Shiatsu as an adjuvant therapy for schizophrenia: an open-label pilot study.
SHIATSU AS AN ADJUVANT THERAPY FOR SCHIZOPHRENIA: AN OPEN-LABEL PILOT STUDY
Pesach Lichtenberg, MD; Agnes Vass, MD; Hamutal Praya; Shany Edelman, MA; Uriel Hersesco-Levy, MD

Context • Studies have suggested a possible role for shiatsu in treating a variety of mental and physical ailments.
Objective • To determine if shiatsu can provide clinical benefit to individuals diagnosed with schizophrenia.
Design • An open-label pilot study.
Setting • An inpatient psychiatric ward at Herzog Memorial Hospital, Jerusalem, Israel.
Patients • Twelve hospitalized patients with chronic schizophrenia.
Intervention • Shiatsu treatment provided in a course of eight 40-minute biweekly sessions over 4 weeks.
Main Outcome Measures • All subjects were evaluated at baseline, 2 weeks, 4 weeks (end of treatment), and 12 weeks (follow-up). The tools used for assessment included the Clinical Global Impression (CGI), the Brief Psychiatric Rating Scale (BPRS), the Positive and Negative Syndrome Scale (PANSS), the Hamilton Rating Scale for Depression (HAM-D), the Hamilton Anxiety Rating Scale (HAM-A), and the Nurses’ Observation Scale for Inpatient Evaluation (NOSIE). Side effects were measured using the Simpson-Angus Scale for Extrapyramidal Symptoms (SAS) and the Abnormal Involuntary Movement Scale (AIMS).
Results • On all scales of psychopathology and side effects, the subjects showed a statistically and clinically significant improvement by the end of treatment. This improvement was maintained at the 12-week follow-up. These findings, while encouraging, must be considered preliminary and require confirmation and cross-validation in larger-scale controlled studies. (Altern Ther Health Med. 2009;15(3):44-46.)

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Shiatsu is a holistic form of medicine originating in Japan but now widely practiced throughout the world. Shiatsu involves applying pressure to “meridian points” of the body, much like acupuncture but without the need for using needles. Studies have suggested a possible role for shiatsu in treating preoperative anxiety,1 pain from radial fractures,2 lower back pain,3 and nausea and vomiting.4

While shiatsu has never been evaluated as a treatment for psychotic illness, acupuncture has been subjected to several trials. Five randomized trials evaluating the efficacy of acupuncture for schizophrenia have been conducted, as summarized for the Cochrane Database by Rathbone and Xia.5 Acupuncture as adjuvant therapy with antipsychotic medication seemed to improve outcomes on clinical rating scales and side effect profiles, though overall the evidence was insufficient to reach a definitive conclusion.

Acupuncture and shiatsu are ultimately alternate means of stimulating the same meridian points. However, it is possible that acupuncture, by using needles, may arouse uncomfortable connotations and recollections in some patients with psychosis, while shiatsu, devoid of needles, might be better suited and less threatening when treating these individuals. We therefore undertook what at our knowledge is the first study aimed at assessing the effect of shiatsu therapy in schizophrenia.

METHODS
Sample and Setting
All patients included in the study were patients with chronic schizophrenia hospitalized in an inpatient psychiatric ward at the time of enrollment. To be included in the study, a patient had to be diagnosed with schizophrenia according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria, determined by a semistructured interview and review of all medical records by 2 board-certified psychiatrists. Further inclusion criteria required that the patient be aged 18 to 60 years, relatively stable for at least 1 month prior to the start of the study (as determined by the treating psychiatrist), and capable of cooperating within the 40-minute shiatsu sessions. Patients with unstable medical conditions, recent fractures or other orthopedic problems, active infection in skin or soft tissues, or other skin conditions that could render shiatsu treatment unsafe or painful were excluded from the study.
All patients provided their written informed consents for participation in the study. This project was approved by the institutional Helsinki Committee for Medical Ethics and by the Israel Ministry of Health. The study was registered in the National Institute of Health Clinical Trials registry with ID NCT00425399.

**Intervention**

Shiatsu diagnosis was conducted by a senior shiatsu therapist according to the principles of traditional Chinese medicine (TCM) and was based on a standardized guidebook. To arrive at a diagnosis, the therapist took note of the patient’s appearance, his or her voice, and the specific complaints and medical history of the patient. The therapist also touched areas of the patient’s body in order to reveal zones of excessive or diminished energy in the body or internal organs and autonomic nervous system. Treatment, conducted by applying pressure to the relevant trigger points of the meridians, was individualized, as determined by the diagnostic process and in accordance with the principles of TCM as presented in the same guidebook.

Three certified shiatsu therapists with at least 2 years of post-training experience provided the shiatsu treatment. Treatment was conducted on an individual basis in 40-minute sessions. A course of shiatsu treatment included 2 weekly sessions for a total of 8 shiatsu treatments over 4 weeks. Each patient had the same therapist throughout the treatment. The shiatsu therapist and patient were of the same gender. The patient was fully clothed during treatment.

No changes in ongoing pharmacotherapy were permitted during the study, except in the event of an exacerbation, defined as an increase of 20% in the total Positive and Negative Syndrome Scale (PANSS) score. In that case, participants were to be withdrawn from the study and the appropriate treatment instituted.

**Outcome Measures**

All subjects were evaluated at baseline, 2 weeks (half-way through the treatment), 4 weeks (end of treatment), and 12 weeks (2-month follow-up). The tools used for assessment by the rater included the following:

1. The Clinical Global Impression (CGI) is an overall assessment of illness severity on a scale of 1 to 7.
2. The Brief Psychiatric Rating Scale (BPRS) contains 19 items of psychopathology rated on a scale of 1 to 7.
3. PANSS, with a total score comprised of subscales for positive, negative, and global psychopathology, includes 30 items also on a scale of 1 to 7.
4. The Hamilton Rating Scale for Depression (HAM-D) has 21 items for rating various aspects of depression.
5. The Hamilton Anxiety Rating Scale (HAM-A) includes 14 items assessing emotional and somatic symptoms of anxiety rated on a scale of 0 to 4.
6. The Nurses’ Observation Scale for Inpatient Evaluation (NOSIE) is a 30-item scale assessing various aspects of daily functioning, such as sociability and attention to hygiene.
7. The Simpson-Angus Scale (SAS) is a 10-item measure of extrapyramidal symptoms, a frequent side effect of antipsychotic medication, rated 0 to 4.
8. The Abnormal Involuntary Movement Scale (AIMS) measures involuntary movements of various parts of the body, also on a scale of 0 to 4. These movements can also be a side effect of antipsychotic pharmacotherapy.

For all scales, higher scores reflect greater severity.

**Statistical Analysis**

In order to determine whether the participant’s condition improved, each of the rating scales was analyzed by separate analysis of covariance (ANCOVA) models, where the change from baseline to the end of treatment (week 4) was assessed and adjusted for baseline value, age, gender, age at first hospitalization, number of prior hospitalizations, and duration of current hospitalization. The appropriateness of the use of analysis of variance was assessed by testing each of the rating scales for non-normality in the change from baseline to end of treatment with the Shapiro-Wilk test. A $P$ value of $0.05$ was considered statistically significant.

In order to determine that the improvement was maintained at the follow-up (week 12), noninferiority tests were conducted. The 1-sided 95% confidence intervals of the mean difference (which was estimated via an ANCOVA model similar to that above) between the end of study visit (week 4) and the follow-up visit (week 12) value of the scores for all rating scales were computed.

**RESULTS**

Twelve patients (8 females, 4 males) entered the study and completed the full 4-week course of treatment. Table 1 presents their demographic and clinical characteristics. There were no exacerbations or pharmacotherapy adjustments during the period of the research.

<table>
<thead>
<tr>
<th>TABLE 1 Demographic and Clinical Characteristics of Study Sample</th>
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<tr>
<td>Age, years</td>
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<td>Gender (M/F)</td>
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<tr>
<td>Mean age at first hospitalization, years</td>
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<tr>
<td>Number of prior hospitalizations</td>
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<td>Duration of current hospitalization, years</td>
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<tr>
<td>Ongoing antipsychotic medication</td>
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</table>

The scores of the patients on the various assessments are shown in Table 2. On all scales of psychopathology and side effects the subjects showed a statistically and clinically significant improvement compared with baseline by the end of treatment. At the follow-up at 12 weeks, this improvement was maintained for all scales.

**DISCUSSION**

We report what is to our knowledge the first study undertaken...
<table>
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<th>TABLE 2 Effect of Shiatsu Adjuvant Therapy in Schizophrenia</th>
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<tr>
<td>Study Week</td>
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<tr>
<td>Assessment Measure*</td>
</tr>
<tr>
<td>CGI</td>
</tr>
<tr>
<td>BPRS</td>
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<tr>
<td>PANSS total</td>
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<tr>
<td>HAM-D</td>
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<tr>
<td>HAM-A</td>
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<tr>
<td>NOSIE total</td>
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<tr>
<td>SAS</td>
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<td>AIMS</td>
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*CGI indicates Clinical Global Impression; BPRS, Brief Psychiatric Rating Scale; PANSS, Positive and Negative Syndrome Scale; HAM-D, Hamilton Rating Scale for Depression; HAM-A, Hamilton Anxiety Rating Scale; NOSIE, Nurses' Observation Scale for Inpatient Evaluation; SAS, Simpson-Angus Scale for Extrapyramidal Symptoms; AIMS, Abnormal Involuntary Movement Scale.

Significance of improvement from baseline (week 0) to end of treatment (week 4).

for the purpose of assessing shiatsu in the treatment of psychotic illness. In a group of 12 inpatients, ill for long periods of time with schizophrenia and undergoing multiple hospitalizations, the addition to standard psychopharmacological and psychosocial interventions of twice-weekly shiatsu treatments for 4 weeks produced a significant improvement in the patients' clinical status.

This pilot study was conducted without blinding or control groups; therefore, the findings must be considered preliminary and require confirmation and cross-validation in larger-scale controlled studies. The improvement seemingly produced by shiatsu in this study might actually be a placebo effect, provided by the caring attention of dedicated shiatsu therapists inducing a sense of calm and positive anticipation in their clients. Alternatively, it is possible that the additional weeks of conventional pharmacological therapy led to the improvement in the patients' condition.

Nevertheless, the improvement in a range of scores measuring positive and negative symptoms, depression, and anxiety, is impressive and certainly warrants further investigation. Moreover, the study was designed so that the patients were not acutely ill, were stable for a month prior to the start of the study, and during that month and the subsequent duration of the research, no changes were made in their medications. This strongly suggests that it was the shiatsu intervention that brought about an improvement in the participants' condition.

The mechanism, at least in conventional medical terms, by which shiatsu may ameliorate the symptoms of schizophrenia is unknown. A possibly productive avenue of research may be to assess the cytokine system, which appears to be involved in the psychopathology and treatment of schizophrenia and which may be affected by manipulations of the meridians in TCM.

Future studies should be conducted under double-blind condi-

tions. Blinding is a challenge in the assessment of all kinds of non-pharmacologic therapeutic interventions, where the comparison treatment must somehow mimic the study treatment while maintaining blindness. Yet without the rigorous methodology of a carefully randomized and placebo-controlled double-blind study, the suspicion will remain that the apparent therapeutic effect obtained by shiatsu (or for that matter by other forms of complementary medicine) is actually a nonspecific placebo effect produced by cultivating the patient's optimistic expectations in the context of a good therapeutic relationship.

To achieve double blindness, a shiatsu diagnostician could direct the shiatsu therapist as to which meridian points he should be pressing, yet unbeknownst to the therapist as well as to the patient half of these directed treatments would actually be nonspecific. We are currently undertaking such a study, which we hope will confirm the beneficial role of shiatsu as adjuvant therapy in schizophrenia.

Acknowledgments

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REFERENCES