

# HOMEOPATHY FOR DEPRESSION, MUSIC FOR POSTOPERATIVE RECOVERY, RED YEAST RICE FOR HIGH CHOLESTEROL, ACUPUNCTURE FOR SEASONAL ALLERGIC RHINITIS, AND GINGER FOR OSTEOARTHRITIS

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## INDIVIDUALIZED HOMEOPATHIC TREATMENT MAY BE MORE EFFECTIVE THAN PLACEBO FOR DEPRESSION IN PERIMENOPAUSAL AND POSTMENOPAUSAL WOMEN

*Level 2 (mid-level) evidence*

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An estimated 21% of women will develop major depressive disorder (MDD) at some point in their lives.<sup>1</sup> Menopausal transition is associated with a higher risk of MDD,<sup>2,3</sup> and those with a prior history of depression are at a greater risk of recurrence during this time.<sup>4</sup> Fluoxetine and related antidepressants are beneficial for treating

depression in all stages of adult life. However, effect sizes compared to placebo vary considerably across studies,<sup>5,6</sup> and there is some evidence that the magnitude of benefit is smallest in older adults.<sup>7</sup> Homeopathy is based on the “principle of similars.” Natural substances that cause constellations of symptoms when given to healthy subjects are given to patients with the same symptoms in highly diluted form. In individualized homeopathic treatment (IHT), a trained practitioner uses information gathered from a comprehensive diagnostic evaluation to prescribe a homeopathic remedy tailored to that individual’s distinctive clinical presentation.<sup>8</sup> This is relatively unusual; most users of homeopathy self-select a product off the shelf to treat their most predominant symptom.

In this Mexican trial, researchers set out to compare the effectiveness of IHT and fluoxetine to placebo among 133 perimenopausal and postmenopausal women (ages 45–60) with MDD (14–24 on the 17-item Hamilton Rating Scale for Depression).<sup>9</sup> Participants had not received psychotherapy or taken antidepressant medications, estrogen, or homeopathic remedies for at least three months prior to enrollment. Patients were randomized into the following three groups: IHT plus fluoxetine placebo, fluoxetine 20 mg plus IHT placebo, and IHT placebo plus fluoxetine placebo. All treatments were administered daily for six weeks and all patients, irrespective of group assignment, had a full homeopathic evaluation at baseline and again at four

weeks. Individualized homeopathic medicines were prescribed in the centesimal (C)-potency range, which are produced by first diluting a drop of parent substance in 99 drops of ethanol and agitating the resulting solution (1C). This procedure is repeated in consecutive agitated dilutions until the desired potency is reached. The greater the number of dilutions, the higher the “potency” of the remedy. Potencies of either 30C or 200C were used (i.e., 30 or 200 consecutive dilutions) at the discretion of the homeopath. Homeopathic prescription adjustments could be made at the four-week follow-up. Baseline scores were statistically equivalent across all groups for the Hamilton Rating Scale for Depression (HRSD: scale 0–50), Beck Depression Inventory (BDI: 0–63) and Greene Climacteric Scale (GCS: scale: 0–63). Patients, homeopathic practitioners, outcome assessors and statisticians were all blinded to group assignment.

At the end of six weeks, mean HRSD scores for IHT, fluoxetine and placebo were 9.9 (95% CI: 9.0–10.9), 11.7 (10.5–12.9), and 15.0 (15.9–18.3). Differences were statistically significant for IHT vs. placebo (5.1 points) and fluoxetine vs. placebo (3.3 points), but not for IHT vs. fluoxetine. Mean GCS scores differed between IHT and placebo [18.1 (15.7–20.6) vs. 26.8 (22.8–30.7)], but not for fluoxetine vs. placebo or IHT vs. fluoxetine. There were no significant between-group differences for BDI. Response rates ( $\geq 50\%$  reduction in baseline HRSD score) at six weeks were 54.5%,

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41.3%, and 11.6% for IHT, fluoxetine, and placebo, respectively. The numbers needed to treat (NNT) were three for IHT and four for fluoxetine compared to placebo. Remission rates (HSRD score  $\leq 7$ ), however, were not statistically different across the three groups. There were no serious adverse events.

Based on these results, six weeks of IHT appeared to be more effective than placebo in perimenopausal and postmenopausal women with moderate to severe depression as measured by HRSD, but not BDI. An effect size of 5.1 in the HRDS is likely to be clinically relevant.<sup>6</sup> No significant difference was detected comparing IHT to fluoxetine. The individualized homeopathic prescription method used in this trial has its advantages and disadvantages. The approach is most consistent with the healing philosophy of homeopathy. However, it provides no information regarding the effectiveness of specific homeopathic remedies and potencies. There is no widely accepted pharmacologic mechanism to explain how such highly diluted substances acting alone could produce any biologic effects. Since all study participants reportedly underwent individualized assessments by a blinded homeopathic practitioner, performance bias is an unlikely alternative explanation, which only serves to compound the mystery.

### MUSIC MAY FACILITATE POSTOPERATIVE RECOVERY IN ADULTS

*Level 2 (mid-level) evidence*

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The majority of Americans undergo a surgical procedure at some point in their lives.<sup>10</sup> Over 51 million operations are performed in short-stay hospitals annually in the United States.<sup>11</sup> Preoperative interventions such as patient education and nutritional supplementation may reduce the use of postoperative analgesics and enhance patients' satisfaction.<sup>12,13</sup> Exposing surgical patients to pre-recorded music through headphones, musical pillows, or background sound systems is highly practical, and it is safer and less expensive than pharmaceuticals.<sup>14</sup> The provision of pre-recorded music differs from music therapy, which

involves the services of a trained therapist.

In the present systematic review, researchers set out to determine the effectiveness of music exposure for postoperative recovery in patients undergoing any type of surgery (as long as hearing was unaffected by the procedure) with or without general anesthesia.<sup>10</sup> There was significant variability among the 72 studies analyzed. Trials ranged in size from 20 to 458 participants. Type of music (mostly calming) was chosen by patient or researcher and was delivered before, during, and/or after the procedure. Duration of exposure ranged from a few minutes to several days. Comparators included routine care, headphones with no music, headphones with white noise, or quiet bed rest. Outcomes were assessed for up to six postoperative weeks. Study reports contained insufficient information to fully judge the risk of bias. Adequate allocation concealment, patient blinding (which was only possible when music was delivered during general anesthesia), and/or blinding of investigators and outcome assessors was either absent or unreported in the great majority of trials.

Music was associated with a reduction in postoperative pain [standard mean difference (SMD) =  $-0.77$  (95% CI:  $-0.99$  to  $-0.56$ ) in analysis of 45 trials], anxiety [ $-0.68$  ( $-0.95$  to  $-0.41$ ) in analysis of 43 trials] and use of analgesics [ $-0.37$  ( $-0.54$  to  $-0.20$ ) in analysis of 34 trials], and an increase in patient satisfaction [ $1.09$  ( $0.51$ – $1.68$ ) in analysis of 16 trials]. There was, however, no effect on hospital length of stay ( $-0.11$  [ $-0.35$  to  $0.12$ ]). Music was also associated with a decrease in pain scores by an average of 23 (16.9–29.9) mm on 0–100 visual analog scale and by 6.4 (3.86–8.94) units on the State-Trait Anxiety Inventory Scale (range: 20–80) compared to controls. In subgroup analyses, benefits persisted irrespective of comparator type, timing of pain assessment (0–4 vs.  $> 4$  h post-op), or who chose the music (patient vs. researcher). Pain was reduced most to least when music was played preoperatively, intraoperatively, or postoperatively, [SMD =  $-1.28$  ( $-2.03$  to  $-0.54$ ),  $-0.89$  ( $-1.20$  to  $-0.57$ ), or  $-0.71$  ( $-1.03$  to  $-0.39$ )], respectively. A similar pattern was

found for anxiety and analgesic use. Interestingly, intraoperative music was associated with postoperative pain reduction even under general anesthesia, but was more prominent without it [SMD =  $-0.49$  ( $-0.74$  to  $-0.25$ ) vs.  $-0.05$  ( $-0.45$  to  $-0.64$ )].

According to this review, perioperative exposure to music appears to reduce pain, anxiety, and analgesic use during recovery. Estimated effect sizes for pain, and possibly anxiety, were clinically meaningful. It is interesting to note that even intraoperative music under general anesthesia was beneficial. High or unknown risk of bias across virtually all trials and broad inclusion criteria (resulting in significant heterogeneity) compromise the clinical applicability of these findings. Notwithstanding these limitations, music is a safe and simple intervention that has the potential to enhance the postoperative experience of surgical patients.

### RED YEAST RICE EXTRACT REDUCES LDL-CHOLESTEROL BUT SAFETY IS UNCERTAIN

*Level 3 (lacking direct) evidence*

*Atherosclerosis* 2015;240(2):415–23

Red yeast rice (RYR), or Hon Qu, is a traditional Chinese herbal preparation made by fermenting white rice with the yeast, *Monascus purpureus*.<sup>15</sup> While it has a variety of culinary and medicinal uses in China, RYR primarily serves as an alternative to statins in patients wishing to avoid drug therapy or who are among the roughly 10% who are statin intolerant.<sup>16,17</sup> RYR contains varying quantities of monacolins, which inhibit hydroxymethylglutaryl-coenzyme A (HMG CoA) reductase. Monacolin K (MonK), the predominant form, is chemically identical to lovastatin.<sup>15</sup> Although RYR proponents claim it is safer than statins, the structural similarity of its active ingredient suggests it would cause similar adverse effects. In fact, RYR has been associated with cases of myopathy, hepatotoxicity, and rhabdomyolysis.<sup>18,19</sup> Other potential cholesterol-lowering constituents include plant sterols, isoflavones, and monosaturated fatty acids.<sup>20</sup>

In the present systematic review, researchers analyzed 20 randomized, controlled trials investigating the

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