Acupuncture and reflexology for insomnia: a feasibility study

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ABSTRACT

Objective: To assess the feasibility of patient recruitment and retention, logistics of intervention and outcome measure sensitivity for a study designed to investigate the use of acupuncture and reflexology for the management of insomnia.

Design: Feasibility study for a randomised controlled trial.

Setting: University of Ulster Clinic.

Participants: Thirteen participants with sleep disturbances.

Interventions: Participants were randomised to receive one of three treatments, either: acupuncture (n = 5), reflexology (n = 4) or music therapy (n = 4). These treatments were administered six times over a 3-week period.

Main outcome measures: The Pittsburgh Sleep Quality Index (PSQI) and Short Form 36 version 2 (SF-36v2) were recorded at baseline, post-treatment and follow-up. Each participant also completed a Sleep Diary.

Results: Ten participants completed treatment. In the acupuncture and reflexology groups, a clinically relevant improvement in two out of three participants was observed on the PSQI following treatment. Music therapy produced improvement in two out of three participants. No clinically important improvements were observed in the acupuncture and reflexology groups. No statistically significant differences were observed between the acupuncture and reflexology groups.

Insomnia is the most commonly reported sleep problem in industrialised nations worldwide. It is characterised by an inability to initiate or maintain sleep for a sufficient amount of time during regular sleeping hours and is associated with a complaint of daytime dysfunction. Acute insomnia is defined as sleep difficulty lasting one night to a few weeks in duration. Chronic insomnia is defined as sleep difficulty lasting at least three nights per week for 1 month or more. The prevalence of insomnia in the general population is approximately 35%, with 10–15% of this being moderate to severe insomnia. Prevalence rates for chronic insomnia are found to be generally higher in women and increasing with age.

Present treatment falls into two main categories, pharmacological and non-pharmacological. Pharmacological consists of prescribed and non-prescribed hypnotics and sedatives. However, due to their adverse side effects, “patients and doctors alike have become increasingly wary of hypnotic medication … as evidenced by the marked decline in prescriptions over the past two decades.” Non-pharmacological treatment consists mainly of behavioural and cognitive therapies. Unfortunately, doctors in general practice often lack the necessary evaluation skills and awareness of non-pharmacological treatment, and so an attitude of medication or nothing, in some cases, has arisen. Due to these factors, many insomniacs seek complementary and alternative medicine (CAM) to alleviate their condition, and as a result insomnia has become one of the top five conditions treated by CAM.

A review of the literature on acupuncture and insomnia highlighted a small number of randomised controlled trials which evaluated the use of acupuncture or body/ear pressure for insomnia. These trials gave mixed results, but three out of the seven studies showed that acupuncture/acupressure was more effective in patients than sham treatment. A recent Cochrane review suggested that acupuncture and acupressure may help to improve sleep quality scores when compared with placebo or no treatment, but that studies reporting subjective insomnia outcomes showed that acupuncture was no more effective than the control and that significant statistical heterogeneity was observed.

A review of the literature on reflexology found no trials which specifically evaluated reflexology and sleep disturbances. However, eight papers were identified which used sleep quality as an outcome measure, when assessing the effects of reflexology on quality of life, in patients with other disorders such as cancer and multiple sclerosis. These papers indicated that reflexology may be of benefit for the treatment of sleep disturbance. No papers comparing acupuncture and reflexology were found. The dearth of research in these areas has therefore prompted our group to undertake a pilot study to assess the feasibility of a trial to investigate the effectiveness of acupuncture and reflexology for insomnia in the general population. The feasibility of patient recruitment and retention, logistics of intervention and outcome measure sensitivity for such a study design was carried out. These data will also provide the basis of a power analysis to determine numbers for a future trial.

MATERIALS AND METHODS

People with a sleep disturbance were recruited from the University of Ulster’s staff base at the Jordanstown campus via an internal email. Two emails were circulated over a 4-week period. Each applicant was screened by an independent researcher, for sleep disturbances before participation in the study by completing the Pittsburgh Sleep Quality Index, FSQI. A score of more than 5 was set as a minimum for participation. Each applicant was also screened for depression, using the Beck Depression Inventory version 2 (BDI-II). The BDI-II is a self-administered 21-item self-report scale measuring supposed manifestations.
of depression. The BDI-II takes approximately 10 min to complete, although participants require a fifth-sixth grade reading age to adequately understand the questions. A score of 14 or more indicates mild depression, and so a maximum of 13 was taken, as a cut-off mark for excluding candidates. Candidates were also excluded if they were currently on sleep medication. After screening, 13 candidates were selected to take part in the study. Ethical approval for the study was obtained from the University of Ulster’s Research Ethical Committee and was carried out in accordance with the ethical standards set forth in the Helsinki Declaration of 1975. Each participant provided written, informed consent prior to commencing the trial. Each participant’s age, gender, general health, duration and type of sleep disturbance were recorded at baseline.

Participants were randomly allocated using a random number table, into one of three treatment groups: acupuncture, reflexology or music therapy control. Randomisation was performed by a member of staff within the research group who was not involved in the day-to-day running of the trial, and was concealed from the researcher recruiting participants and the independent assessor.

Clinical interventions
A total of six treatments were administered twice per week over the course of 3 weeks. Each treatment lasted approximately 40 min and was performed in a room at the University of Ulster’s clinic. The therapists were requested not to give any additional advice to the participants with regard to their condition.

Acupuncture
Acupuncture was applied by inserting fine needles along the meridians on the body, to stimulate particular points. In this study, points were chosen individually based on traditional Chinese medical (TCM) diagnosis, and the common points considered for each type of insomnia were:10-14
- Liver Fire: LR3, GB20, HT7, BL20, SP6;
- Phlegm-Heat/Stomach Disharmony: ST44, ST40, PC6, SP6;
- Deficiency of Kidney: PC7, KI3, BL15, BL23, SP6;
- Deficiency of Heart and Spleen: BL20, BL15, HT7, SP6;
- Deficiency of Heart and Gallbladder Qi: BL15, BL19, PC7, GB40, BL20.

The mean number of needles inserted for each participant in each session ranged from four to ten. The needles were retained for 50 min, and manually stimulated every 5 min by rotating, thrusting, stirring, etc, to obtain “De Qi,” an acupuncture-specific sensation, which can be described as a feeling of aching, numbness, extension, heaviness, prickling or stinging.16 Filiform needles were single-use, sterile and prepacked with guide tubes. Sizes (diameter x length) were 0.25 x 25 mm, 0.25 x 50 mm and 0.25 x 75 mm. Because moxibustion was generally used by most TCM practitioners to improve the effectiveness of acupuncture, which could be regarded as a component of traditional Chinese acupuncture,16 17 it was applied as supplementary therapy to needling in the trial if necessary. Acupuncture therapy was carried out by an experienced acupuncturist who was also a medical doctor in China since 1998.

Reflexology
Participants in the reflexology group received precision reflexology using point location according to published charts.18 There is no specific reflex point for sleep, so areas of the central nervous system, and the thyroid, pineal and pituitary glands, were emphasised, that is increased stimulation, as advised by reflexology textbooks19 and as determined through discussions with clinical practitioners. Treatments in the reflexology groups involved the use of standardised base oil. Reflexology was carried out by an experienced reflexologist.

Music therapy control
Participants in the music therapy group lay down and listened to relaxing music (CD, label: Body and Soul-Relaxation (Resting the Mind Reviving the Body) by various artists) via the speakers of a portable hi-fi, in a darkened room for the duration of the therapy session.

Outcome measures
Outcome measurements were recorded at baseline, prior to the first treatment session, at the end of the 3-week treatment period (post-treatment) and 2 weeks following the end of treatment (follow-up). These measurements were recorded by an independent researcher who was unaware of group allocation. In addition to these measurements, each participant was required to complete a sleep diary for the 5-week period.

The primary outcome measure was the PSQI, a self-rated questionnaire assessing sleep quality and disturbances over the month and across 19 individual items. These 19 items are combined to form seven “component” scores for subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction. The seven components scores are then added to generate an overall score ranging from 0 to 21 points, with a cut-off score of 5 indicating a threshold for sleep problems. Lower scores indicate a higher quality of sleep, and higher scores indicate a poorer quality of sleep. Although not designed for insomnia, the questionnaire is widely used as an end point in clinical trials for insomnia.20 It has excellent psychometric properties and has been validated against polysomnography (PSG), making it now one of the most commonly used assessments for evaluation of insomnia severity in sleep research.21

The Short Form 36 version 2 (SF-36v2),22 is a short-form health survey comprising 36 questions. It produces eight subscale scores of physical functioning, role—physical, bodily pain, general health, vitality, social functioning, role—emotional and mental health. The sleep diary was used to record the time the participant went to bed, time to sleep, time they woke up, any disturbances during the night and any improvement. The diary was completed retrospectively each morning about the previous night’s sleeping pattern.

At the end of the study, each participant also completed an exit questionnaire which recorded participants’ attitudes towards the treatment they received. Questions included whether they would recommend the treatment to a friend, if they were satisfied, if they received any benefit and if they would consider receiving the treatment again.

Data analysis
After data collection, data were coded and then analysed using the Statistical Package for the Social Science (SPSS, Chicago) version 11.0 for Windows. Data were analysed using descriptive statistics only. Difference scores for the PSQI were calculated by subtracting the score at the end of treatment from that at the start of treatment. An improvement in sleep symptoms was calculated as the score at the end of treatment from that at the start of treatment. An improvement in sleep symptoms was calculated as a negative score, and following a personal communication with D Buysse, the author of the PSQI, a change of three points or more was chosen to indicate a minimal clinically important difference (MCID). The SF-36v2 scores were transformed scale scores with a
range of 0–100 and compared with the norms for the 1998 USA general population.22

Study feasibility

The criterion set to determine whether recruitment and retention was feasible was identified as the ability to recruit and retain sufficient numbers of participants within this 1-month period which, when expanded to a fully powered trial, would enable the trial to be completed within a reasonable time frame, that is less than 2 years. The logistics of the intervention were considered satisfactory if the participants were agreeable to being randomised into any of the intervention groups and if the majority of participants (>60%)23 would attend for the total number treatments. Outcome measure sensitivity was considered acceptable if the chosen outcomes would be sufficiently sensitive to detect clinically significant changes in sleep parameters following intervention.

RESULTS

Participant flow and retention are shown in fig 1. Only one participant out of 13 failed to complete the intervention phase of the study giving a drop out rate of 8%. Two further participants were lost to follow-up. Among the 10 participants who completed the study, 60% (n = 6) of the participants were female, and the mean age of the participants was 47.2 (SD 10.5) years. The health of the participants was generally reported as good (80%), one participant described their general health as quite good, and one did not specify. Disorders reported among the participants included irritable bowel syndrome, menopause, migraine, diverticulitis and an underactive thyroid. The length of time the participants in this study had experienced insomnia ranged from 1 to 32 years, and the difficulties reported included problems with sleep onset, sleep maintenance and early-morning awakening. Table 1 shows the baseline characteristics for all participants and in each treatment group. These characteristics include the distribution of gender, age and the screening scores for the BDI-II and the PSQI. The participants’ screening PSQI scores ranged from 7 to 14 points.

OUTCOME MEASURES

Figure 2 displays the PSQI scores for each participant, in each treatment group, at baseline, end of treatment and 2-week follow-up, and fig 3 shows the difference in scores at the end of treatment and at follow-up. Only four participants showed an MCID in their PSQI scores following intervention, two in the reflexology group and two in the acupuncture group. The MCID was either maintained or increased in the follow-up period (n = 2 acupuncture, n = 1 reflexology).

Table 2 lists the median scores and range of scores for each item of the SF-36v2, at baseline, end of treatment and 2-week follow-up, for the reflexology, music therapy and acupuncture groups. No trends were noted within the SF-36v2 results. When compared with the 1998 General US population means and standard deviations, each item was in keeping with the US population values, with the exception of vitality.

From the sleep diary, it was possible to obtain total sleep time (TST), sleep onset latency (SOL) and number of awakenings (NOA) for each participant on a nightly basis, 2 weeks prior to treatment, during 3 weeks of treatment and 2 weeks following treatment. However, due to problems with compliance, there were many missing values in these data, and as a result the data were not analysed.

Table 3 lists the data collected from the exit questionnaires. For each of the three therapies, all participants were either satisfied or very satisfied with the treatment they received. No adverse effects from the interventions were noted.

POWER CALCULATION

Based on the changes observed in this study, a power calculation was performed. For analysis of the PSQI, it the MCID was taken to be 3 scale points, and the within-group SD was taken to be 4.5 scale points. With these figures, a point estimate of the sample size for 80% power of a three-group test with a size of 5% would result in 43 participants per group. However, since the sample size is very small (the resulting degrees of freedom

Table 1 Baseline characteristics: distribution of gender, median scores and range of scores for age, Beck Depression Inventory Version 2 and Pittsburgh Sleep Quality Index for each group

<table>
<thead>
<tr>
<th></th>
<th>All subjects</th>
<th>Reflexology group</th>
<th>Music therapy group</th>
<th>Acupuncture group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 males</td>
<td>2 males</td>
<td>1 male</td>
<td>1 male</td>
</tr>
<tr>
<td>Female</td>
<td>6 females</td>
<td>1 female</td>
<td>2 females</td>
<td>3 females</td>
</tr>
<tr>
<td>Age median (range)</td>
<td>50 (25 to 62)</td>
<td>52 (33 to 62)</td>
<td>50 (49 to 51)</td>
<td>49.5 (25 to 51)</td>
</tr>
<tr>
<td>Beck Depression Inventory Version 2 median (range)</td>
<td>6 (0 to 13)</td>
<td>7 (7)</td>
<td>6 (2 to 13)</td>
<td>2 (0 to 12)</td>
</tr>
<tr>
<td>Pittsburgh Sleep Quality Index screening median (range)</td>
<td>12 (7 to 14)</td>
<td>12 (7 to 14)</td>
<td>12 (10 to 13)</td>
<td>12.5 (10 to 14)</td>
</tr>
</tbody>
</table>
DISCUSSION

The aim of this preliminary study was to assess the feasibility of a trial designed to investigate the effectiveness of acupuncture and reflexology in the management of primary insomnia. Therefore, the main objectives of the current study were to determine the suitability of the study design in terms of recruitment, retention, logistics of treatment regimes and outcome measure sensitivity.

Although this study was based on small participant numbers, the recruitment process was satisfactory, as 17 respondents were obtained within a 4-week period, and of these 14 were eligible for randomisation. An 8% dropout rate also indicates excellent retention possibilities for such a study, as similar clinical trials using insomnia participants have demonstrated dropout rates of 14–40%. Ong et al. found that one of the main reasons for dropout from an insomnia trial was participant depression as a comorbidity. Exclusion of depression from the current pilot may have contributed towards the low dropout rates achieved. Using the recruitment figures obtained for the current study, it would be possible to recruit the numbers of participants required for a fully powered study (140) over a 1-year period. This time frame for a fully powered RCT is acceptable, and so recruitment methods and retention were considered feasible.

Participant baseline characteristics were variable. This may be due to the heterogeneity of the insomnia population. Insomnia has been associated with various socio-demographic variables and comorbid conditions. Therefore, it may be useful to consider limitations on inclusion criteria such as comorbidities to allow inclusion of a more homogeneous group in the study. For example, the study of primary insomnia would be of interest, as this patient group is not associated with any psychiatric or medical conditions. However, feasibility of recruitment of such a population would require investigation before a trial could be completed.

Although not designed for insomnia, the PSQI questionnaire is widely used as an end point in clinical trials for insomnia. It has excellent psychometric properties and has been validated against polysomnography (PSG), making it now one of the most commonly used assessments for evaluation of insomnia.
### Table 2

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline</th>
<th>Post-treatment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical functioning</strong></td>
<td>52.82(48.61 to 55.05)</td>
<td>54.93(50.72 to 59.38)</td>
<td>57.03(52.82 to 57.03)</td>
</tr>
<tr>
<td><strong>Role—physical</strong></td>
<td>54.93(47.19 to 61.27)</td>
<td>58.74(54.93 to 62.12)</td>
<td>59.38(54.93 to 62.12)</td>
</tr>
<tr>
<td><strong>Bodily pain</strong></td>
<td>50.29(42.86 to 55.05)</td>
<td>52.15(47.19 to 57.03)</td>
<td>53.86(49.44 to 57.03)</td>
</tr>
<tr>
<td><strong>General health</strong></td>
<td>50.55(45.94 to 55.05)</td>
<td>54.83(49.44 to 54.93)</td>
<td>55.34(50.89 to 55.34)</td>
</tr>
<tr>
<td><strong>Social functioning</strong></td>
<td>51.61(47.19 to 55.05)</td>
<td>55.34(50.89 to 55.34)</td>
<td>55.88(50.89 to 55.34)</td>
</tr>
<tr>
<td><strong>Mental health</strong></td>
<td>52.82(48.61 to 55.05)</td>
<td>55.34(50.89 to 55.34)</td>
<td>55.88(50.89 to 55.34)</td>
</tr>
</tbody>
</table>

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**Note:** Median and range of Short Form 36 version 2 scores for reflexology, music therapy and acupuncture groups: median and range of transformed scale scores calculated for each group at baseline, end of treatment and 2-week follow-up.

**CONCLUSION**

Recruitment and retention rates indicate that a fully powered trial may be completed over a 1-year period, which, according to...
predefined criteria, would be feasible. Randomisation and intervention logistics were feasible, as all participants agreed to be randomised, and 92% of participants attended all scheduled treatments. The primary outcome measure was considered feasible, as clinically significant changes were identified following intervention. Therefore, the results of the current study indicate that it would be feasible to conduct a fully powered RCT to determine if treatment with acupuncture and reflexology produces an improvement in sleep quality in patients with insomnia using the described intervention regime and primary outcome measure.

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Patient consent: Obtained.

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