of treatment for LBP the last 9 months.

Patient and public involvement

No patients were involved in the planning of the study or in the recruitment and the conduct of the study. The study participants were informed that the results of the study would be presented at the study Facebook page. The burden of the intervention could be reported by the patients through the questionnaires of global improvement and adverse events.

Statistical analysis

Study sample size was calculated to be 270 participants, with 80% power to detect a 3 days' difference in median time to recovery with an α level of 0.05 and a true hazard ratio (HR) of 1.429. This was based on the assumption of a 365 days follow-up period, an accrual period of 0 days and a median survival of 7 days.[34] The study allowed for a dropout rate of up to 10%.

Details of the protocol for randomization and allocation procedures were published previously.[22] Statistical analyses were performed using the programs IBM SPSS Statistics® 25 and StataSE® 15. Data were analysed by a statistician who was blinded to group status, and the results presented in tables and figures were finalized before codes were revealed. The

analyses were performed per protocol, analysing just participants not excluded during the allocation, lost to follow-up or excluded from analyses of other reasons (Figure 1). The NRS data were transformed to the first day of recovery, independent of any intermittent missing answers. We calculated the difference in days to recovery for the two groups using the log-rank test, and late missing answers were censored, leaving the last specified value for analysis.

The time to recovery was expressed by the median days to recovery for the two groups, and Cox proportional hazard regression models were used to assess the effect of treatment on pain duration (in days). We checked the Cox proportionality assumption and concluded that our model satisfied the assumption of proportionality.

Numeric secondary outcomes such as NRS were analysed using linear multilevel models with patient random effects, while binary outcomes such as medication use and work absence were analysed using binary multilevel logistic regression models. With numeric outcomes, mean changes over time in the groups were obtained, while estimates of odds ratios with their 99% confidence intervals were obtained for binary outcomes.

For primary outcomes, a p-value of <0.05 was considered statistically significant. For the secondary outcomes, a p-value of <0.01 was considered significant, and 99% confidence intervals (CIs) given.

RESULTS

The study flow chart shows that of a total of 185 participants that were randomised into the two groups, 167 were included in the analysis, 86 in the CG and 81 in the AG (Figure 1). Recruitment of participants at the 11 GP offices varied considerably, and there were also differences in exclusions at each site (Supplementary file 1). The overall recruitment was

poorer than expected, and even if the inclusion period was extended with one year, the planned sample size was not met. Possible causes can be less LBP patients seeking the GPs due to previous public campaigns, patients seeking other therapists, and the circumstances of the trial taking place in busy GP practices with voluntary work by both GPs and health secretaries with no professional research network to help.

The overall response rate in the trial was 87.4%, but varied in each survey and decreased over time. One year into the observation period, 66 participants in the AG and 61 in the CG had answered the survey, resulting in a response rate of 76.0%. Supplementary file 2 shows the numbers of missing answers per survey for the primary outcome and Supplementary file 3 for the secondary outcomes. There were no statistically significant differences between the groups in response rate, except for primary outcome at day 2 ($p = 0.037$). One participant in the AG underwent an operation for sciatica during the follow-up period.

Table 1 shows the baseline characteristics with sociodemographic data and clinical features of the participants. There were no statistically significant differences between the groups in any of the variables. There were small differences between the groups for obesity and smoking, which is known risk factors to LBP,[35] but testing for these variables did not change the results of the primary outcome.

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Characteristic	Control (n = 86)	Acupuncture (n = 81)
Age (year), mean (SD)	39.3 (9.4)	39.8 (11.4)
Female, n (%)	44 (51.2)	41 (50.6)
Living with a partner, n (%)	57 (67.9)	65 (83.3)
Born in Norway, n (%)	78 (92.9)	69 (88.5)
Level of education >13 years, n (%)	28 (33.3)	30 (38.5)
Work status		
Employed, n (%)	77 (91.7)	70 (87.5)
Student, n (%)	7 (8.3)	6 (7.5)
Unpaid work, n (%)	1 (1.2)	1 (1.3)
Unemployed, n (%)	2 (2.4)	3 (3.8)
Sick leave, n (%)	3 (3.6)	3 (3.8)
BMI		
<25 (normal), n (%)	28 (33.3)	30 (38.5)
25.00–29.99 (overweight), n (%)	29 (34.5)	29 (37.2)
>30 (obese), n (%)	27 (32.1)	19 (24.4)
Smoking, n (%)	20 (23.8)	14 (17.9)
Alcohol several times a week, n (%)	10 (11.9)	8 (10.3)
Serious life events last 12 months, n (%)	15 (17.9)	17 (21.3)
Previous LBP, n (%)	63 (73.3)	58 (71.6)
Treatment preference: acupuncture, n (%)	66 (78.6)	58 (74.4)
Belief in acupuncture treatment (0–10), mean (SD)	6.6 (2.6)	6.6 (2.5)
Back pain intensity (0–10), mean (SD)	6.3 (1.8)	6.2 (1.9)
Leg pain intensity (0–10), mean (SD)	2.7 (2.6)	2.4 (2.7)
RMDQ (0–24), mean (SD)	14.8 (4.4)	15.0 (4.2)
EQ-5D, mean (SD)	0.40 (0.33)	0.41 (0.31)
DDD non-opioid medication, mean (SD)	0.66 (0.85)	0.93 (0.97)
DDD opioid medication, mean (SD)	0.09 (0.27)	0.09 (0.31)
Days from randomisation to treatment, median (IQR)	0 (0 – 0)	0 (0 – 0)
Örebro		
Low risk, n (%)	41 (48.8)	47 (60.3)
Medium risk, n (%)	25 (29.8)	19 (24.4)
High risk, n (%)	18 (21.4)	12 (15.4)
SHC, mean (SD)	11.25 (7.44)	9.12 (5.36)
Missing	2	3

Data in n (%), mean (SD) or median (IQR). SD indicates standard deviation; IQR, interquartile range; BMI, body mass index; LBP, low back pain; RMDQ (0–24), Roland Morris Disability Questionnaire, higher score represents greater overall disability; DDD, defined daily dose; SHC, subjective health complaints, higher score means more reported health complaints. EQ-5D, higher score represents better health state; NRS (0–10), higher score represents more pain. There were no significant differences between the groups in any of the variables.

The duration of the consultations in the AG were 20.2 minutes (99% CI 19.0, 21.5), versus 17.0 minutes (99% CI 15.4, 18.5) in the CG, and the difference of 3.2 minutes were statistically significant ($p \leq 0.001$). In the study 21.9% (99% CI 10.4, 33.4) of the patients in the CG were treated by their regular GP versus 40.0% (99% CI 26.0, 54.0) in the AG ($p = 0.011$).

Primary outcome

Median time to recovery was 14 days for the CG (IQR 6-84) and 9 days for AG (IQR 4-84). Based on the Cox regression model, the difference of 5 days was not statistically significant, despite achieving the a priori threshold for clinical relevance of 3 days, with a HR 1.37 (95% CI 0.95, 1.96), ($p = 0.089$).

Time to recovery for 365 days and the first 28 days are shown in Figure 2. The log-rank test for 365 days is based on 56 observed and 65.3 expected events in the CG and 64 observed and 54.7 expected events in the AG, which was not statistically significant ($p = 0.072$). We also performed a sensitivity analysis on the four excluded participants with the same result.

For one extra person to recover during the whole study period, the NNT was 7.2 (95% CI 3.7, 210.3).[36]

Secondary outcomes

Pain intensity during the study period reduced in both groups with no clinically relevant nor statistically significant differences between the two groups at each time point (Figure 3). The mean difference in pain between the two groups during the whole study overall was 0.48 (99% CI 0.25, 0.71) ($p < 0.001$) in favour of the AG. This equals a standardized mean difference (SMD) of 0.13.

The same pattern was seen for back-related disability by RMDQ, which showed an improvement during the year for both groups but with no statistically significant difference between the two groups (Figure 4).

There were no statistically significant differences in sick leave between the groups at any of the time points (Supplementary file 4).

The participants' perception of global improvement (feeling better or much better), was highly significantly better in the AG group on day 0 after treatment (OR 8.00, 99% CI 2.88, 22.05), but later the difference became gradually smaller, with statistically significance on just one other day (day 4) (Supplementary file 5).

There were no statistically significant differences in the use of medication, unless for day 3 when fewer participants in the AG used non-opioid medication than in the CG (Supplementary file 6).

The estimated number of new visits to the GP through the study period was 2.7 (99% CI 2.0, 3.5) in the CG and 2.6 (99% CI 1.9, 3.3) in the AG, difference 0.1 (99% CI -0.9, 1.1) ($p = 0.76$). Health-related quality of life measured by EQ-5D-3L did not show statistically significant differences between the two groups at any time point during the study (Supplementary file 7). There were more, but statistically nonsignificant, LBP episodes in the CG after 1 year, 3.2 (99% CI 2.4, 3.9) versus 2.4 (99% CI 1.7, 3.2) in the AG, difference 0.7 (99% CI -0.3, 1.8) ($p = 0.06$).

No serious adverse events were reported in the study. Sixteen participants (18.6%, 99% CI 7.8, 29.4) in the CG reported some adverse effects compared with 11 (13.6%, 99% CI 3.8, 23.4) in the AG, difference 5,0% (99% CI -9.9, 19.9) ($p = 0.38$). Two participants reported pain/soreness in their hand because of the needles the day after the treatment. Twenty-two participants reported gastrointestinal symptoms, 14 of them in the CG. Other less frequent symptoms were tiredness, headache, dyspnoea, and muscle pain.

DISCUSSION

Principle findings

This study showed that adding one single session of 8–9 minutes of acupuncture treatment to standard guideline-based care to patients with ALBP resulted in a 5 days faster recovery of pain, but the result was not statistically significant. Similarly, adding acupuncture to standard guideline-based primary care did not show any statistically significant effect in the secondary outcome measures of disability, work absence and quality of life. For the secondary outcomes of pain, self-reported global improvement and medication, we found small differences without clinical relevance. Finally, the acupuncture treatment was safe, with no significant differences of major symptoms or serious adverse events.

Strengths and limitations of the study

The main strength of this study was the standardised intervention procedures, leading to no attention bias between the two groups. Another strength was the performance of a pilot study which led to logistic changes that contributed to both an equality of the groups and an improved response rate. The innovative process of developing our own logistic software (SESAMe) was central in this quality improvement.[21]

The main limitation of this study was the low power due to lower inclusion rates than expected, even after we extended the inclusion period with 1 year. This led to weaker conclusions about the effectiveness of the treatment. The results of the primary outcome could well be due to a type II error. However, low power in a trial reduces the likelihood that the observed effect represents a true effect.[37] The wider standard deviations in an underpowered study make it more likely to reach clinical relevant values.[37] The very small effect size on

pain (SMD = 0.13) and the lack of effect on disability, can imply that the 5 days faster time to recovery can be a spurious finding. Another limitation is that we were not able to perform the intended intention-to-treat analysis. Of logistic reasons, we had to perform the last eligibility-evaluation by the GP in the consultation. That is why 14 participants were randomised, but excluded before intervention was given. In addition, 4 participants were excluded from analysis, three of them because of statistical challenges (left censoring) and one because of exclusion criteria. However, a sensitivity analysis did not change the results. On the other hand, the exclusion after randomisation may have caused bias. Lack of fidelity check list to measure the fidelity of the interventions is another limitation. Even considering the significance level of 0.01 on secondary outcomes, with the large number of statistical tests performed, there is a possibility that any of the observed differences could be due to false positives. In addition, many of the confidence intervals are wide, so the estimated effects lack precision.

Relation to other studies

The acupuncture treatment provided in this trial consisted of both shorter treatment time and fewer treatment sessions than usual.[38 39] This may have caused less chances to detect a real difference in effectiveness. On the other side, a longer treatment time and more sessions could have caused more attention bias. Our results could not support Vas et al. showing the effectiveness of acupuncture compared to conventional therapy.[12] The short-term effect of only one acupuncture treatment session for LBP was previously shown by Shin et al.,[13] but MacPherson et al. showed that pain outcomes were influenced by increased numbers of needles and more sessions, and thus the dose was important.[39] After the trials of Vickers and MacPherson,[39 40] the US National Center for Complementary and Integrative Health (NCCIH) announced a need for pragmatic acupuncture trials for pain management, testing the

effectiveness in "real world" conditions, while efficacy studies seek effect under ideal conditions.[41 42] Because this was a pragmatic trial in accordance with the NCCIH recommendations, the participants and GPs were not blinded. Some may argue that this is a problem in acupuncture trials, and it would be a limitation in an efficacy study. However, a large systematic review with individual patient data meta-analysis by Vickers et al. in 2012 has evaluated the efficacy of acupuncture for pain, and the authors showed that acupuncture has a small, specific effect on pain.[40] The difference between true acupuncture and sham or placebo acupuncture is small, and trials will need large sample sizes to emphasize these differences, which Vas et al. demonstrated to be also true for ALBP.[12] In our study, there were nonsignificant differences in pain for each time-point, but statistically significant difference in pain overall. Because the effect size was very small and the difference was considered not clinically relevant, this result should be interpreted with caution.

The highly significant difference in the early perception of global improvement could be a result of the positive expectations, but it could also be due to the experience of a faster recovery with less pain. The findings are in accordance with the systematic review by Lee et al. in which acupuncture is compared with the use of NSAIDs.[11] However, subjective outcomes have been shown to exaggerate effect estimates in trials that were not blinded.[43] In addition, the slightly higher response rates in the acupuncture group the first days could have contributed to a possible strengthening of the positive subjective outcomes.

The two study groups scored equal for treatment preferences and belief in acupuncture prior to the treatment. For the AG, this might represent a positive expectation bias when receiving the treatment, while those in the CG might have had a negative expectation bias when not receiving the acupuncture they had wanted. This would be in accordance with other research demonstrating an effect of treatment preferences and belief in the treatment in pain studies.[44 45]

There are not many trials of non-pharmacological treatments reporting NNT. Despite the lack of effect between the two groups in the present study, the NNT from our trial was comparable to both other LBP trials[46 47] and acupuncture trials.[48 49]

The few observed differences between the two groups can be due to specific and nonspecific needle effects, the contribution of the mobilization movements, the extra consultation time, or the attention bias provided by the overall extra treatment ritual. There could also be an operator effect of a less or more enthusiastic behaviour in the consultation. The patient-practitioner relationship is shown to influence the placebo effect, even in standardised intervention procedures.[50] However, this could be a phenomenon in both groups, and also influenced by the prescribing of medication, performing a physical examination or not, empathic behaviour and time spent. Short consultation times are a key challenge to implementing best practices for LBP,[5] but in our study, we cannot conclude whether the extra time for acupuncture compensated for possibly less time for giving advice.

More participants in the AG than in the CG met with their regular GP during the consultation. Continuity in the doctor–patient relationship, including previous knowledge about the patient, is associated with improved patient outcomes.[51 52]

Conclusion

This trial showed that adding one treatment session of acupuncture in combination with mobilization movements had similar effect as usual care for patients with ALBP during one year of follow-up. On primary outcome, the observed difference of 5 days earlier recovery in the acupuncture group was not statistically significant. On secondary outcomes, there was no statistically significant differences in self-reported outcome measures of disability and health-related quality-of-life. On pain reduction, there was a statistically significant but not clinically relevant difference.

Acknowledgements

The authors would like to thank the participating GPs and health secretaries, and Finn Steen whose contribution to the data collection was essential through the development of SESAMe.

Competing Interests

The authors report no conflict of interest.

Funding

This study was funded by Institute of Health and Society, University of Oslo. The study received also some funding for logistic expenses by private endowments, the "Gidske and Peter Jacob Sørensens fund" and the "Trygve Gythfeldts fund".

Author Contributions

TS and HS had the idea for the project. TS, HS, MB, MG and AF contributed to conceptualization and design of the study. TS, AK and Finn Steen developed the software for data collection. TS and IM performed the statistical analyses. TS and EA performed the health-economic analyses. TS drafted the article. All authors have discussed the results and revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Data sharing statement

The additional unpublished data are available from the corresponding author on request.

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LEGENDS

Figure 1 CONSORT flow diagram in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Figure 2 Time to recovery for acute low back pain with acupuncture and standard treatment compared with standard treatment alone. One-year follow-up and first 28 days (n = 167).

Figure 3 Pain intensity during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Figure 4 Disability by Roland Morris Disability Questionnaire (RMDQ) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 1 Number of participants included and excluded at each general practitioner's (GP's) office in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone, by treatment group.

Supplementary file 2 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain

when applied in addition to standard treatment, compared with standard treatment alone — primary outcome.

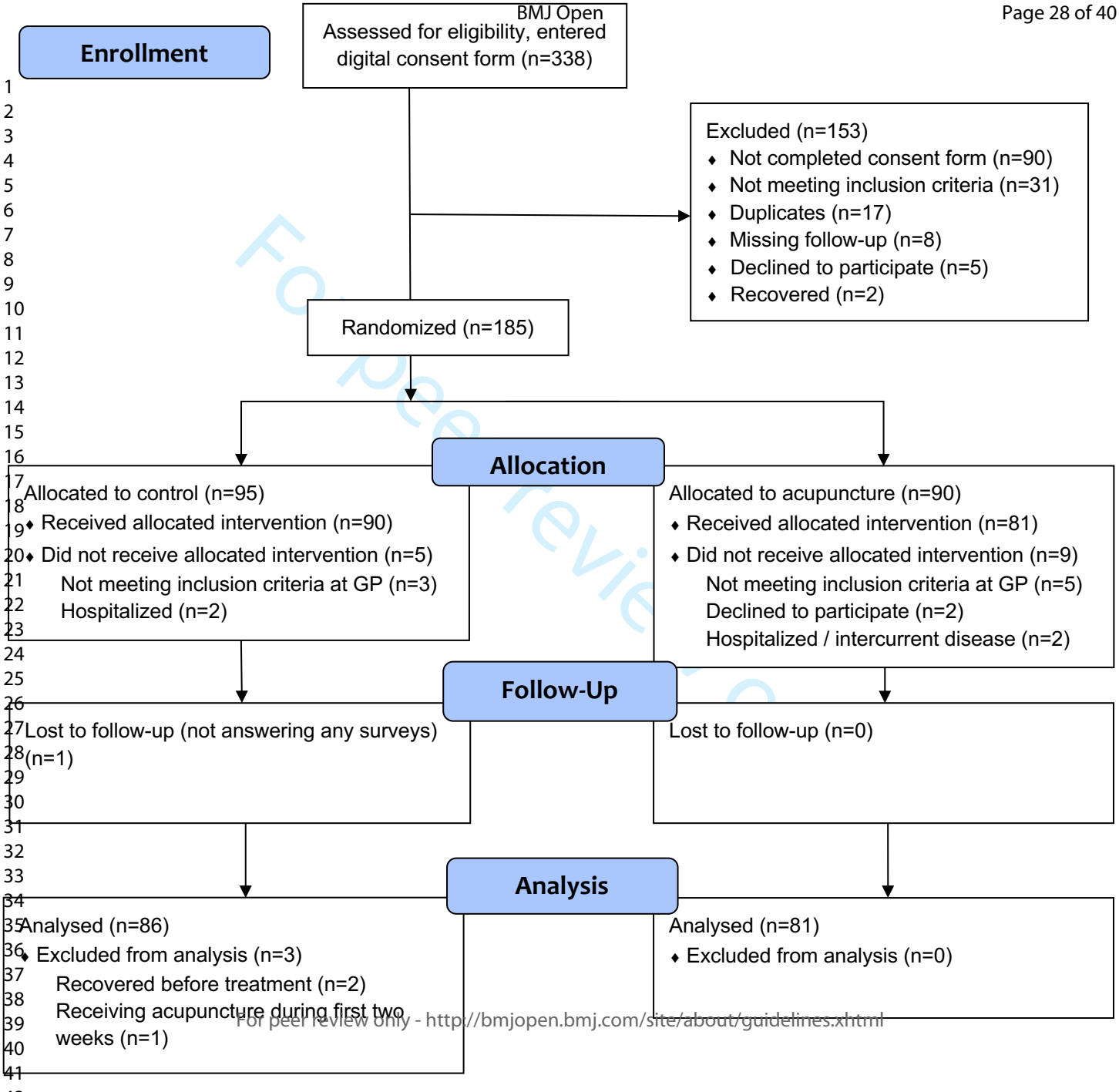
Supplementary file 3 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — secondary outcomes.

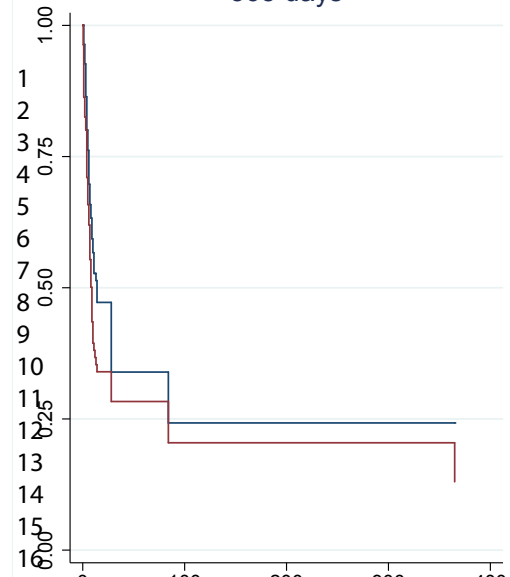
Supplementary file 4 Work absence and work presence during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 147).

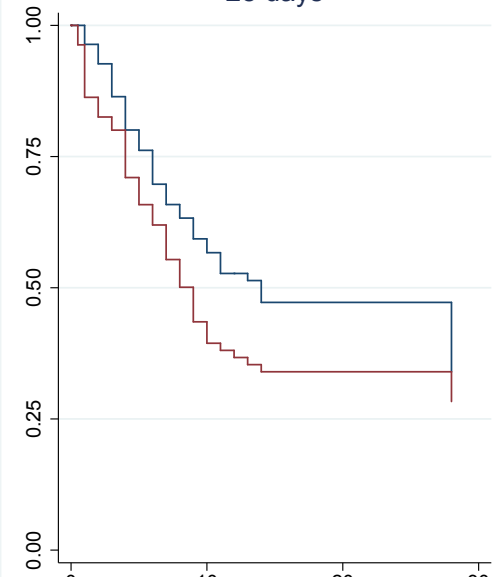
Supplementary file 5 Participants' perception of global improvement during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 6 Use of medication during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

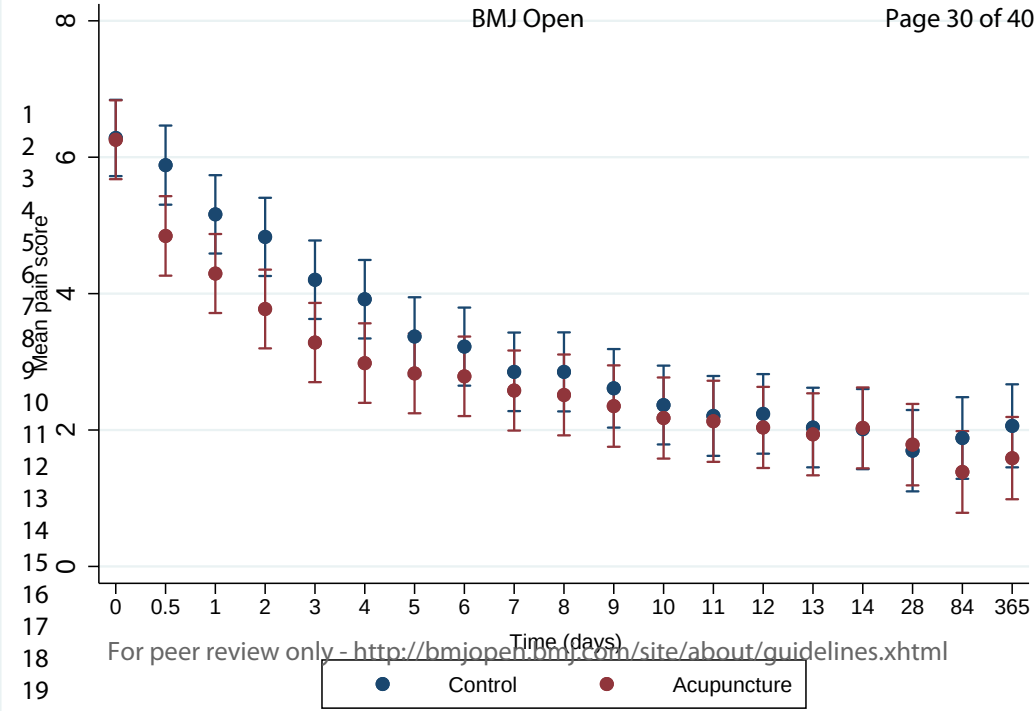
Supplementary file 7 Health-related quality-of-life by the EuroQoL (EQ-5D) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

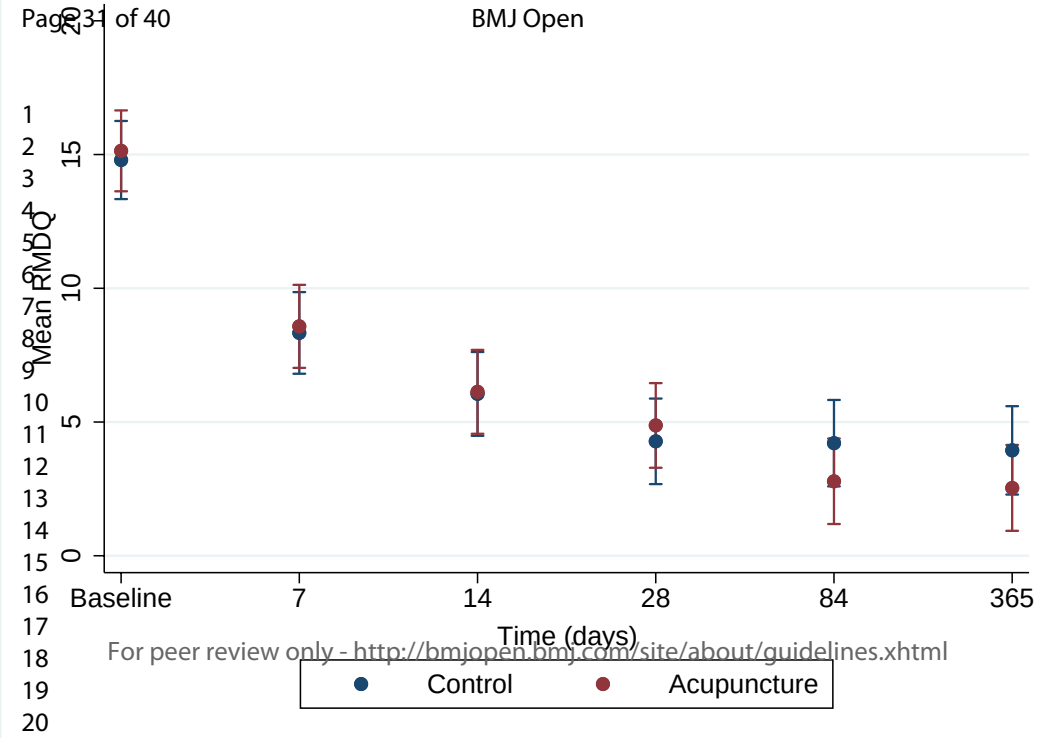






Control Acupuncture





GP Office	Inclusion			Exclusion		
	Control (n=86)	Acupuncture (n=81)	Total (n=167)	Control (n=8)	Acupuncture (n=10)	Total (n=18)
1	20	16	36	1	1	2
2	10	11	21	1	0	1
3	3	3	6	0	0	0
4	1	1	2	0	0	0
5	11	14	25	4	0	4
6	1	2	3	0	0	0
7	10	10	20	0	0	0
8	10	5	15	1	2	3
9	2	1	3	0	0	0
10	0	1	1	0	0	0
11	18	17	35	1	7	8

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Counterpuncture group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Pain intensity + medication

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Global improvement

	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																		
Missing	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																		
Missing	6	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	75	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	93	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																		
Missing	19	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	148	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Return to work

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																	
Missing	14	11	15	12	14	11	14	15	15	15	19	19	19	19	24	21	27
Answers	72	75	71	74	72	75	72	71	71	71	67	67	67	67	62	65	59
Response rate (%)	84	87	83	86	84	87	84	83	83	83	78	78	78	78	72	76	69
Acupuncture group (n=81)																	
Missing	8	6	10	11	12	9	8	11	14	13	13	12	16	12	15	13	17
Answers	73	75	71	70	69	72	73	70	67	68	68	69	65	69	66	68	64
Response rate (%)	90	93	88	86	85	89	90	86	83	84	84	85	80	85	81	84	79
Total (n=167)																	
Missing	22	17	25	23	26	20	22	26	29	28	32	31	35	31	39	34	44
Answers	145	150	142	144	141	147	145	141	138	139	135	136	132	136	128	133	123
Response rate (%)	87	90	85	86	84	88	87	84	83	83	81	81	79	81	77	80	74

RMDQ

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	12	14	15
Answers	78	73	71	69	67	66
Response rate (%)	96	90	88	85	83	81
Total (n=167)						
Missing	5	19	26	32	36	41
Answers	162	148	141	135	131	126
Response rate (%)	97	89	84	81	78	75

EQ5D

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	14	14	15
Answers	78	73	71	67	67	66
Response rate (%)	96	90	88	83	83	81
Total (n=167)						
Missing	5	19	26	34	36	41
Answers	162	148	141	133	131	126
Response rate (%)	97	89	84	80	78	75

	Baseline	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=77)																		
Work absence (n)	3	38	42	39	35	35	28	23	21	21	19	18	16	16	15	7	3	6
Work absence (%)	4	49	55	51	45	45	36	30	27	27	25	23	21	21	19	9	4	8
Work presence (n)	74	29	27	28	32	31	40	44	45	45	46	43	47	46	46	49	53	47
Work presence (%)	96	38	35	36	42	40	52	57	58	58	60	56	61	60	60	64	69	61
Missing (n)	0	10	8	10	10	11	9	10	11	11	12	16	14	15	16	21	21	24
Acupuncture group (n=70)																		
Work absence (n)	3	31	32	30	28	28	25	17	16	14	15	14	11	11	11	8	9	9
Work absence (%)	4	44	46	43	40	40	36	24	23	20	21	20	16	16	16	11	13	13
Work presence (n)	67	36	36	38	38	37	41	48	46	46	47	47	50	47	51	53	51	51
Work presence (%)	96	51	51	54	54	53	59	69	66	66	67	67	71	67	73	76	73	73
Missing (n)	0	3	2	2	4	5	4	5	8	10	8	9	9	12	8	9	10	10
Total (n=147)																		
Work absence (n)	6	69	74	69	63	63	53	40	37	35	34	32	27	27	26	15	12	15
Work absence (%)	4	47	50	47	43	43	36	27	25	24	23	22	18	18	18	10	8	10
Work presence (n)	141	65	63	66	70	68	81	92	91	91	93	90	97	93	97	102	104	98
Work presence (%)	96	44	43	45	48	46	55	63	62	62	63	61	66	63	66	69	71	67
Missing (n)	0	13	10	12	14	16	13	15	19	21	20	25	23	27	24	30	31	34

Global improvement

	Better or Not after treatment?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 0 (after treatment)	62	11	31	44	8.00	2.88, 22.05
Day 1	37	39	25	53	2.01	0.86, 4.72
Day 2	30	47	17	62	2.33	0.93, 5.80
Day 3	25	51	13	64	2.41	0.90, 6.44
Day 4	22	54	9	67	3.03	1.02, 8.97
Day 5	17	59	11	64	1.68	0.57, 4.87
Day 6	21	57	13	63	1.79	0.65, 4.85
Day 7	11	65	9	65	1.22	0.37, 4.02
Day 8	15	59	12	59	1.25	0.43, 3.66
Day 9	11	65	6	63	1.78	0.48, 6.57
Day 10	11	64	7	63	1.55	0.44, 5.46
Day 11	6	65	9	61	0.63	0.16, 2.43
Day 12	8	64	7	63	1.13	0.30, 4.26
Day 13	9	63	7	60	1.22	0.33, 4.52
Day 14	9	61	12	59	0.73	0.22, 2.37
Day 28	7	59	4	65	1.93	0.41, 9.01
Day 84	10	55	5	63	2.29	0.56, 9.22
Day 365	14	47	11	55	1.49	0.48, 4.58

Non-opioid medication

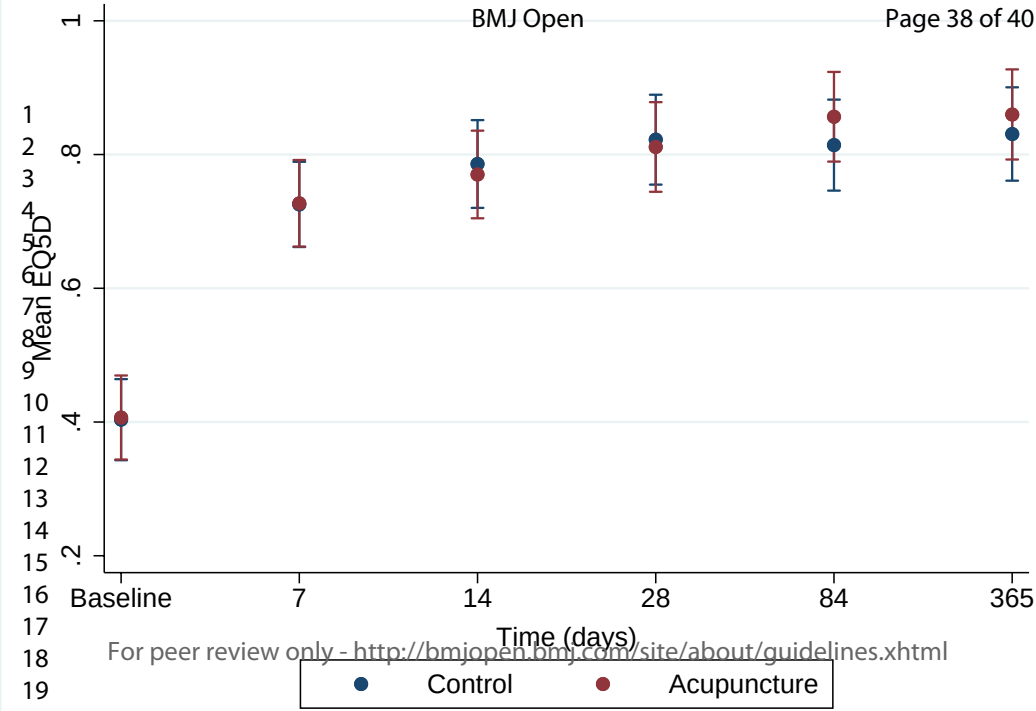
	Using non-opioid medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	21	54	28	50	0.69	0.29, 1.69
Day 2	22	54	33	46	0.57	0.24, 1.35
Day 3	24	51	41	36	0.41	0.17, 0.98
Day 4	34	41	45	31	0.57	0.25, 1.33
Day 5	38	37	46	29	0.64	0.28, 1.51
Day 6	44	33	50	26	0.69	0.30, 1.63
Day 7	45	30	48	26	0.81	0.34, 1.93
Day 8	44	29	49	22	0.68	0.28, 1.67
Day 9	51	24	46	23	1.06	0.43, 2.63
Day 10	54	20	52	18	0.93	0.36, 2.44
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	55	16	60	10	0.57	0.19, 1.74
Day 13	55	16	56	11	0.68	0.23, 2.01
Day 14	53	16	56	15	0.89	0.32, 2.48
Day 28	55	11	59	10	0.85	0.26, 2.76
Day 84	57	8	62	6	0.69	0.17, 2.76
Day 365	54	7	60	6	0.77	0.19, 3.19

Opioid medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	57	18	65	13	0.48	0.18, 1.33
Day 2	63	13	66	13	0.95	0.33, 2.80
Day 3	57	18	67	10	0.47	0.16, 1.40
Day 4	62	13	65	11	0.81	0.27, 2.46
Day 5	63	12	67	8	0.63	0.19, 2.10
Day 6	67	10	68	8	0.79	0.23, 2.73
Day 7	64	11	65	9	0.81	0.24, 2.66
Day 8	65	8	66	5	0.62	0.15, 2.60
Day 9	69	6	62	7	1.30	0.32, 5.30
Day 10	66	8	63	7	0.92	0.24, 3.48
Day 11	66	5	66	4	0.80	0.16, 4.08
Day 12	65	6	67	3	0.49	0.00, 2.66
Day 13	66	5	62	5	1.06	0.22, 5.05
Day 14	65	4	65	6	1.50	0.31, 7.25
Day 28	63	3	65	4	1.29	0.21, -
Day 84	63	2	66	2	0.95	-
Day 365	61	0	65	1	-	-

Medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	19	56	23	55	0.81	0.32, 2.04
Day 2	21	55	27	52	0.74	0.30, 1.79
Day 3	22	53	36	41	0.47	0.20, 1.13
Day 4	33	42	40	36	0.71	0.31, 1.63
Day 5	35	40	43	32	0.65	0.28, 1.51
Day 6	42	35	48	28	0.70	0.30, 1.63
Day 7	43	32	46	28	0.82	0.35, 1.92
Day 8	43	30	49	22	0.64	0.26, 1.57
Day 9	50	25	44	25	1.14	0.47, 2.78
Day 10	53	21	51	19	0.94	0.37, 2.42
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	54	17	59	11	0.59	0.20, 1.74
Day 13	55	16	53	14	0.91	0.32, 2.57
Day 14	52	17	53	15	1.04	0.38, 2.84
Day 28	53	13	58	11	0.77	0.25, 2.39
Day 84	55	10	62	6	0.53	0.14, 2.04
Day 365	54	7	59	7	0.92	0.23, 3.63



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1/1-2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3/1-4/9
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5/1-6/16
	2b	Specific objectives or hypotheses	6/13-16
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6/20-7/3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7/11-16
Participants	4a	Eligibility criteria for participants	7/24 – 8/2
	4b	Settings and locations where the data were collected	6/22-8/14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/16-9/14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9/16-10/9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10/18-21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6/24-7/3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6/24-7/3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6/24-7/10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6/20-8/14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7/9-10,

		assessing outcomes) and how	10/24-25
	11b	If relevant, description of the similarity of interventions	8/16-9/14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10/17-11/18
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10/17-11/18
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11/22-23 +Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6/23-24
	14b	Why the trial ended or was stopped	6/23-24
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12/14-18 + Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12/6-13 + Suppl. file 2+3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14/8-16/25 + Fig2-4+SF4-7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	(SF 5+6)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14/1-5 + 15/17-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15/20-25
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16/14-17/13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16/1-19/25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16/1-19/25
Other information			
Registration	23	Registration number and name of trial registry	4/12 + 7/17
Protocol	24	Where the full trial protocol can be accessed, if available	7/11 + Ref. 22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20/7-10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on page/line number
Title	Identification of the study as randomized	1/1
Authors *	Contact details for the corresponding author	1/4-11
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	3/8
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	3/10, 3/12-14
Interventions	Interventions intended for each group	3/16-19
Objective	Specific objective or hypothesis	3/4-6
Outcome	Clearly defined primary outcome for this report	3/21
Randomization	How participants were allocated to interventions	3/16-17
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	3/19
Results		
Numbers randomized	Number of participants randomized to each group	4/1
Recruitment	Trial status	4/1-3
Numbers analysed	Number of participants analysed in each group	4/2-3
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	4/4-5
Harms	Important adverse events or side effects	4/5-6
Conclusions	General interpretation of the results	4/8-9
Trial registration	Registration number and name of trial register	4/12
Funding	Source of funding	-

**this item is specific to conference abstracts*

BMJ Open

Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034157.R3
Article Type:	Original research
Date Submitted by the Author:	02-Jul-2020
Complete List of Authors:	Skonnord, Trygve; University of Oslo, Department of General Practice, Institute of Health and Society Skjeie, Holgeir; University of Oslo, Department of General Practice, Institute of Health and Society Brekke, Mette; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Klovning, Atle; University of Oslo, Department of General Practice, Institute of Health and Society Grotle, Margreth; Oslo Metropolitan University, Department of Physiotherapy; Oslo universitetssykehus Ulleval, Research and Communication Unit for Musculoskeletal Health Aas, Eline; University of Oslo, Department of Health Management and Health Economics, Institute of Health and Society; Akershus University Hospital, Health Services Research Unit Mdala, Ibrahimu; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society Fetveit, Arne; University of Oslo, General Practice Research Unit (AFE), Department of General Practice, Institute of Health and Society
Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	General practice / Family practice, Rehabilitation medicine
Keywords:	COMPLEMENTARY MEDICINE, Back pain < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS, PAIN MANAGEMENT

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Acupuncture for acute nonspecific low back pain: A randomised, controlled, multicentre intervention study in general practice — the Acuback study

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Word count:

4156

Key words

Acupuncture Therapy, Low Back Pain, Randomised Controlled Trial, General Practice

ABSTRACT

Objectives

The aim of this study was to evaluate whether a single treatment session of acupuncture, when applied in addition to standard treatment for acute low back pain (ALBP), reduces the time to recovery compared with standard treatment alone.

Design

A multicentre, randomised, controlled trial.

Setting

Conducted at 11 Norwegian general practitioners' (GPs') offices.

Participants

171 adults aged 20–55 years seeking their GP for ALBP (≤ 14 days) between March 2014–2017. Patients with secondary back pain and previous sick leave and acupuncture treatment were excluded.

Interventions

The participants were randomised to either the control group (CG) or the acupuncture group (AG) by online software. The CG received standard treatment according to the Norwegian guidelines, while the AG received one session of Western medical acupuncture treatment in addition to standard treatment. The statistician was blinded to group status.

Primary and secondary outcome measures

The primary outcome was median days to recovery. Secondary outcomes were pain intensity, global improvement, back-specific functional status, sick leave, medication, and adverse effects.

Results

185 participants were randomised, 95 in the CG, 90 in the AG. 14 participants did not receive the allocated intervention, and four were excluded from analysis. Thus, 167 participants were included in the analysis, 86 in the CG, 81 in the AG. The groups were similar according to baseline characteristics. The median time to recovery was 14 days for the control group and 9 days for the acupuncture group, HR 1.37 (95% CI 0.95, 1.96), (p = 0.089). No serious adverse effects were reported.

Conclusions

We did not find any statistically significant reduction in time-to-recovery after a single session of acupuncture for ALBP compared with standard care.

Trial registration

NCT01439412

Strengths and limitations of this study

- The standardised intervention procedures.
- The performance of a pilot study and the development of software led to improved logistics and increased response rate.
- Lower inclusion rates than expected reduced the power, leading to weaker conclusions about the effectiveness of the treatment.
- Trial logistic reasons led to per protocol analysis instead of intention-to-treat analysis.

INTRODUCTION

Low back pain (LBP) is a common symptom and an important cause of disability globally.[1 2] The causes of LBP are multifactorial, and most episodes of LBP are categorized as nonspecific.[1 3] The majority of patients affected by acute LBP (ALBP) experience a decrease in pain and disability within a month, but a significant number will experience recurrences or develop chronic pain.[1 4]

Most cases of ALBP are treated in primary health care. Clinical guidelines for treatment of ALBP recommend information and education, advice to stay active and to avoid bed rest.[5] The Norwegian guidelines of 2007 still include pain treatment with paracetamol and/or nonsteroidal anti-inflammatory drugs (NSAIDs),[6] which is nowadays internationally less emphasized.[5 7-9] In the 2017 US guideline pharmacological treatment is recommended only if nonpharmacological treatment does not succeed.[7] Some guidelines recommend acupuncture as first-line treatment, despite lack of high-quality evidence.[7 10]

In 2013, Lee et al. published a systematic review of acupuncture for ALBP and found that evidence is sparse.[11] They concluded that acupuncture might be more effective than medication for symptom improvement and pain relief than sham acupuncture (SA). However, the authors suggested new trials with better design and reporting of results.

After this systematic review, there has been published four RCTs of acupuncture for ALBP. [12-15] Vas et al. compared different acupuncture types with conventional therapy (CT), and found that the intervention groups fared significantly better than the CT groups.[12] However, there was no difference between valid acupuncture according to Traditional Chinese Medicine (TCM), SA, or placebo acupuncture. Hasegawa et al. concluded that Yamanoto's new scalp acupuncture (YNSA) was more effective than sham treatment in ALBP for both pain relief and other outcomes, although their intervention did not reach the

predefined values for the primary outcome.[14] In 2013, Shin et al. reported that one session of motion-style acupuncture treatment (MSAT), consisting of walking with the needles inserted, was superior to one intramuscular injection of diclofenac with respect to pain reduction and function.[13] In the latest publication for this topic, Fox et al. performed a pilot study with 30 participants evaluating a type of ear acupuncture, "Battlefield acupuncture" (BFA).[15] The authors concluded that BFA was feasible as a non-pharmacological treatment in addition to standard care for LBP in a civilian emergency department.[15]

The idea for the present study was based on clinical experience from GPs, who experienced faster recovery in patients receiving acupuncture for ALBP, often after the first treatment session. We found no other studies with time-to-recovery as primary outcome, but the single treatment session was supported by two previous studies.[13 16 17] The treatment was also in accordance with textbooks on acupuncture.[18 19]

Our study aimed to evaluate if a single treatment session with acupuncture could result in a faster recovery when applied in addition to standard treatment for ALBP compared with standard treatment alone. Our aim was also to describe pain intensity, disability, work absence, adverse effects and use of medication.

METHODS

Study design and randomization

The study was a multicentre, randomised, controlled trial (RCT) undertaken in 11 Norwegian GPs' offices. The study period was from March 2014 to March 2017 with the last follow-up in March 2018, after an extension of 1 year due to slow patient recruitment. The participants were randomised by a health secretary into an acupuncture group (AG) or a control group

(CG) in a ratio of 1:1, using a web-based randomization system developed and administered by the Unit of Applied Clinical Research, Norwegian University of Science and Technology,[20] which performs block randomisation with various block sizes.

Data collection was performed by electronic surveys at 19 different time points; before and after treatment on the day of treatment, and each day for the following 2 weeks; then, after 4 weeks, 12 weeks, and 1 year. To administer the logistics of the surveys, we developed software, SESAMe, which is described in a previous publication.[21]

In a pre-study power calculation, we estimated the sufficient sample size to be 135 in each group.[22] Each patient was blinded to the group allocation when reporting baseline data, but from the time of consultation neither the patient nor the GP was blinded.

The protocol of the present study was published in 2012 and includes further details.[22] Prior to the main study, we conducted a pilot study that included eight participants during October 2013 to January 2014. The results from the pilot study led to the web-based version of SESAMe,[21] an exclusion criterion of previous acupuncture, and advices to the participating GP offices about medication standardization, study logistics, and efforts to minimize differences in placebo effects.

The study is registered in ClinicalTrials.gov (NCT01439412). Ethical approval was given by the Regional Ethics Committee of South-Eastern Norway (reference 2013/611/REK sør-øst A). The reporting of the study follows the CONSORT statement[23] and the STRICTA recommendations.[24]

Participants and recruitment procedure

Patients with ALBP lasting 14 days or less who contacted their GP office were asked to participate in the trial. We included adults aged 20–55 years with nonspecific ALBP who

gave informed consent. Exclusion criteria were nerve root affection, “red flags”, pregnancy, disability pension, sick leave of more than 14 days, and acupuncture during the last month.

The inclusion/exclusion process was performed by the health secretary at the GP’s office and in an initial online survey with information and the consent. She also administered the emails in SESAMe and asked the patient to answer the baseline survey before the consultation. If the GP revealed any exclusion criteria during the consultation, the patient was excluded. This, as well as the time spent in the consultation, was recorded by the GPs.

At each GP office, one GP was trained in acupuncture and treated the AG, and from one to four other GPs treated the CG. All acupuncture GPs were specialists in family medicine, and the mean time of acupuncture experience was 7.4 years (range 1–19 years). Nine of the GPs had at least 320 hours of education in acupuncture.

Most treating GPs in the CG were experienced specialists in family medicine, but some of them were working in the internship program; thus, the overall experience of the treating GPs varied more than for the AG.

Study interventions

Standard treatment (CG) consisted of advice about activity, prescription of analgesic medication (paracetamol and/or ibuprofen), and sick leave, if needed, according to the Norwegian national guidelines.[6]

The AG received the same standard treatment as the CG and, in addition, one session of acupuncture treatment with Western medical acupuncture style. This session consisted of 1 minute with two needles of Seirin® type B-8a 0.30 × 30 mm in the acupuncture points, Lumbar Pain Points (Yaotongxue/Yaotongdian) on the right hand, stimulated to a powerful needle sensation, called “de Qi” in TCM. With the needles in the hand, the patient was asked

to rise and perform mobilization movements (slow rotating pelvic movements) for 2 minutes, followed by 5 minutes on a bench while the patient received six needles of the SEIRIN® type J-8 0.30 × 50 mm in the local points Huatuojiaji ("Jiaji") in the L2–L4-segments, stimulated until needle sensation. The needles remained in place until all the needles were removed after a total treatment time of 8–9 minutes. The short treatment and the choice of only one session of acupuncture were an attempt to reduce potential attention bias. The details of the procedure and the process of choosing the specific and standardized treatment are briefly described in the published protocol, based on clinical experience, literature and feedback from a medical acupuncture expert group.[22]

Prior to the study, the health secretaries and many GPs (including all acupuncture doctors) were gathered at a workshop to ensure they understood the study logistics, the standard ALBP treatment, and the standardization of the acupuncture treatment. During the trial, we arranged two workshops to remind the GP offices of the need of inclusion and update about the study logistics.

Outcome measurements and data collection

The primary outcome in the study was days to recovery, defined as the first day the patient scored 0 or 1 on the Numerical Rating Scale (NRS).[25 26] This definition is in line with the definition of "sustained recovery" with an NRS of 0 or 1 for seven consecutive days.[26 27] We defined a minimum of a 3-day faster recovery as a clinically relevant difference between the groups, based on clinical experience and previous studies.[28 29]

The secondary outcome measurements were pain intensity,[25] disability by Roland Morris Disability Questionnaire (RMDQ),[30] sick leave, 5-point global improvement (Likert scale), use of medication, new visits at the GP's office, health-related quality of life by the

EuroQol (EQ-5D-3L), using UK tariff for time trade-off,[31] and adverse effects. RMDQ and EQ-5D-3L were collected at baseline, 1, 2, 4, 12 weeks, and 1 year, while the other secondary outcomes were collected at all time points. In addition, at baseline, we asked for sociodemographic variables, patient preferences for treatment options, expectations with respect to the effect of acupuncture and psychosocial risk profile according to the Örebro screening form for musculoskeletal pain.[32 33]

We also asked the participants in the 1-year survey about the number of new LBP episodes, work absence, and if they had received any other kind of treatment for LBP the last 9 months.

Patient and public involvement

No patients were involved in the planning of the study or in the recruitment and the conduct of the study. The study participants were informed that the results of the study would be presented at the study Facebook page. The burden of the intervention could be reported by the patients through the questionnaires of global improvement and adverse events.

Statistical analysis

Study sample size was calculated to be 270 participants, with 80% power to detect a 3 days' difference in median time to recovery with an α level of 0.05 and a true hazard ratio (HR) of 1.429. This was based on the assumption of a 365 days follow-up period, an accrual period of 0 days and a median survival of 7 days.[34] The study allowed for a dropout rate of up to 10%.

Details of the protocol for randomization and allocation procedures were published previously.[22] Statistical analyses were performed using the programs IBM SPSS Statistics® 25 and StataSE® 15. Data were analysed by a statistician who was blinded to group status, and the results presented in tables and figures were finalized before codes were revealed. The

analyses were performed per protocol, analysing just participants not excluded during the allocation, lost to follow-up or excluded from analyses of other reasons (Figure 1). Participants who did not receive their allocated intervention for some reason, were excluded from the analyses. The NRS data were transformed to the first day of recovery, independent of any intermittent missing answers. We calculated the difference in days to recovery for the two groups using the log-rank test, and late missing answers were censored, leaving the last specified value for analysis.

The time to recovery was expressed by the median days to recovery for the two groups, and Cox proportional hazard regression models were used to assess the effect of treatment on pain duration (in days). We checked the Cox proportionality assumption and concluded that our model satisfied the assumption of proportionality. Unfortunately, we were not able to use days of pain duration before inclusion as baseline covariate as described in the protocol because this question seemed to be interpreted differently among the participants, as some thought the question was meant to explore the overall history of back pain, not the acute episode.

Numeric secondary outcomes such as NRS were analysed using linear multilevel models with patient random effects, while binary outcomes such as medication use and work absence were analysed using binary multilevel logistic regression models. With numeric outcomes, mean changes over time in the groups were obtained, while estimates of odds ratios with their 99% confidence intervals were obtained for binary outcomes.

For primary outcomes, a p-value of <0.05 was considered statistically significant. For the secondary outcomes, a p-value of <0.01 was considered significant, and 99% confidence intervals (CIs) given.

RESULTS

The study flow chart shows that of a total of 185 participants that were randomised into the two groups, 167 were included in the analysis, 86 in the CG and 81 in the AG (Figure 1). Recruitment of participants at the 11 GP offices varied considerably, and there were also differences in exclusions at each site (Supplementary file 1). The overall recruitment was poorer than expected, and even if the inclusion period was extended with one year, the planned sample size was not met. Possible causes can be less LBP patients seeking the GPs due to previous public campaigns, patients seeking other therapists, and the circumstances of the trial taking place in busy GP practices with voluntary work by both GPs and health secretaries with no professional research network to help.

The overall response rate in the trial was 87.4%, but varied in each survey and decreased over time. One year into the observation period, 66 participants in the AG and 61 in the CG had answered the survey, resulting in a response rate of 76.0%. Supplementary file 2 shows the numbers of missing answers per survey for the primary outcome and Supplementary file 3 for the secondary outcomes. There were no statistically significant differences between the groups in response rate, except for primary outcome at day 2 ($p = 0.037$). One participant in the AG underwent an operation for sciatica during the follow-up period.

Table 1 shows the baseline characteristics with sociodemographic data and clinical features of the participants. There were no statistically significant differences between the groups in any of the variables. There were small, non-significantly differences between the groups for obesity and smoking, which are known risk factors to LBP.[35]

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Characteristic	Control (n = 86)	Acupuncture (n = 81)
Age (year), mean (SD)	39.3 (9.4)	39.8 (11.4)
Female, n (%)	44 (51.2)	41 (50.6)
Living with a partner, n (%)	57 (67.9)	65 (83.3)
Born in Norway, n (%)	78 (92.9)	69 (88.5)
Level of education >13 years, n (%)	28 (33.3)	30 (38.5)
Work status		
Employed, n (%)	77 (91.7)	70 (87.5)
Student, n (%)	7 (8.3)	6 (7.5)
Unpaid work, n (%)	1 (1.2)	1 (1.3)
Unemployed, n (%)	2 (2.4)	3 (3.8)
Sick leave, n (%)	3 (3.6)	3 (3.8)
BMI		
<25 (normal), n (%)	28 (33.3)	30 (38.5)
25.00–29.99 (overweight), n (%)	29 (34.5)	29 (37.2)
>30 (obese), n (%)	27 (32.1)	19 (24.4)
Smoking, n (%)	20 (23.8)	14 (17.9)
Alcohol several times a week, n (%)	10 (11.9)	8 (10.3)
Serious life events last 12 months, n (%)	15 (17.9)	17 (21.3)
Previous LBP, n (%)	63 (73.3)	58 (71.6)
Treatment preference: acupuncture, n (%)	66 (78.6)	58 (74.4)
Belief in acupuncture treatment (0–10), mean (SD)	6.6 (2.6)	6.6 (2.5)
Back pain intensity (0–10), mean (SD)	6.3 (1.8)	6.2 (1.9)
Leg pain intensity (0–10), mean (SD)	2.7 (2.6)	2.4 (2.7)
RMDQ (0–24), mean (SD)	14.8 (4.4)	15.0 (4.2)
EQ-5D, mean (SD)	0.40 (0.33)	0.41 (0.31)
DDD non-opioid medication, mean (SD)	0.66 (0.85)	0.93 (0.97)
DDD opioid medication, mean (SD)	0.09 (0.27)	0.09 (0.31)
Days from randomisation to treatment, median (IQR)	0 (0 – 0)	0 (0 – 0)
Örebro		
Low risk, n (%)	41 (48.8)	47 (60.3)
Medium risk, n (%)	25 (29.8)	19 (24.4)
High risk, n (%)	18 (21.4)	12 (15.4)
SHC, mean (SD)	11.25 (7.44)	9.12 (5.36)
Missing	2	3

Data in n (%), mean (SD) or median (IQR). SD indicates standard deviation; IQR, interquartile range; BMI, body mass index; LBP, low back pain; RMDQ (0–24), Roland Morris Disability Questionnaire, higher score represents greater overall disability; DDD, defined daily dose; SHC, subjective health complaints, higher score means more reported health complaints. EQ-5D, higher score represents better health state; NRS (0–10), higher score represents more pain. There were no significant differences between the groups in any of the variables.

The duration of the consultations in the AG were 20.2 minutes (99% CI 19.0, 21.5), versus 17.0 minutes (99% CI 15.4, 18.5) in the CG, and the difference of 3.2 minutes were statistically significant ($p \leq 0.001$). In the study 21.9% (99% CI 10.4, 33.4) of the patients in the CG were treated by their regular GP versus 40.0% (99% CI 26.0, 54.0) in the AG ($p = 0.011$).

Primary outcome

Median time to recovery was 14 days for the CG (IQR 6-84) and 9 days for AG (IQR 4-84). Based on the Cox regression model, the difference of 5 days was not statistically significant, despite achieving the a priori threshold for clinical relevance of 3 days, with a HR 1.37 (95% CI 0.95, 1.96), ($p = 0.089$).

Time to recovery for 365 days and the first 28 days are shown in Figure 2. The log-rank test for 365 days is based on 56 observed and 65.3 expected events in the CG and 64 observed and 54.7 expected events in the AG, which was not statistically significant ($p = 0.072$). We also performed a sensitivity analysis on the four excluded participants with the same result. Sensitivity analyses with the baseline variables obesity and smoking did not change the results of the primary outcome either.

For one extra person to recover during the whole study period, the NNT was 7.2 (95% CI 3.7, 210.3).[36] This was based on 64 recovered participants in the AG and 56 recovered participants in the CG after one year, leading to an absolute risk reduction of 0.139 (95% CI 0.005. 0.273).

Secondary outcomes

Pain intensity during the study period reduced in both groups with no clinically relevant nor statistically significant differences between the two groups at each time point (Figure 3). The mean difference in pain between the two groups during the whole study overall was 0.48

(99% CI 0.25, 0.71) ($p < 0.001$) in favour of the AG. This equals a standardized mean difference (SMD) of 0.13.

The same pattern was seen for back-related disability by RMDQ, which showed an improvement during the year for both groups but with no statistically significant difference between the two groups (Figure 4).

There were no statistically significant differences in sick leave between the groups at any of the time points (Supplementary file 4).

The participants' perception of global improvement (feeling better or much better), was highly significantly better in the AG group on day 0 after treatment (OR 8.00, 99% CI 2.88, 22.05), but later the difference became gradually smaller, with statistically significance on just one other day (day 4) (Supplementary file 5).

There were no statistically significant differences in the use of medication, unless for day 3 when fewer participants in the AG used non-opioid medication than in the CG (Supplementary file 6).

The estimated number of new visits to the GP through the study period was 2.7 (99% CI 2.0, 3.5) in the CG and 2.6 (99% CI 1.9, 3.3) in the AG, difference 0.1 (99% CI -0.9, 1.1) ($p = 0.76$). Health-related quality of life measured by EQ-5D-3L did not show statistically significant differences between the two groups at any time point during the study (Supplementary file 7). There were more, but statistically nonsignificant, LBP episodes in the CG after 1 year, 3.2 (99% CI 2.4, 3.9) versus 2.4 (99% CI 1.7, 3.2) in the AG, difference 0.7 (99% CI -0.3, 1.8) ($p = 0.06$).

No serious adverse events were reported in the study. Sixteen participants (18.6%, 99% CI 7.8, 29.4) in the CG reported some adverse effects compared with 11 (13.6%, 99% CI 3.8, 23.4) in the AG, difference 5,0% (99% CI -9.9, 19.9) ($p = 0.38$). Two participants reported pain/soreness in their hand because of the needles the day after the treatment. Twenty-two

participants reported gastrointestinal symptoms, 14 of them in the CG. Other less frequent symptoms were tiredness, headache, dyspnoea, and muscle pain.

DISCUSSION

Principle findings

This study showed that adding one single session of 8–9 minutes of acupuncture treatment to standard guideline-based care to patients with ALBP resulted in a 5 days faster recovery of pain, but the result was not statistically significant. Similarly, adding acupuncture to standard guideline-based primary care did not show any statistically significant effect in the secondary outcome measures of disability, work absence and quality of life. For the secondary outcomes of pain, self-reported global improvement and medication, we found small differences without clinical relevance. Finally, the acupuncture treatment was safe, with no significant differences of major symptoms or serious adverse events.

Strengths and limitations of the study

The main strength of this study was the standardised intervention procedures, leading to no attention bias between the two groups. Another strength was the performance of a pilot study which led to logistic changes that contributed to both an equality of the groups and an improved response rate. The innovative process of developing our own logistic software (SESAMe) was central in this quality improvement.[21]

The main limitation of this study was the low power due to lower inclusion rates than expected, even after we extended the inclusion period with 1 year. This led to weaker conclusions about the effectiveness of the treatment. The results of the primary outcome could well be due to a type II error. However, low power in a trial reduces the likelihood that the

observed effect represents a true effect.[37] The wider standard deviations in an underpowered study make it more likely to reach clinical relevant values.[37] The very small effect size on pain (SMD = 0.13) and the lack of effect on disability, can imply that the 5 days faster time to recovery can be a spurious finding. Another limitation is that we were not able to perform the intended intention-to-treat analysis. Of logistic reasons, we had to perform the last eligibility-evaluation by the GP in the consultation. That is why 14 participants were randomised, but excluded before intervention was given. In addition, 4 participants were excluded from analysis, three of them because of statistical challenges (left censoring) and one because of exclusion criteria. However, a sensitivity analysis did not change the results. On the other hand, the exclusion after randomisation may have caused bias. Lack of fidelity check list to measure the fidelity of the interventions is another limitation. Even considering the significance level of 0.01 on secondary outcomes, with the large number of statistical tests performed, there is a possibility that any of the observed differences could be due to false positives. In addition, many of the confidence intervals are wide, so the estimated effects lack precision.

Relation to other studies

The acupuncture treatment provided in this trial consisted of both shorter treatment time and fewer treatment sessions than usual.[38 39] This may have caused less chances to detect a real difference in effectiveness. On the other side, a longer treatment time and more sessions could have caused more attention bias. Our results could not support Vas et al. showing the effectiveness of acupuncture compared to conventional therapy.[12] The short-term effect of only one acupuncture treatment session for LBP was previously shown by Shin et al.,[13] but MacPherson et al. showed that pain outcomes were influenced by increased numbers of needles and more sessions, and thus the dose was important.[39] After the trials of Vickers and

MacPherson,[39 40] the US National Center for Complementary and Integrative Health (NCCIH) announced a need for pragmatic acupuncture trials for pain management, testing the effectiveness in "real world" conditions, while efficacy studies seek effect under ideal conditions.[41 42] Because this was a pragmatic trial in accordance with the NCCIH recommendations, the participants and GPs were not blinded. Some may argue that this is a problem in acupuncture trials, and it would be a limitation in an efficacy study. However, a large systematic review with individual patient data meta-analysis by Vickers et al. in 2012 has evaluated the efficacy of acupuncture for pain, and the authors showed that acupuncture has a small, specific effect on pain.[40] The difference between true acupuncture and sham or placebo acupuncture is small, and trials will need large sample sizes to emphasize these differences, which Vas et al. demonstrated to be also true for ALBP.[12] In our study, there were nonsignificant differences in pain for each time-point, but statistically significant difference in pain overall. Because the effect size was very small and the difference was considered not clinically relevant, this result should be interpreted with caution.

The highly significant difference in the early perception of global improvement could be a result of the positive expectations, but it could also be due to the experience of a faster recovery with less pain. The findings are in accordance with the systematic review by Lee et al. in which acupuncture is compared with the use of NSAIDs.[11] However, subjective outcomes have been shown to exaggerate effect estimates in trials that were not blinded.[43] In addition, the slightly higher response rates in the acupuncture group the first days could have contributed to a possible strengthening of the positive subjective outcomes.

The two study groups scored equal for treatment preferences and belief in acupuncture prior to the treatment. For the AG, this might represent a positive expectation bias when receiving the treatment, while those in the CG might have had a negative expectation bias when not receiving the acupuncture they had wanted. This would be in accordance with other

research demonstrating an effect of treatment preferences and belief in the treatment in pain studies.[44 45]

There are not many trials of non-pharmacological treatments reporting NNT. Despite the lack of effect between the two groups in the present study, the NNT from our trial was comparable to both other LBP trials[46 47] and acupuncture trials.[48 49]

The few observed differences between the two groups can be due to specific and nonspecific needle effects, the contribution of the mobilization movements, the extra consultation time, or the attention bias provided by the overall extra treatment ritual. There could also be an operator effect of a less or more enthusiastic behaviour in the consultation. The patient-practitioner relationship is shown to influence the placebo effect, even in standardised intervention procedures.[50] However, this could be a phenomenon in both groups, and also influenced by the prescribing of medication, performing a physical examination or not, empathic behaviour and time spent. Short consultation times are a key challenge to implementing best practices for LBP,[5] but in our study, we cannot conclude whether the extra time for acupuncture compensated for possibly less time for giving advice.

More participants in the AG than in the CG met with their regular GP during the consultation. Continuity in the doctor–patient relationship, including previous knowledge about the patient, is associated with improved patient outcomes.[51 52]

Conclusion

This trial showed that adding one treatment session of acupuncture in combination with mobilization movements had similar effect as usual care for patients with ALBP during one year of follow-up. On primary outcome, the observed difference of 5 days earlier recovery in the acupuncture group was not statistically significant. On secondary outcomes, there was no statistically significant differences in self-reported outcome measures of disability and health-

related quality-of-life. On pain reduction, there was a statistically significant but not clinically relevant difference.

Acknowledgements

The authors would like to thank the participating GPs and health secretaries, and Finn Steen whose contribution to the data collection was essential through the development of SESAMe.

Competing Interests

The authors report no conflict of interest.

Funding

This study was funded by Institute of Health and Society, University of Oslo. The study received also some funding for logistic expenses by private endowments, the "Gidske and Peter Jacob Sørensens fund" and the "Trygve Gythfeldts fund".

Author Contributions

TS and HS had the idea for the project. TS, HS, MB, MG and AF contributed to conceptualization and design of the study. TS and AK developed the software for data collection. TS and IM performed the statistical analyses. TS and EA performed the health-economic analyses. TS drafted the article. All authors have discussed the results and revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Data sharing statement

The additional unpublished data are available from the corresponding author on request.

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LEGENDS

Figure 1 CONSORT flow diagram in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone.

Figure 2 Time to recovery for acute low back pain with acupuncture and standard treatment compared with standard treatment alone. One-year follow-up and first 28 days (n = 167).

Figure 3 Pain intensity during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Figure 4 Disability by Roland Morris Disability Questionnaire (RMDQ) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

Table 1 Baseline characteristics of participants in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 1 Number of participants included and excluded at each general practitioner's (GP's) office in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone, by treatment group.

Supplementary file 2 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain

when applied in addition to standard treatment, compared with standard treatment alone — primary outcome.

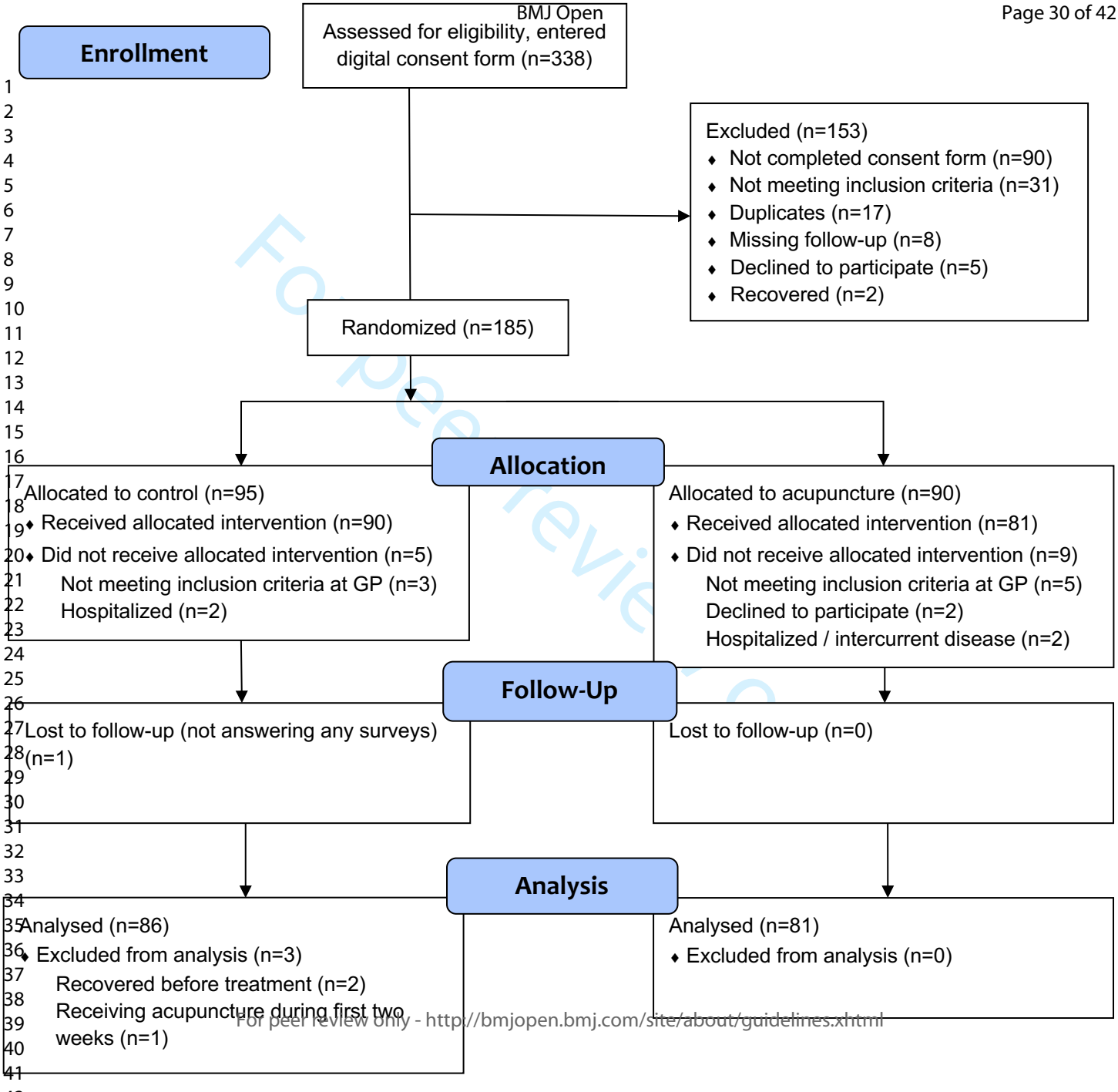
Supplementary file 3 Numbers of missing answers and response rate per survey for each group and in total in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone — secondary outcomes.

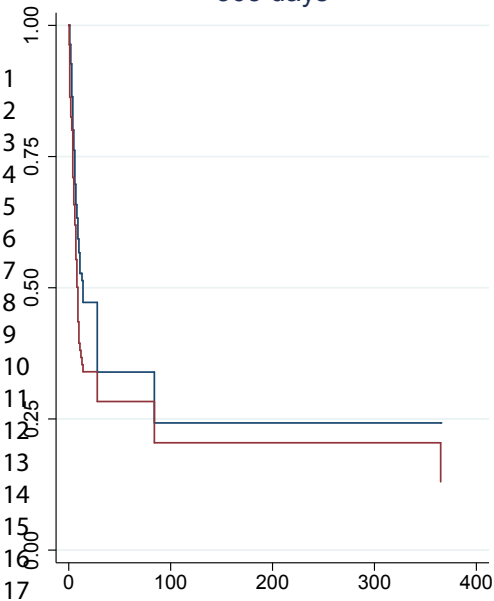
Supplementary file 4 Work absence and work presence during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 147).

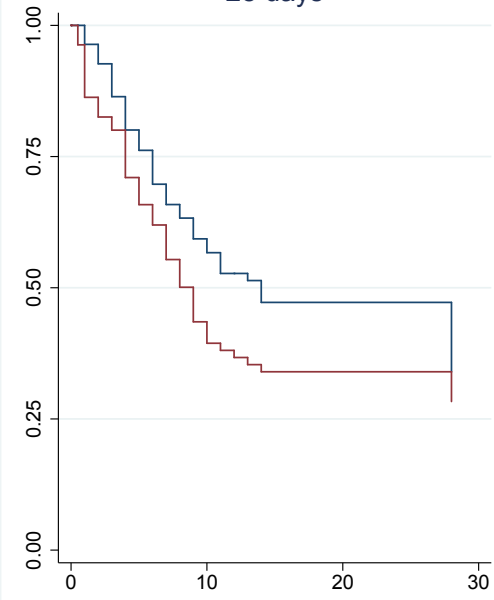
Supplementary file 5 Participants' perception of global improvement during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

Supplementary file 6 Use of medication during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (n = 167).

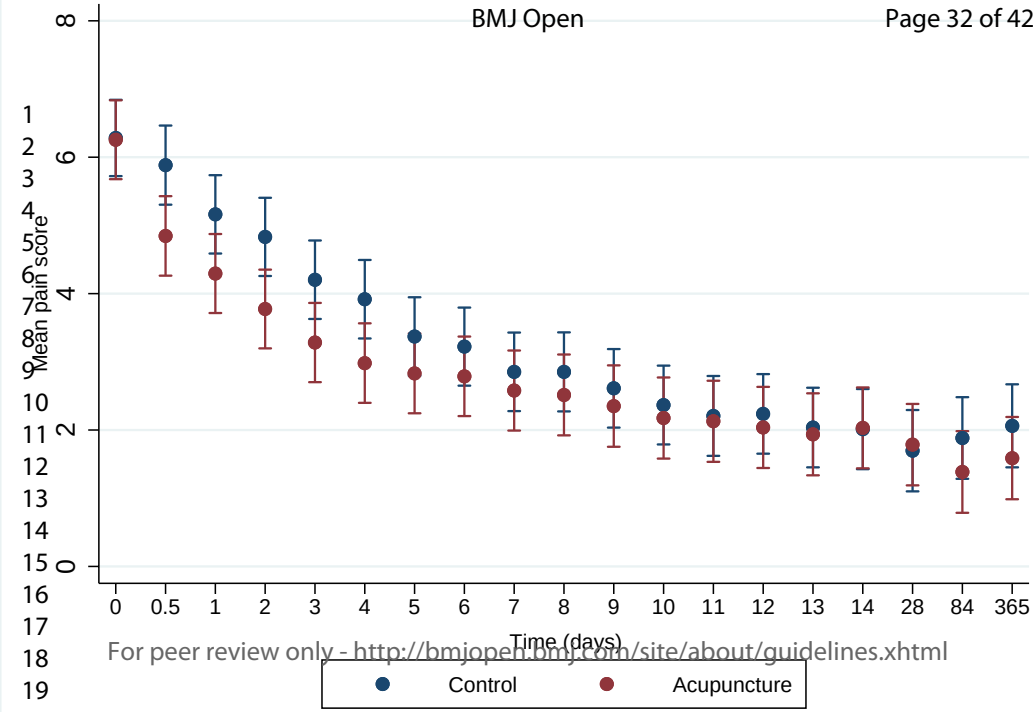
Supplementary file 7 Health-related quality-of-life by the EuroQoL (EQ-5D) during a 1-year follow-up period in a trial of acupuncture for acute nonspecific low back pain when applied in addition to standard treatment, compared with standard treatment alone (99% CI).

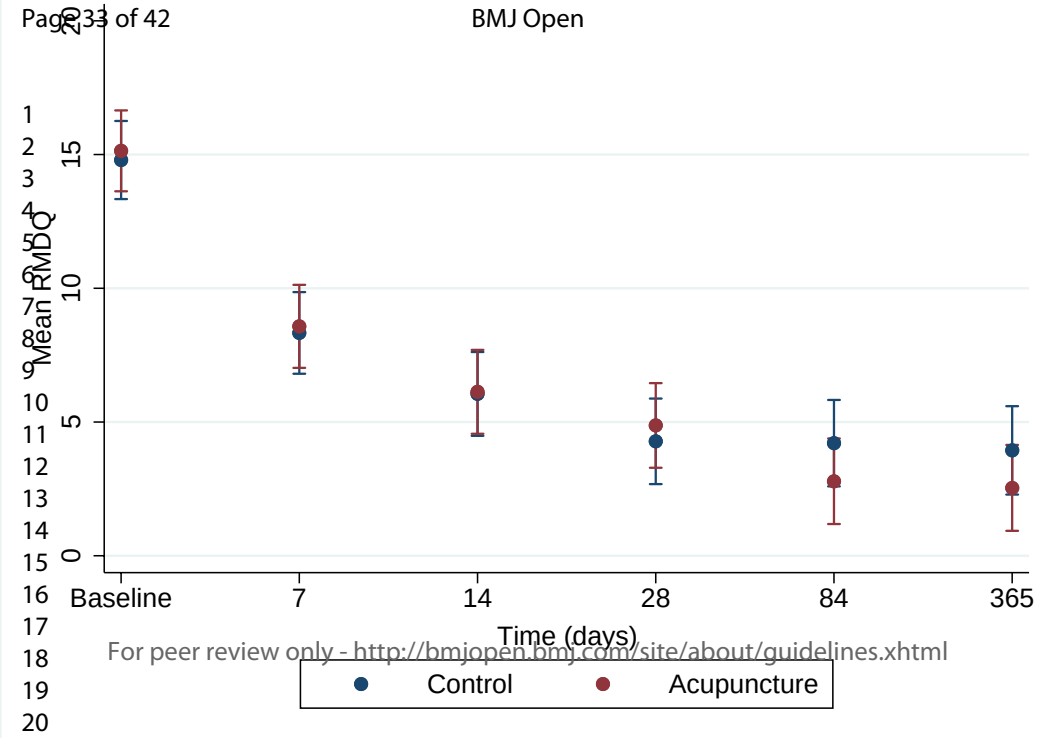






Control Acupuncture





GP Office	Inclusion Control (n=86)	Acupuncture (n=81)	Total (n=167)	Exclusion Control (n=8)	Acupuncture (n=10)	Total (n=18)
1	20	16	36	1	1	2
2	10	11	21	1	0	1
3	3	3	6	0	0	0
4	1	1	2	0	0	0
5	11	14	25	4	0	4
6	1	2	3	0	0	0
7	10	10	20	0	0	0
8	10	5	15	1	2	3
9	2	1	3	0	0	0
10	0	1	1	0	0	0
11	18	17	35	1	7	8

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Pain intensity + medication

	Baseline	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																			
Missing	2	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	84	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	98	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																			
Missing	3	5	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	78	76	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	96	94	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																			
Missing	5	18	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	162	149	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	97	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Global improvement

	Day 0 after	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																		
Missing	13	10	9	10	10	10	8	10	12	10	11	15	14	14	16	20	21	25
Answers	73	76	77	76	76	76	78	76	74	76	75	71	72	72	70	66	65	61
Response rate (%)	85	88	90	88	88	88	91	88	86	88	87	83	84	84	81	77	76	71
Acupuncture group (n=81)																		
Missing	6	3	2	4	5	6	5	7	10	12	11	11	11	14	10	12	13	15
Answers	75	78	79	77	76	75	76	74	71	69	70	70	70	67	71	69	68	66
Response rate (%)	93	96	98	95	94	93	94	91	88	85	86	86	86	83	88	85	84	81
Total (n=167)																		
Missing	19	13	11	14	15	16	13	17	22	22	22	26	25	28	26	32	34	40
Answers	148	154	156	153	152	151	154	150	145	145	145	141	142	139	141	135	133	127
Response rate (%)	89	92	93	92	91	90	92	90	87	87	87	84	85	83	84	81	80	76

Return to work

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=86)																	
Missing	14	11	15	12	14	11	14	15	15	15	19	19	19	19	24	21	27
Answers	72	75	71	74	72	75	72	71	71	71	67	67	67	67	62	65	59
Response rate (%)	84	87	83	86	84	87	84	83	83	83	78	78	78	78	72	76	69
Acupuncture group (n=81)																	
Missing	8	6	10	11	12	9	8	11	14	13	13	12	16	12	15	13	17
Answers	73	75	71	70	69	72	73	70	67	68	68	69	65	69	66	68	64
Response rate (%)	90	93	88	86	85	89	90	86	83	84	84	85	80	85	81	84	79
Total (n=167)																	
Missing	22	17	25	23	26	20	22	26	29	28	32	31	35	31	39	34	44
Answers	145	150	142	144	141	147	145	141	138	139	135	136	132	136	128	133	123
Response rate (%)	87	90	85	86	84	88	87	84	83	83	81	81	79	81	77	80	74

RMDQ

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	12	14	15
Answers	78	73	71	69	67	66
Response rate (%)	96	90	88	85	83	81
Total (n=167)						
Missing	5	19	26	32	36	41
Answers	162	148	141	135	131	126
Response rate (%)	97	89	84	81	78	75

EQ5D

	Baseline	Day 7	Day 14	Day 28	Day 84	Day 365
Control group (n=86)						
Missing	2	11	16	20	22	26
Answers	84	75	70	66	64	60
Response rate (%)	98	87	81	77	74	70
Acupuncture group (n=81)						
Missing	3	8	10	14	14	15
Answers	78	73	71	67	67	66
Response rate (%)	96	90	88	83	83	81
Total (n=167)						
Missing	5	19	26	34	36	41
Answers	162	148	141	133	131	126
Response rate (%)	97	89	84	80	78	75

	Baseline	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 28	Day 84	Day 365
Control group (n=77)																		
Work absence (n)	3	38	42	39	35	35	28	23	21	21	19	18	16	16	15	7	3	6
Work absence (%)	4	49	55	51	45	45	36	30	27	27	25	23	21	21	19	9	4	8
Work presence (n)	74	29	27	28	32	31	40	44	45	45	46	43	47	46	46	49	53	47
Work presence (%)	96	38	35	36	42	40	52	57	58	58	60	56	61	60	60	64	69	61
Missing (n)	0	10	8	10	10	11	9	10	11	11	12	16	14	15	16	21	21	24
Acupuncture group (n=70)																		
Work absence (n)	3	31	32	30	28	28	25	17	16	14	15	14	11	11	11	8	9	9
Work absence (%)	4	44	46	43	40	40	36	24	23	20	21	20	16	16	16	11	13	13
Work presence (n)	67	36	36	38	38	37	41	48	46	46	47	47	50	47	51	53	51	51
Work presence (%)	96	51	51	54	54	53	59	69	66	66	67	67	71	67	73	76	73	73
Missing (n)	0	3	2	2	4	5	4	5	8	10	8	9	9	12	8	9	10	10
Total (n=147)																		
Work absence (n)	6	69	74	69	63	63	53	40	37	35	34	32	27	27	26	15	12	15
Work absence (%)	4	47	50	47	43	43	36	27	25	24	23	22	18	18	18	10	8	10
Work presence (n)	141	65	63	66	70	68	81	92	91	91	93	90	97	93	97	102	104	98
Work presence (%)	96	44	43	45	48	46	55	63	62	62	63	61	66	63	66	69	71	67
Missing (n)	0	13	10	12	14	16	13	15	19	21	20	25	23	27	24	30	31	34

Global improvement

	Better or Not after treatment?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 0 (after treatment)	62	11	31	44	8.00	2.88, 22.05
Day 1	37	39	25	53	2.01	0.86, 4.72
Day 2	30	47	17	62	2.33	0.93, 5.80
Day 3	25	51	13	64	2.41	0.90, 6.44
Day 4	22	54	9	67	3.03	1.02, 8.97
Day 5	17	59	11	64	1.68	0.57, 4.87
Day 6	21	57	13	63	1.79	0.65, 4.85
Day 7	11	65	9	65	1.22	0.37, 4.02
Day 8	15	59	12	59	1.25	0.43, 3.66
Day 9	11	65	6	63	1.78	0.48, 6.57
Day 10	11	64	7	63	1.55	0.44, 5.46
Day 11	6	65	9	61	0.63	0.16, 2.43
Day 12	8	64	7	63	1.13	0.30, 4.26
Day 13	9	63	7	60	1.22	0.33, 4.52
Day 14	9	61	12	59	0.73	0.22, 2.37
Day 28	7	59	4	65	1.93	0.41, 9.01
Day 84	10	55	5	63	2.29	0.56, 9.22
Day 365	14	47	11	55	1.49	0.48, 4.58

Non-opioid medication

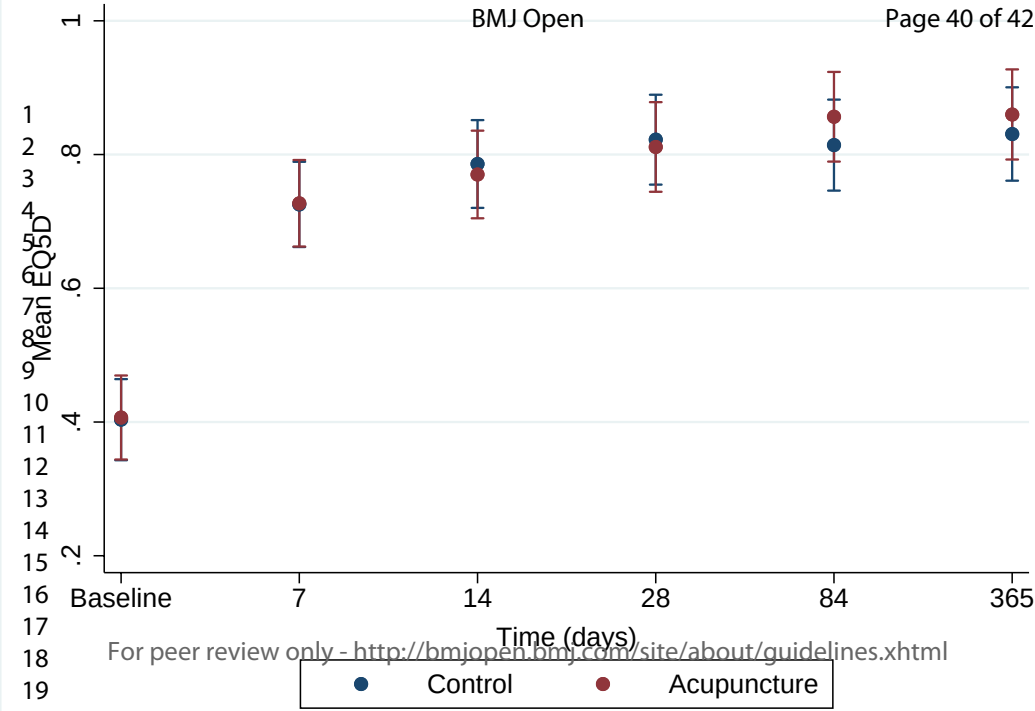
	Using non-opioid medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	21	54	28	50	0.69	0.29, 1.69
Day 2	22	54	33	46	0.57	0.24, 1.35
Day 3	24	51	41	36	0.41	0.17, 0.98
Day 4	34	41	45	31	0.57	0.25, 1.33
Day 5	38	37	46	29	0.64	0.28, 1.51
Day 6	44	33	50	26	0.69	0.30, 1.63
Day 7	45	30	48	26	0.81	0.34, 1.93
Day 8	44	29	49	22	0.68	0.28, 1.67
Day 9	51	24	46	23	1.06	0.43, 2.63
Day 10	54	20	52	18	0.93	0.36, 2.44
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	55	16	60	10	0.57	0.19, 1.74
Day 13	55	16	56	11	0.68	0.23, 2.01
Day 14	53	16	56	15	0.89	0.32, 2.48
Day 28	55	11	59	10	0.85	0.26, 2.76
Day 84	57	8	62	6	0.69	0.17, 2.76
Day 365	54	7	60	6	0.77	0.19, 3.19

Opioid medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	57	18	65	13	0.48	0.18, 1.33
Day 2	63	13	66	13	0.95	0.33, 2.80
Day 3	57	18	67	10	0.47	0.16, 1.40
Day 4	62	13	65	11	0.81	0.27, 2.46
Day 5	63	12	67	8	0.63	0.19, 2.10
Day 6	67	10	68	8	0.79	0.23, 2.73
Day 7	64	11	65	9	0.81	0.24, 2.66
Day 8	65	8	66	5	0.62	0.15, 2.60
Day 9	69	6	62	7	1.30	0.32, 5.30
Day 10	66	8	63	7	0.92	0.24, 3.48
Day 11	66	5	66	4	0.80	0.16, 4.08
Day 12	65	6	67	3	0.49	0.00, 2.66
Day 13	66	5	62	5	1.06	0.22, 5.05
Day 14	65	4	65	6	1.50	0.31, 7.25
Day 28	63	3	65	4	1.29	0.21, -
Day 84	63	2	66	2	0.95	-
Day 365	61	0	65	1	-	-

Medication

	Using medication?					
	Control		Acupuncture			
	No	Yes	No	Yes	OR	99% CI
Day 1	19	56	23	55	0.81	0.32, 2.04
Day 2	21	55	27	52	0.74	0.30, 1.79
Day 3	22	53	36	41	0.47	0.20, 1.13
Day 4	33	42	40	36	0.71	0.31, 1.63
Day 5	35	40	43	32	0.65	0.28, 1.51
Day 6	42	35	48	28	0.70	0.30, 1.63
Day 7	43	32	46	28	0.82	0.35, 1.92
Day 8	43	30	49	22	0.64	0.26, 1.57
Day 9	50	25	44	25	1.14	0.47, 2.78
Day 10	53	21	51	19	0.94	0.37, 2.42
Day 11	51	20	54	16	0.76	0.28, 2.02
Day 12	54	17	59	11	0.59	0.20, 1.74
Day 13	55	16	53	14	0.91	0.32, 2.57
Day 14	52	17	53	15	1.00	0.36, 2.79
Day 28	53	13	58	11	0.77	0.25, 2.39
Day 84	55	10	62	6	0.53	0.14, 2.04
Day 365	54	7	59	7	0.92	0.23, 3.63



Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on page/line number
Title	Identification of the study as randomized	1/1
Authors *	Contact details for the corresponding author	1/4-11
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	3/8
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	3/10, 3/12-14
Interventions	Interventions intended for each group	3/16-19
Objective	Specific objective or hypothesis	3/4-6
Outcome	Clearly defined primary outcome for this report	3/21
Randomization	How participants were allocated to interventions	3/16-17
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	3/19
Results		
Numbers randomized	Number of participants randomized to each group	4/1
Recruitment	Trial status	4/1-3
Numbers analysed	Number of participants analysed in each group	4/2-3
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	4/4-5
Harms	Important adverse events or side effects	4/5-6
Conclusions	General interpretation of the results	4/8-9
Trial registration	Registration number and name of trial register	4/12
Funding	Source of funding	-

**this item is specific to conference abstracts*

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1/1-2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3/1-4/9
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5/1-6/16
	2b	Specific objectives or hypotheses	6/13-16
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6/20-7/3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7/11-16
Participants	4a	Eligibility criteria for participants	7/24 – 8/2
	4b	Settings and locations where the data were collected	6/22-8/14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/16-9/14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9/16-10/9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10/18-21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6/24-7/3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6/24-7/3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6/24-7/10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6/20-8/14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7/9-10,

		assessing outcomes) and how	10/24-25
	11b	If relevant, description of the similarity of interventions	8/16-9/14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10/17-11/23
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10/17-11/23
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12/2-3 +Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6/23-24
	14b	Why the trial ended or was stopped	6/23-24
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12/19-22 + Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12/11-18 + Suppl. file 2+3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15/8-16/2 + Fig2-4+SF4-7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	(SF 5+6)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	15/1-5 + 16/19-21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16/22-17/2
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17/16-18/15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17/4-21/2
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17/4-21/2
Other information			
Registration	23	Registration number and name of trial registry	4/12 + 7/17
Protocol	24	Where the full trial protocol can be accessed, if available	7/11 + Ref. 22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22/7-10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.