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BACK PAIN

ABSTRACT & COMMENTARY

Low Back Pain Best Prevented with Exercise and Education

By Ellen Feldman, MD

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Dr. Feldman reports no financial relationships relevant to this field of study.

SYNOPSIS: In a meta-analysis of studies on preventing low back pain, researchers found a combination of exercise and education were the most likely interventions to prevent recurrence of this potentially debilitating condition.

SOURCE: Steffens D, Maher CG, Pereira LS, et al. Prevention of low back pain. *JAMA Intern Med* 2016;176:199-208.

Low back pain (LBP) has been making headlines.[1] Why? Consider these five facts: 1) LBP exists as a global health problem, affecting at least 12% of the world population.[2] 2) Although LBP is generally self-limiting, it is quite painful and acute episodes often impair functioning — recovering patients want to know how to prevent recurrences.[3] 3) Estimated recurrence rates are high, ranging from 24% to 80%.[3] 4) Recent studies have shown promise in treating LBP via nonpharmacological interventions.[4] 5) There are no clear guidelines for the prevention of LBP.

Responding to the lack of guidelines for the prevention of LBP, the authors of this study conducted a large-scale literature search to identify evidence-based studies that investigated prevention of LBP. From a base of more than 6,000 published studies, they extracted 21 unique randomized clinical trials that met stringent criteria for inclusion in their meta-analysis. The pooled group included more than 30,000 unique subjects.

Eligible studies had specific criteria required for inclusion in the meta-analysis: active investigation for prevention of LBP, control groups, and participants with either no LBP at baseline or LBP that did not interfere with functioning at baseline. There were no exclusions or inclusions regarding etiology of LBP. From these studies, investigators extracted and analyzed raw

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[INSIDE]

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Summary Points

- This meta-analysis used data from 21 randomized clinical trials with more than 30,000 participants. Studies were graded according to quality of methodology and evidence; outcomes were recurrent episodes and sick-leave days.
- Exercise alone had low-quality evidence of a protective effect against recurrence of low back pain (LBP) in short-term studies (< 12 months) and low-quality evidence of reduced sick leave in long-term studies.
- Exercise combined with education had moderate-quality evidence of a protective effect against recurrence of LBP in short-term studies and low-quality evidence of this same effect in long-term studies; there is low-quality evidence of no protective effect on reduced sick leave.
- Education alone, shoe insoles, and back belts have very low to moderate quality evidence of no effect on recurrence of LBP in short or long term.
- Ergonomic interventions have very low quality evidence of no effect on sick leave in short-term studies, making it difficult to form a conclusion regarding this intervention.

data, determined the quality of the trials' specific methods, and identified the strength of evidence overall. The pooled results were analyzed; quality of the studies was reported along with data generated.

The PEDro scale[5] (specific for physiotherapy studies) was used to score methodology; this score was used as part of the determination of the overall quality of evidence. The quality of evidence was determined using the GRADE[6] system, a structured method to evaluate quality of evidence and strength of recommendations in healthcare studies. Each group of pooled results was given a quality score: *high, moderate, low,* or *very low*.

Three factors primarily influenced the GRADE classification and ultimately determined quality. The factors affecting the scores were: 1) design limitation as noted by the PEDro scale, 2) inconsistent results, and 3) "imprecision" defined as < 400 participants per outcome.

Results. Six different prevention interventions were investigated in the 21 randomized clinical trials meeting inclusion criteria: exercise, education, exercise and education regarding back care, back belts, shoe insoles, and ergonomic program of instruction. In almost all of the studies, participants were of working age; outcome results included workdays missed as well as a recurrent episode of LBP.

All results were reported according to length of study (short- or long-term) and outcome (recurrence of LBP and/or days off work). See Tables 1-6 for study results. In general, the authors concluded that exercise and education combined is the most likely intervention to reduce the risk of recurrence of LBP, with moderate-quality evidence in short-term studies and low-quality evidence in long-term studies. Exercise alone may reduce the likelihood of recurrent LBP in the short term, and there is very-low quality evidence that exercise alone can reduce sick leave in the long term. The other interventions alone (education, shoe insoles, back belts, ergonomic adjustments) are not supported by evidence to prevent recurrence of LBP. The authors noted that there is only very-low quality evidence that ergonomic adjustments do not have an effect on sick leave, making it difficult to draw conclusions about this intervention.

■ COMMENTARY

In March 2016, the Centers for Disease Control and Prevention (CDC) announced new guidelines for the use of opioids, which recommend limiting or eliminating opioids in the treatment of chronic pain outside of specific diagnoses or conditions (such as cancer treatment and palliative care.) The comprehensive CDC document references LBP specifically and frequently, pointing to evidence that non-opioid interventions and nonpharmacological interventions are not

Table 1: Exercise vs. Control

Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	898: 4 trials	Low quality	Protective
Long-term	Incidence of LBP	334: 2 trials	Very low quality	No effect
Long-term	Days of missed work/sick leave	128: 2 trials	Very low quality	Protective
Note: There was no standardization of exercise techniques.				

Table 2: Exercise and Education vs. Control

Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	442: 4 trials	Moderate quality	Protective
Short-term	Days of missed work/sick leave	228: 3 trials	Low quality	No effect
Long-term	Incidence of LBP	138: 2 trials	Low quality	Protective
Long-term	Days of missed work/sick leave	138: 2 trials	Low quality	Protective
Note: There was no standardization of exercise techniques. There was no standardization of type of education recommended or implemented.				

Table 3: Education vs. Control

Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	2,343: 3 trials	Moderate quality	No effect
Short-term	Days of missed work/sick leave	366: 2 trials	Very low quality	No effect
Long-term	Incidence of LBP	13,242: 2 trials	Moderate quality	No effect
Note: There was no standardization of educational interventions.				

only less harmful but also more effective and sustainable than the potentially addicting opioid agents.[7] In this meta-analysis, Seffan and his colleagues did not look at interventions for chronic pain. However, their work serves a parallel function and equally essential role in treatment of pain — reviewing interventions that work to prevent pain from becoming recurrent and potentially chronic.

These authors conclude that based on the current body of literature, the most likely effective intervention to reduce the risk of recurrence of LBP is a combination of exercise and education. The lack of standardization of the etiology of LBP as well as the interventions is a weakness and a ripe area for future investigation. For now, it seems useful and medically sound to inform patients that back exercises, along with education regarding back care, may guard against future episodes of LBP in the year following an episode.

This may lead to a question of why the effect was not shown to persist after one year with exercise alone (noting the evidence for effect of exercise on sick leave was very low quality for a protective effect in long-term studies.) The authors speculated that teaching or implementing long-term behavioral changes in the form of exercise and physical activity is key to extending the protective effect of this intervention.

Few of us in medical practice would argue with this conclusion or with the idea that behavioral change that encourages a more active lifestyle and includes exercise for LBP has the potential of protecting against recurrent LBP episodes. However, a 2009 study looking at prescriptions for exercise in chronic back and neck pain found that fewer than one-half of diagnosed patients received exercise instruction or advice, and that of those who did, most of the suggestions or prescriptions came from non-physician healthcare professionals.[8]

There is hope that this trend is changing. In 2012, the American Board of Internal Medicine (ABIM) launched Choosing Wisely with a goal of "advancing a national dialogue on avoiding wasteful or unnecessary medical tests, treatments, and procedures."[9] ABIM has partnered with other specialties and *Consumer Reports* to create

Table 4: Back Belts vs. Control				
Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	329: 2 trials	Very low quality	No effect
Short-term	Days of missed work/sick leave	282: 1 trial	Low quality	No effect
Long-term	Incidence of LBP	8,472: 1 trial	Moderate quality	No effect

Table 5: Shoe Insole vs. Control				
Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	1,833: 4 trials	Low quality	No effect

Table 6: Other, Including Ergonomic Training, vs. Control				
Length of study	Outcomes Measured	Number of Participants and Number of Trials	Quality of Evidence	Effect
Short-term	Incidence of LBP	3,047: 2 trials	Moderate quality	No effect
Short-term	Days of missed work/sick leave	360: 1 trial	Very low quality	No effect

patient-friendly handouts and pamphlets explaining current evidence-based interventions. A search of the site reveals straightforward advice regarding the essential role of exercise in the prevention of recurrent LBP.[9] The site encourages healthcare professionals to distribute the materials directly to patients.

Together, the CDC recommendations about limiting opioid use and the Choosing Wisely guidelines can support front-line medical providers in prescribing combined exercise and education as treatment for prevention of recurrent LBP. The potential for these interventions to be useful in prevention of recurrent episodes of LBP is clear, but our patients deserve more than potential! With more studies looking for specific exercises and interventions for specific populations, the answers look well within our reach. ■

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COGNITION

ABSTRACT & COMMENTARY

Fitness and Cognition in the Elderly

By William C. Haas III, MD, MBA

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Dr. Haas reports no financial relationships relevant to this field of study.

SYNOPSIS: Peak levels of cardiorespiratory fitness are positively correlated with enhanced cognitive function among older adults.

SOURCE: Freudenberger P, Petrovic K, Sen A, et al. Fitness and cognition in the elderly: The Austrian Stroke Prevention Study. *Neurology* 2016;86:418-424.

Despite overwhelming evidence supporting the benefits of regular physical activity, relatively few older adults achieve the minimum recommended amount of weekly physical activity.[1] The trend toward increasing physical inactivity among the elderly raises concern, especially in light of research suggesting that physically active adults have a lower risk of cognitive decline and dementia compared to inactive adults.[2] Efforts to slow cognitive decline and dementia are paramount given the lack of effective treatment options in addition to the associated social and economic burdens.

The precise neuroprotective mechanism resulting from enhanced physical activity remains unclear. One of the prevailing hypotheses suggests that improved cardiovascular fitness reduces cerebrovascular disease.[3] Cardiovascular fitness, defined as the body's maximal capacity for oxygen consumption (VO_2max), is an important variable for consideration, as cardiovascular fitness declines with age, but can be increased with regular physical activity.

Drawing upon patients from the original Austrian Stroke Prevention Study, Freudenberger and colleagues conducted a follow-up cohort study to clarify the connection between cardiorespiratory fitness and cognitive function. The primary purpose of the study was to determine the effect of VO_2max on global and domain-specific cognitive function. The researchers also attempted to determine whether the effect of VO_2max on cognitive function was mediated by signs of brain aging seen on magnetic resonance imaging (MRI).

The authors recruited 877 patients from the Austrian Stroke Prevention Study to participate. The original prevention study was a community-based cohort study that evaluated the effects of vascular risk factors on brain structure and function in elderly patients without a history of stroke or dementia. Participants recruited for the follow-up study underwent additional testing, including cognitive testing, exercise ECG, and MRI of the brain. Cognitive testing consisted of a battery of validated tests involving memory, motor skills, and executive function. Exercise ECG was performed to estimate VO_2max based on the formula: 15 x (maximum heart rate/resting heart rate). MRI of the brain was performed to quantify lacunar infarct burden, white matter lesions, and atrophy. Vascular risk factors also were assessed and included cigarette smoking, hypertension, cholesterol, type 2 diabetes mellitus, and body mass index.

With regard to the main outcome, VO_2max displayed a positive linear trend for enhanced memory, executive function, and global cognition. The differences in effect size between the lowest and the highest quartile of VO_2max were 0.298 for memory (P = 0.001), 0.117 for executive function (P = 0.005), and 0.260 for global cognition (P = 0.001). Interestingly, the differences displayed by individuals in the highest vs. lowest quartile of VO_2max corresponded to an age difference of 4, 6, and 7 years for global cognition, memory, and executive function, respectively. Finally, with regard to secondary outcomes, the effect of VO_2max on cognition was not mediated by the presence of lacunar infarcts, white matter lesions, or atrophy.

Summary Point

- Higher peak cardiorespiratory fitness is associated with enhanced cognitive function when compared to lower levels of cardiorespiratory fitness.

■ COMMENTARY

Before forming clinical recommendations based on these results, it is important to revisit the purpose of the study. The researchers specifically attempted to determine whether greater cardiorespiratory fitness was associated with better cognitive function based on protection of cortical and subcortical brain structures. Although the researchers did not find evidence to support their neuro-structural protection hypothesis, they did establish a positive correlation between VO_2max and cognitive performance. In fact, participants with the highest VO_2max demonstrated a significantly younger cognitive age compared to participants with the lowest VO_2max.

Despite positive correlations between VO_2max and cognitive performance, caution should be advised when recommending vigorous physical activity to elderly patients based solely on the results of this study. VO_2max represents the ability of the cardiopulmonary system to uptake, transport, and use oxygen during bouts of maximal physical exertion. It is a measure of peak cardiorespiratory fitness and is not synonymous with general physical fitness. Although consistent exercise at sub-maximal exertion levels can improve VO_2max, such vigorous exercise is unlikely to be advisable for the majority of elderly patients. It is also important to note that up to 65% of VO_2max may be attributed to non-modifiable genetic factors.[4]

A few inherent limitations of the study should be considered. The cross-sectional nature reflects correlations only at a moment in time. The ability to improve cognitive function with improvements in VO_2max can only be inferred. It should also be noted that one of the main variables, VO_2max, was estimated

and not directly measured, which could alter the actual results.

This study shines light on the important topic of preserving cognitive function with aging. Cardiorespiratory fitness indeed appears to function as a protective factor against cognitive decline. However, the study falls short of establishing a connection between improvements in cardiorespiratory fitness and improvements in cognitive function. Until additional studies are performed with regard to optimizing cognitive function, clinicians should continue to counsel their patients on age-appropriate exercise given the many other well-known health benefits. ■

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WOMEN'S HEALTH

ABSTRACT & COMMENTARY

Individualized Homeopathy for Moderate to Severe Depression in Menopausal Women

By Carrie Decker, ND

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Dr. Decker reports no financial relationships relevant to this field of study.

SYNOPSIS: A higher risk of depressive symptoms has been observed in the menopausal transition period. Antidepressant medications are often recommended; however, many meta-analyses have only shown modest benefit of such medications over placebo. This study compares individual homeopathic treatment vs. placebo and the antidepressant medication fluoxetine vs. placebo for the treatment of moderate to severe depression in peri- and postmenopausal women.

SOURCE: Macías-Cortés Edel C, Llanes-Gonzalez L, Aguilar-Faisal L, et al. Individualized homeopathic treatment and fluoxetine for moderate to severe depression in peri- and postmenopausal women (HOMDEP-MENOP study): A randomized, double-dummy, double-blind, placebo-controlled trial. *PLoS One* 2015;10:e0118440.

In this double-blind, double-dummy, placebo-controlled trial, 133 women with moderate to severe peri- and postmenopausal depression were randomized to treatment with individualized homeopathic treatment, 20 mg of fluoxetine a day, or a placebo. The study took place at the public, academic, and research Hospital Juárez de Mexico in Mexico City, and participants were recruited by advertisements on the internet, community groups, and posters and brochures posted in the hospital. To be eligible for participation, depression level was required to be classified as moderate to severe using the DSM-IV criteria. Participants were between 40-65 years of age. Additional criteria to be eligible for the study included no use of hormone replacement therapies, homeopathic treatment, medication for depression or anxiety, or psychotherapy for at least three months prior to (and during) the study. Individuals with psychiatric disorders other than moderate to severe depression, including alcohol or substance use disorders, were also excluded from the study. Of the initial 534 individuals who desired to participate in the study, 133 met study criteria and were enrolled.

Individualized homeopathic remedies were prescribed by a certified medical doctor with 18 years of experience in classical homeopathy based on Hahnemann's methodology. All patients experienced a full homeopathic intake and the most characteristic symptoms were organized by hierarchy. Additional general symptoms were taken into consideration secondarily. Remedy selection was facilitated using the computerized system Radar version 10. Remedies with centisimal (C) potencies of 30 C or 200 C were prescribed, with the potency based on the clarity of symptoms, the patient's vitality and sensitivity, and chronicity of symptoms. A single dose of the homeopathic remedy was diluted into a 60 mL bottle of 30% alcohol and water solution. Each placebo group received a loaded "dummy" of the placebo therapy: A sucrose-containing capsule was substituted for fluoxetine and/or a homeopathic placebo containing a 30% alcohol-water solution without a remedy. Instructions were provided to all participants to succuss (agitate) the homeopathic solution or placebo prior to dosing 10 drops orally twice daily and participants took one capsule of 20 mg fluoxetine or placebo daily. The final groups received either verum homeopathic

Summary Points

- This randomized, double-dummy, double-blind, placebo-controlled trial compares individualized homeopathy vs. placebo and fluoxetine vs. placebo for the treatment of moderate to severe depression in menopausal women.
- Treatment with both individualized homeopathy or fluoxetine was found to significantly reduce depression severity compared to placebo as measured by the Hamilton Rating Scale of Depression (HRSD).
- The mean reduction in depression severity as per the HRSD was 5 points greater with homeopathy than placebo, while the fluoxetine-placebo difference was 3.2 points.
- Homeopathy, but not fluoxetine, also significantly reduced menopausal symptoms compared to placebo as measured by the Greene Climacteric Scale.

with placebo fluoxetine, fluoxetine with dummy-loaded homeopathic placebo, or placebo of both fluoxetine and homeopathic. Compliance was assessed by collection of unused capsules and bottles at follow-up.

Assessment of depression and menopausal symptoms occurred at the intake appointment, and at four- and six-week follow-up. Depression was assessed using both the Hamilton Rating Scale of Depression (HRSD) and the Beck Depression Inventory (BDI), while menopausal symptoms were assessed using the Greene Climacteric Scale (GS). If indicated, an alternate homeopathic remedy or potency was selected at the visit at four weeks, or a rescue intervention in case of the lack of efficacy was provided. Rescue intervention for the homeopathy group was fluoxetine 20 mg per day and homeopathy for individuals given placebo or fluoxetine and the participant did not continue in the original allocated intervention. The pharmacist was not blinded to interventions and, thus, was able to make these substitutions if indicated.

The primary outcome was the change in mean total depression score as measured via the HRSD, and secondary outcomes were change in depression score as measured with the BDI and GS score of menopausal symptoms. No significant difference in baseline scores existed among the groups between any of the parameters assessed or with regard to demographic characteristics and risk factors for depression. In the homeopathy, fluoxetine, and placebo groups, two, seven, and six subjects were lost to follow-up, respectively. The intention-to-treat population included all patients who were randomized, regardless of whether they adhered to treatment or completed the study. Missing data due to loss of follow-up were handled by sensitivity analysis.

At 6 weeks follow-up, the HRSD score was significantly lower in the homeopathic treatment group (mean, 9.9; standard deviation [SD], 3.0; 95% confidence interval [CI], 9.0-10.9) and fluoxetine group (mean, 11.7; SD, 3.7; 95% CI, 10.5-12.9) than the placebo group (mean, 15.0; SD, 3.7; 95% CI, 15.9-18.3) ($P = 0.000$). The mean HRSD score was not significantly different between the homeopathy group and the fluoxetine group ($P = 0.082$). No significant difference existed among the three groups with regard to the BDI score; however, this index decreased in all groups. The GS score in the homeopathy group (mean, 18.1; SD, 7.8; 95% CI, 15.7-20.6) was significantly better than the placebo (mean, 26.8; SD, 11.7; 95% CI, 22.8-30.7) ($P = 0.002$), while the GS score of the fluoxetine group (mean, 23.1; SD, 12.3; 95% CI, 19.2-27.1) was not significantly different from placebo. The mean GS score was not significantly different between the homeopathy group and the fluoxetine group ($P = 0.115$).

"Homeopathic aggravation" (temporary intensification of symptoms before improving) and new symptoms that occurred during homeopathic treatment were reported as adverse events. There were no serious adverse events in either group. One patient taking fluoxetine had increased anxiety and insomnia. In this case, the pharmacist told the doctor which group she was in and she was given the "rescue" individualized homeopathy treatment; she did not continue in the previously allocated intervention. No one prescribed the homeopathic treatment had an aggravation requiring a rescue intervention or withdrawal from the study. Mild adverse events reported during the study included nausea, constipation, diarrhea, headache, insomnia, anxiety, dizziness, fatigue, and dyspepsia. Frequency of occurrence was not significantly different between groups.

■ COMMENTARY

An increased rate of depressive symptoms in the menopausal transition period has been observed in many studies.[1,2] Factors that may contribute to depression may include disrupted sleep, family history, hormonal changes, lifestyle, and relationships. Meta-analyses of the efficacy of antidepressant medications have shown little benefit relative to placebo for the treatment of depression overall,[3] and other treatments such as hormone replacement therapy have been investigated for the treatment of depression in the menopausal transition.[4]

Many women seek complementary and alternative medical treatment for menopausal symptoms.[5,6] However, many of these treatments have not been well studied to determine if an effect exists greater than the

placebo effect. Studies surrounding homeopathy in particular are poorly designed, lack a placebo, or have not shown an effect more significant from placebo.[7] In addition, homeopathic treatments are often standardized and do not consider the principles inherent to the practice of individualized homeopathic medicine as detailed in Hahnemann's *Organon of Medicine*, the gold standard of homeopathic care.[8]

The National Institute for Health and Clinical Excellence (NICE) has recommended a drug–placebo difference as a 3-point change in depression severity as measured by the HRSD to be considered clinically significant.[9] In the current study, the improvement over placebo experienced in the fluoxetine group was 3.2 points while that of the individualized homeopathy was 5 points. A similar double-dummy investigation comparing individualized homeopathy to a control of 20-40 mg of fluoxetine for a general population with moderate-to-severe depression found no significant differences between the percentages of response or remission rates as measured by the Montgomery & Asberg Depression Rating Scale (MADRS) score.[10] In both of these studies, significant improvements in either the HRSD or MADRS score were seen in all groups at the various time points.

A comprehensive homeopathic assessment has characteristics much like a psychotherapy session; that is, discussion concerns not only primary symptoms but also contributing factors, concomitant symptoms, and emotional reactions or states. In this study, the medical history included past and present physical and emotional symptoms, family environment since childhood, stressful life events, and marital satisfaction. Thus, even the placebo group experienced a medical intake that was much like an initial psychotherapy appointment, in which there was an extensive discussion of factors that may contribute to their depression and menopausal symptoms. Although this was not considered an intervention and was necessary for the design of the study, it may have contributed to the improvements observed across all categories in the placebo group as well. Short-term dynamic psychotherapy, which in some ways may be similar to a homeopathic interview (depending on practitioner approach), has been studied for the treatment of depression and has been found to be more effective than control.[11]

A limitation of this study was that although the homeopathic treatment was individualized with consideration for dosage potency and remedy, the medication intervention of fluoxetine was not adjusted. In clinical practice, the dosage of this medication also would have been increased or an alternative medication considered if it was found to be ineffective. Estrogen therapy also has been found to be an effective monotherapy or adjunctive for depression in the menopausal transition, so this also would have been offered as an adjunctive or alternative therapy in a clinical setting.[12]

A longer duration of study also would be more appropriate given the nature of the complaints of menopause and depression, which both may wax and wane over time. Intention-to-treat analysis was used to consider all individuals randomized to treatment, including dropouts and individuals not adherent to treatment, with missing data handled by sensitivity analysis. However, the authors did not state how the individual who received the rescue homeopathic treatment after an adverse response to fluoxetine was handled in the analysis, other than that she did not continue in the previously allocated intervention (fluoxetine). Although exclusion criteria that limited participants from accessing additional support like psychotherapy was necessary to limit variables in this study, it is likely that in a clinical setting, additional support such as this would be recommended.

Compliance with homeopathic dosing is sometimes difficult for patients, particularly when remedies are required to be taken at multiple times away from food each day, a practice known as "clean mouth" by homeopathic prescribers. Cost of homeopathic treatment vs. antidepressant medication also may vary, depending on region and availability of care. In the study population (Mexico), homeopathy was considered the lower cost intervention, while in many regions of the United States the opposite would be true for people with insurance coverage. When prescribing homeopathic treatment, these factors also should be considered to maximize likelihood of compliance.

Overall, this study shows that individualized homeopathic treatment is as effective as a low dose of fluoxetine for the reduction of moderate-to-severe depression in menopausal women. However, similar to the treatment applied in this study, there should be follow-up within a month and adjustment of therapy if the treatment has not been shown to be effective. Patients also should be informed of the alternatives, such as antidepressants or hormone replacement therapy, so they can make informed choices. Adjunctive therapy such as counseling also should be offered, as there often are many factors contributing to depression and the data for combined psychotherapy and pharmaceutical treatments are convincing. ■

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PAIN

ABSTRACT & COMMENTARY

Alexander Technique, Acupuncture, or Routine Care for Chronic Neck Pain

By Mercy Kagoda, MD

Dr. Kagoda reports no financial relationships relevant to this field of study.

SYNOPSIS: Alexander Technique lessons or acupuncture sessions for people with chronic neck pain led to greater decreases in neck pain and disability and a more significant increase in self-efficacy than normal care at 12 months.

SOURCE: MacPherson H, Tilbrook H, Richmond S, et al. Alexander Technique lessons or acupuncture sessions for persons with chronic neck pain. A randomized trial. *Ann Intern Med* 2015;163:653-662.

Chronic neck pain is a significant public health challenge with consequences that include decreased personal well-being, increased healthcare utilization, missed days at work, and loss of productivity.[1,2] Many people suffering from neck pain obtain care from complementary medical practices such as acupuncture and Alexander Technique lessons. The clinical effectiveness of these practices has only been marginally studied, with this study being the first to have a usual care group and 12-month follow-up. Prior reviews suggest that Alexander Technique improves balance, decreases general pain, and improves posture.[3] MacPherson et al reviewed outcomes of patients with chronic neck pain at 1 year after random assignment to Alexander Technique or acupuncture in addition to usual care vs. usual care alone. This is not a comparison between Alexander Technique and acupuncture, but rather an assessment of Alexander Technique plus usual care to usual care alone or acupuncture plus usual care to usual care alone.

This study was carried out in the United Kingdom with a predominantly white British population. Study participants were identified through their general practitioners. Inclusion criteria included: age > 18 years, neck pain for a minimum of three months, recent contact with their primary care physician/general practitioner in the past 2 years, Northwick Park Questionnaire (NPQ) score of more than 27%, which signified neck pain affecting activities of daily living. Exclusion criteria included severe underlying pathology, pregnancy, currently receiving acupuncture, or prior attendance of Alexander Technique lessons in the previous two years. A total of 577 study participants were randomly assigned to one of three groups: acupuncture plus usual care (n = 173), Alexander Technique plus usual care (n = 172), or usual care alone (n = 172). Study participants were mostly female (69%) and white British (90%). (*See Table 1.*) Randomization allowed the study designers to control for selection bias, improving the methodology.

Participants assigned to the acupuncture group were presented with the opportunity to attend twelve

Summary Point

- Compared to usual care, both acupuncture and Alexander Technique lessons were associated with statistically and clinically significant decreases in chronic neck pain and increased ability to acquire lifelong skills that decreased neck pain.

50-minute sessions for a total of 600 minutes in addition to the usual care. Acupuncture was one on one, and also included lifestyle advice such as engaging in exercise, relaxing, eating healthy foods, and resting. Advice by acupuncturists also included the use of magnets and herbs. Participants assigned to the Alexander Technique group were presented with the opportunity to attend twenty 30-minute sessions for a total of 600 minutes in addition to the usual care. Alexander Technique was one on one, and also included hands on and verbal guidance. Alexander Technique is a method of self-care that involves unlearning harmful habits of physical movement to optimize activities of daily living, such as walking, sitting, standing, and speaking, with the goals of maintaining balance and preventing pain. The technique also develops self and spatial awareness through quieting the mind and learning new ways of physical movement that enliven the musculature of the back and spinal cord while allowing the head to be freely poised. The Alexander Technique is based on three key principles. First, to remain pain free there needs to be a dynamically maintained axis and proper head poise. Second, muscle tension from negative emotional or physical reactions to everyday living affect how the axis is dynamically maintained, leading to decreased mobility and pain. Third, restoring balance of the body axis can be achieved by relearning new habits that allow for a dynamically maintained axis and head poise. During the Alexander Technique lessons, participants were shown how to maintain body awareness to maintain the dynamic axis, which allowed them to engage in activities with more thoughtfulness and hence prevent injuries.

The instructors for acupuncture or Alexander Technique lessons were part of a larger governing body for the respective practices, which suggests that the sessions offered were standardized.

Usual care for neck pain entailed prescribed pain medications and physical therapy. Prescribed pain medications were used by 43% of all study participants between 0 to 6 months after enrolling in the study. Six months prior to enrolling in the study, 59% of participants used neck pain-specific medications.

Prior to the start of the study, the expectations and preferences for acupuncture, Alexander Technique, or usual care were measured. Each randomized group included about the same number of people, with varying expectations and preferences for the options of care.

All sessions were delivered within five months. Alexander Technique lessons were offered twice a week and then every two weeks. The acupuncture sessions were once per week initially and then every two weeks. The primary outcome measure was the NPQ score measured at baseline, three months, six months, and 12 months. Secondary outcome measures included pain level text messages and self-efficacy score.

Developed at the Northwick Park Hospital in Middlesex, England, the NPQ includes nine questions. Each question has five options with a score from 0 to 4; the higher the score, the worse the disability/pain. The score is calculated by cumulative points/36 if 9 questions are answered or /32 if only first 8 questions are answered x 100. The maximum cumulative score is 36 and the minimum score is zero. The items that are rated include: pain intensity; pain and sleeping; pins, needles, or numbness in arms at night; duration of symptoms; pain with carrying; pain while reading and watching TV; working/housework; social activities; driving; and comparison of neck pain on the day the questionnaire was last taken.[5]

The study used various statistical analyses including repeated measures, mixed model, and linear regression. The difference in NPQ score between acupuncture and usual care and Alexander Technique and usual care was statistically significant at all three time points ($P < 0.05$). (*See Tables 2 and 3*.) Self-efficacy improved with both techniques more than in usual care and was measured using the Chronic Pain Self-Efficacy Scale. This scale measures how well people can manage their pain and the degree to which pain interferes with activities of daily living.

Another strength of the study was the long-term follow up at one year. At one year, there was still a significant clinical and statistical decrease in the NPQ score for both acupuncture and Alexander Technique lessons. During the trial, there were 80 adverse events in 73 people, 30 of which were classified as serious and 50 of which were non-serious. None of the serious adverse events were considered "probably or definitely" related to the relevant intervention, but Alexander Technique lessons "possibly" caused pain, muscle spasms, and knee injury; acupuncture "possibly" caused bruising, swelling, numbness, muscle spasms, pain, and respiratory problems; and usual care "possibly" caused pain, incapacity, and complications after surgery.

■ COMMENTARY

The findings in this study showed that acupuncture and Alexander Technique lessons were associated with statistically and clinically significant decreases in chronic neck pain, increased ability to manage pain, and decreased negative effect of pain.

The benefits compare favorably with physical therapy. Overall, the therapies were safe, with increased pain and muscle spasms the most commonly reported adverse effects. During the acute phase, it would be prudent to follow allopathic convention of limiting activity and

Table 1: Baseline Characteristics of Study Participants (n = 517)

Characteristic	Acupuncture (n = 173)	Alexander Technique (n = 172)	Usual Care (n = 17)
Mean age ± SD	52.0 ± 13.8	53.6 ± 14.6	53.9 ± 13.0
Females (n)	119	120	118
White	158	151	152
Mean NPQ score baseline ± SD	39.64 ± 9.71	39.38 ± 11.91	40.46 ± 11.60
Median duration of neck pain (range)	60 (5-600)	60 (6-540)	96 (5-600)

Table 2: Attendance at Sessions

Intervention	Acupuncture	Alexander Technique	Usual Care
Mean attendance	10/12 sessions	14/20 sessions	N/A
% attended all sessions	72%	60%	N/A
% attended no sessions	6%	12%	N/A
Completion of 12 months follow-up	87%	85%	85%

Table 3: Differences in Mean Adjusted NPQ Scores at 3, 6, and 12 Months

	3 months NPQ (95% CI)	6 months NPQ (95% CI)	12 months NPQ (95% CI)
Acupuncture	37.23 (30.35-44.1)	35.35 (28.73-41.96)	37.07 (30.35-43.79)
Usual care	43.46 (35.40-51.5)	40.90 (32.94-48.97)	40.99 (33.01-48.96)
Alexander Technique	38.62 (31.62-45.6)	32.65 (25.92-39.38)	33.39 (26.73-40.05)
Usual care	42.22 (34.07-50.4)	37.64 (29.58-45.69)	37.18 (29.16-45.19)

using pain-relieving medications. Acupuncture may be used during the acute phase in addition to pain-relieving medication. Alexander Technique lessons may then be used after the acute phase to mediate the conditions that caused neck pain by relearning new ways of thinking and moving. Cost will be an issue for some patients as average costs range from $50-100 for acupuncture and $40-70 for Alexander Technique lessons. Out-of-pocket costs can easily reach $1,000.

The main strength of this study was that it randomized participants to intervention and usual care. Some studies in this field do not randomize participants nor do they have a "usual care" group for comparison. Since there were varying degrees of expectations and skepticism about benefits of any of the treatments in all the treatment groups, the techniques may be suggested to all patients. However, it may be that the patients who would benefit most from either acupuncture or Alexander Technique lessons are those most likely to be interested in building self-efficacy. The authors did not address the complex relationship between self-efficacy and the placebo effect: Is self-efficacy a measure of the placebo effect, mutually exclusive from placebo, or perhaps a combination of the two?

The statistical analysis used was appropriate for the study. Repeated measures mixed model was a better choice than the traditional fixed repeated measures. In repeated measures, the same subject also acts as the control; in this study, the baseline NPQ was compared with the NPQ at three, six, and 12 months. With the mixed model, the researchers were able to report both the within-group change and also the between-group change. In addition, a mixed model has the advantage of keeping all other data points of a participant, even if one data point is missing. For example, if a participant did not turn in the NPQ at three months, in the mixed model that data point would be removed; however, the remaining data points would be kept. In the traditional model, even one missing point would lead to dropping that subject and thus losing out on all other points. The authors did not mention how many subjects had all the data points available.

In summary, the study design was robust and provides

strong evidence on the clinical value of adding acupuncture or Alexander Technique lessons to the usual care of people with chronic neck pain. ■

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We Need Your Help!

The *Integrative Medicine Alert* editors are conducting a reader survey to learn more about the professionals who read this publication. Please complete the survey enclosed with this issue or at the following link: https://www.surveymonkey.com/r/2016AMASurvey. Thank you for your help!

CME QUESTIONS

1. Steffens et al's meta-analysis of data regarding interventions for prevention of low back pain (LBP) demonstrates which of the following?
a. There are specific exercises for targeted populations that have been identified to assist in prevention of LBP.
b. Ergonomic improvements in the workplace are essential in prevention of LBP.
c. Exercise alone has low-quality evidence suggesting usefulness in prevention of LBP; evidence is less robust for this intervention alone after a one-year period.
d. Exercise and education regarding LBP has equal efficacy to exercise combined with chronic medication use, but the effect is more long-lasting.

2. VO_2max displayed a positive linear trend for all of the domains of cognitive function *except*:
a. memory.
b. executive function.
c. motor skills.
d. None of the above

3. In peri- and postmenopausal women with moderate to severe depression, individualized homeopathic treatment compared to placebo was found to:
a. significantly reduce depression as measured by the Hamilton Rating Scale of Depression (HRSD) and menopausal symptoms as measured by the Greene Climacteric Scale (GS).
b. significantly reduce depression as measured by the HRSD but not significantly improve menopausal symptoms as measured by the GS.
c. significantly improve menopausal symptoms as measured by the GS but not significantly reduce depression as measured by the HRSD.
d. not significantly reduce depression as measured by the HRSD or improve menopausal symptoms as measured by the GS.

4. In people with chronic neck pain, use of Alexander Technique lessons or acupuncture sessions was found to:
a. increase neck pain after a total of six sessions, but decrease pain after more than six sessions.
b. decrease neck pain after attendance of 12 acupuncture sessions and 20 Alexander Technique lessons.
c. decrease neck pain at one year after attendance of six acupuncture sessions and six Alexander Technique lessons.
d. increase neck pain and increase self-efficacy in comparison to usual care.

[IN FUTURE ISSUES]

Integrative treatments for restless legs syndrome

Mediterranean diet and breast cancer

Herbal viagra

Integrative approaches for autism

Integrative Medicine Alert

2016 Reader Survey

In an effort to learn more about the professionals who read *Integrative Medicine Alert,* we are conducting this reader survey. The results will be used to enhance the content and format of *Integrative Medicine Alert*.

Instructions: Fill in the appropriate answers. Please write in answers to the open-ended questions in the space provided. Either fax the completed questionnaire to 678-974-5419, return it in the enclosed postage-paid envelope, or complete the survey here: https://www.surveymonkey.com/r/2016AMASurvey. The deadline is **July 1, 2016.**

1. Are the articles in *Integrative Medicine Alert* written about issues of importance to you?

- O A. Always
- O B. Most of the time
- O C. Some of the time
- O D. Rarely
- O E. Never

2. In future issues, would you like to see more or less coverage of the following topics?

A. more coverage B. less coverage C. about the same amount

Acupuncture	O A	O B	O C
Biofeedback	O A	O B	O C
Chiropractic	O A	O B	O C
Dietary supplements (herbal therapies)	O A	O B	O C
Dietary supplements (vitamins, minerals, non-herbals)	O A	O B	O C
Energy medicine	O A	O B	O C
Exercise	O A	O B	O C
Massage therapy	O A	O B	O C
Meditation	O A	O B	O C
Nutrition	O A	O B	O C
Yoga/tai chi	O A	O B	O C

3. Please rate your level of satisfaction with the following.

A. excellent B. good C. fair D. poor

Evidence-based reviews	O A	O B	O C	O D
Article selections	O A	O B	O C	O D
Timeliness	O A	O B	O C	O D
Length of publication	O A	O B	O C	O D
Overall value	O A	O B	O C	O D
Customer service	O A	O B	O C	O D

5. What is the primary focus of your clinical practice?

- O A. Family medicine
- O B. Internal medicine
- O C. Obstetrics/gynecology
- O D. Pediatrics
- O E. Hospitalist
- O F. Integrative medicine
- O G. Specialty practice (please specify)_____

6. What degree do you hold?

- O A. Medical doctor/Doctor of osteopathy
- O B. Pharmacy
- O C. Naturopathic doctor
- O D. Nurse practitioner
- O E. Physician assistant
- O F. Chiropractor
- O G. Nurse
- O H. Other_____

7. On average, how much time do you spend reading each issue?

- O A. less than 30 minutes
- O B. 31-60 minutes
- O C. 1-2 hours
- O D. More than 2 hours

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- O D. audio

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- O B. 1 long article reviewing a topic or supplement, four 2- to 3-page abstracts
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17. What topic would you like to see addressed in *Integrative Medicine Alert*?

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18. How has reading *Integrative Medicine Alert* changed your clinical practice? _____

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