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Effectiveness of auriculotherapy on older people with insomnia

(13144061)

Presenter:

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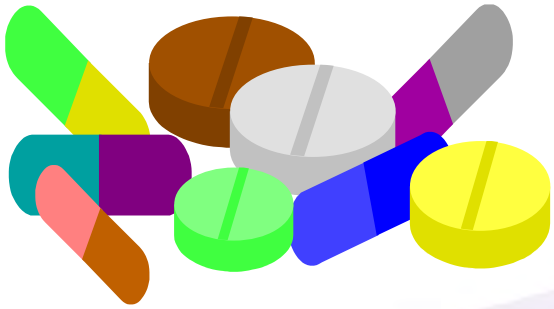
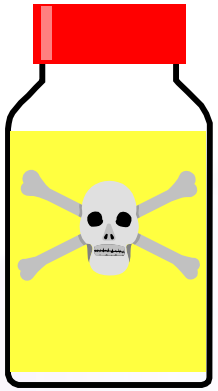
Background

- Insomnia is common among older adults, and the reported prevalence rate could be more than 60% (Gulia & Kumar 2018).
- Sleep loss in the elderly population is associated with increased frequency of accidents and falls, poor health status, and mortality (Chan et al., 2010).
- Given the adverse effects of prolonged use of hypnotics such as morning sedation, impaired balance, drug dependence, depression and amnesia (Buysse 2013; Gulia & Kumar 2018); the exploration of non-invasive and non-pharmacological complementary methods for insomnia among the elders is warranted.





History and Development of Auricular Therapy

- The ear is first mentioned in the earliest Chinese medical book, Yellow Emperor's Classics of Internal Medicine (黃帝內經), published more than 2,000 years ago.
- It states that the ear is related to all parts of the human body and internal organs, and that all meridians converge at the ear.

- In 1957, Dr. Paul Nogier, a well-known French neurosurgeon, made a careful study of the ear and found that the ear is thought to simulate an inverted fetus within the womb.

Figure: The ear represents a simulation of an inverted fetus within the womb (front and back).

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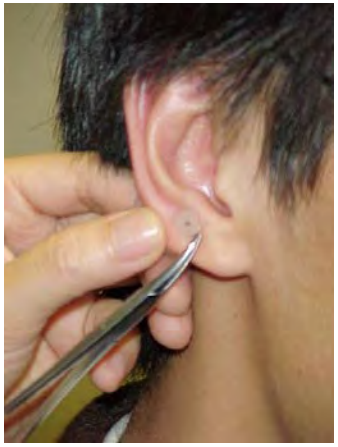
Auriculotherapy

- Auricular therapy (Auriculotherapy) is a therapeutic method by which specific points on the auricle are stimulated to treat various disorders of the body.
- AT is a specialised form of acupuncture in which the ear is viewed as a microsystem of the body (Oleson, 2014).
- In AT, different materials such as acupuncture needles, press-tack needles, semen vaccariae, magnetic pellets, or low-energy laser are applied on acupoints located on the external ear for therapeutic purposes.



Press needle
(埋針)


ON/OFF
INT
SEN
Pointer
Pulse
24/12/2011 15:25


28/12/2011 18:54


Pointer
Pulse
24/12/2011 15:25

- AT has gradually emerged as a popular intervention for treatment of cocaine dependence (Avants et al., 2000) or OA (Xu, 1992).

- The PI of this study has an extensive experience in conducting RCTs using magnetic pellets for AT (MAT) in the clinical treatment of insomnia in the elderly (Suen et al., 2002), low back pain (Suen & Wong, 2008), constipation (Li et al., 2010), and uncontrolled hypertension (Suen et al., 2010). Studies have demonstrated positive results of MAT in these trials.

Research Questions

(1)What is the effect of LAT (Laser AT) plus MAT (Magneto AT) on the improvement of sleep conditions and quality of life in the elderly with insomnia?

(2)What is the effect of using MAT or LAT alone on the improvement of sleep conditions and quality of life in the elderly with insomnia?

Methods

- This is a three-group randomised controlled and double-blinded study.
- Eligible subjects were randomly allocated to three groups by using a computer-generated randomised table and blocked randomisation in accordance with the equal proportion rule (1:1:1).
- Random coding was concealed from the subjects and the evaluator by using opaque envelopes.
- Subjects were recruited from elderly centres in Hong Kong by convenience sampling. A recruitment talk on AT was given to potential subjects in the targeted elderly centres.

Inclusion criteria

- Volunteers aged 65 years or above were recruited after preliminary screening if they have the following: difficulty falling or staying asleep and/or frequent nocturnal awakenings at least three nights per week; sleep disturbance lasting for a minimum of 6 months; and poor quality of sleep as indicated by PSQI score greater than five.
- All the subjects fulfilled the criteria stipulated by the ‘Diagnostic and Statistical Manual of Mental Disorders, fifth edition for the diagnosis of insomnia’ (DSM-5, 2013)

Exclusion criteria

(1) profound physical illness, such as stroke,

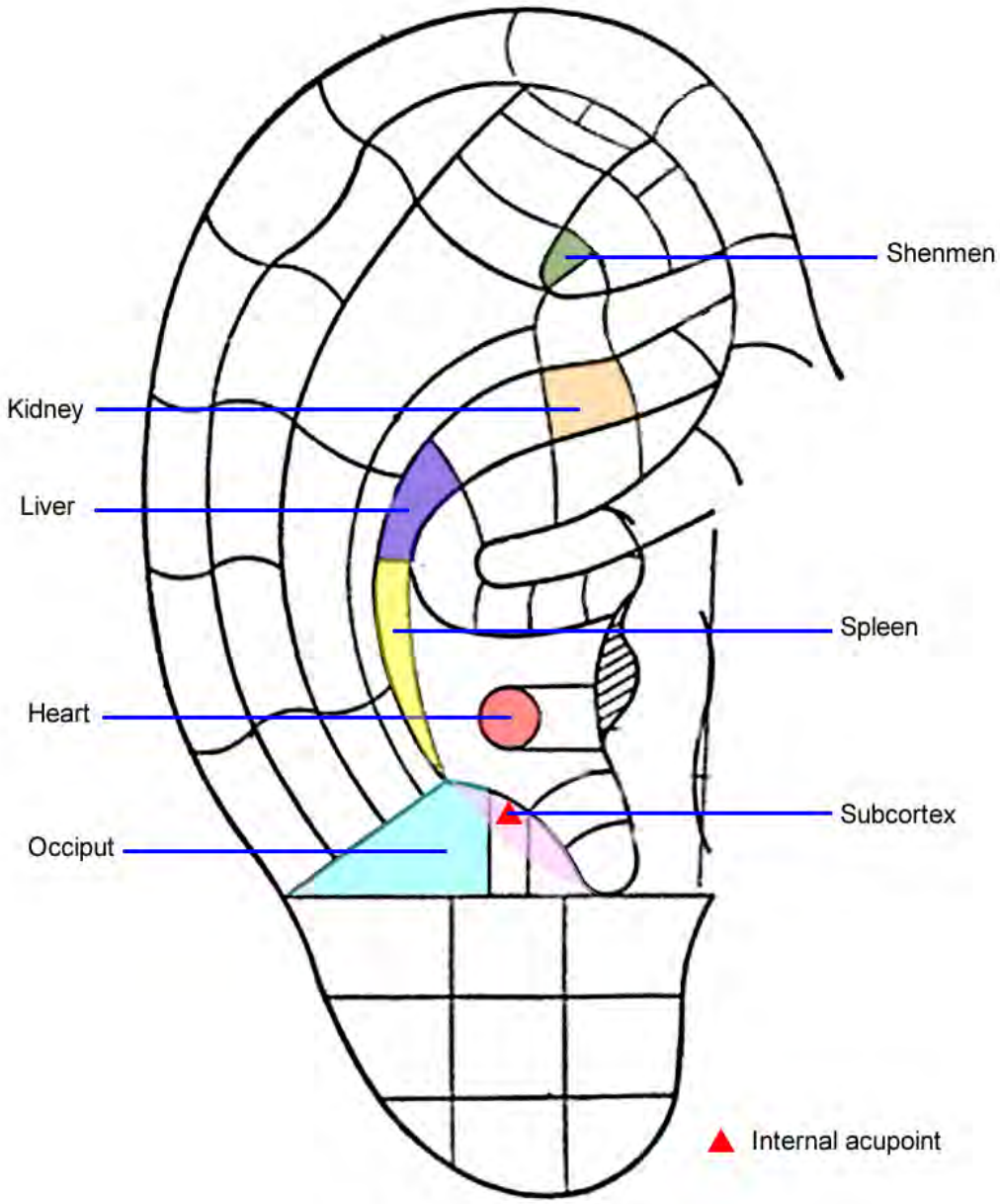
(2) serious neurological disease or psychiatric disorder, such as dementia and schizophrenia,

(3) having a hearing aid or pacemaker in situ (to prevent the magnetic pellets from interfering with the devices),

(4) receiving AT within the preceding 3 months,

(5) suffering from aural injuries or infections,

(6) inability to understand instructions or give consent.



Ear Shenmen
(tranquilize the mind)

Kidney
(tonify the essence)

Liver
(soothe the liver, emotion)

Spleen
(promote digestion and fluid drainage)

Heart
(calm the mind)

Subcortex
(harmonizes excitement and inhibition of the cortex)

Occiput
(treating headache & dizziness)

Group 1 (Placebo LAT + MAT)

- The laser device was switched to ‘power off’ mode (i.e. deactivated laser) for acupoint ‘stimulation’ to achieve blinding and placebo effect, before MAT. The subjects were asked to wear a pair of laser-protective goggles to ‘blind’ them during treatment.
- MAT was then applied by placing magnetic pellets on the selected acupoints. Each magnetic pellet has an average Gauss/pellet magnetic flux density of ~200 Gs (20 mT) and a diameter of 1.76 mm. The pellets were then applied to the acupoints.

Group 2 (LAT + placebo MAT)

- A laser device (Pointer Pulse™) was used for LAT. The device has a wavelength of 650 nm, an average output power of 2.5 mW, an energy density of 0.54 J/cm^2 for 1 minute and a pulse of 10 Hz, which is a common acceptable dosage for clinical use.
- LAT used low-energy laser therapy (LLLT), in which the energy level emitted from the device is comparable with the teaching pointer. The continuous mode of the device was used to directly treat the acupoints for 1 minute.

- Laser-protective goggles were provided to the subjects and the researcher for eye protection. A plaster centred with a small portion of Junci Medulla was given to mimic MAT.
- Junci Medulla is the dried stem of the perennial plant and is soft in texture. Junci Medulla was successfully adopted as a placebo in a previous study conducted by the PI because it did not induce any physical pressure on the acupoints of the ear.

Group 3: Combined AT

- The subjects received the combination of LAT and MAT. The procedures for applying LAT and MAT were identical with the descriptions above.

Procedures

- The auricle of every subject was cleaned with 75% isopropyl alcohol before therapy. Only one ear was treated at a time.
- The treatment was applied to the right ear in the first visit and then to the left ear in the subsequent visit and so on.
- We replaced the experimental objects (i.e. magnetic pellets for true MAT or Junci Medulla for placebo MAT) every other day, that is, three times a week (except Sunday) to prevent local irritation of the acupoints.
- The total treatment period was 6 weeks.

Validity and Reliability

- To ensure the accuracy of the identification of ear acupoints, intensive coaching by the PI (LS) is given to the research personnel administering the therapy, and return demonstration is required.
- The fidelity of the study was ensured by establishing the inter-rater reliability and accuracy of the ear point identification scheme used.
- To achieve observer blinding, the effects of the treatment was evaluated by another researcher (part-time Research Assistant) who was not knowledgeable of the type of treatment modality received by the participants.

Primary Outcomes

- PSQI (Pittsburgh Sleep Quality Index): This instrument is used to collect data related to the sleep patterns of the subjects. The total PSQI score ranges from 0 to 21, with a PSQI score greater than five indicating poor sleep quality. The PSQI has been translated in 55 languages. Chong and Cheung (2012) have validated the Cantonese-PSQI and have reported a high internal consistency of 0.75.

Secondary Outcomes

- Actigraphic monitoring (objective measurement): to collect sleep parameters, including sleep latency (minutes), waking after sleep onset (minutes), total sleep time (hours) and sleep efficiency (%). ‘
- Actiwatch’ Spectrum Plus Device with 0.025G ultra-high sensitivity and 32 Hz sampling rate was used. The subjects should wear the device on the wrist of the nondominant hand 24 hours a day for 7 consecutive days to determine the overall sleep conditions within a certain period.
- Removal of the actiwatch if needed should be recorded by the subjects in a logbook. Data were collected in every 30 second epochs. These epoch-by-epoch data were stored in the internal memory of the device until the stored information was downloaded to a computer. Actiware 6 Actigraph Analysis Software was used for sleep analysis.

- Quality of life: The Chinese (HK) specific SF-12 questionnaire was used to evaluate the quality of life of the subjects. This instrument has been found to have positive psychometric properties for use in the local population (Lam et al., 2005).
- Patient Health Questionnaire (PHQ-9) was also used. This instrument was validated as a useful tool for assessing depression status. The scores range from 0 to 27, and high scores indicate severe depression status (Martin et al. 2006). The scale has a Cronbach's alpha of 0.82 and was found to be a valid screening instrument for depression, with a recommended cut-off score of 8 (Liu et al. 2016).
- Subjects' expectations and satisfaction towards the therapy were evaluated using a 10-point scale, with high scores indicating high expectations/satisfaction towards the therapy.

Findings

- Data were collected from 11 centres for the elderly, and the recruitment rate was 88.6%. A total of 145 eligible subjects were randomly divided into three groups (group 1, 50 subjects; group 2, 46 subjects; and group 3, 51 subjects).

- The recruited subjects had an average age of 75.29 years (SD 6.99), with a mean duration of insomnia for 10.12 ± 10.67 years. The majority of the subjects (70.0%) did not take any medication for managing their sleep problems. The groups were essentially comparable and well balanced in terms of socio-demographic variables, including gender distribution, body mass index, education level, marital status, comorbid illnesses and regular medications taken.

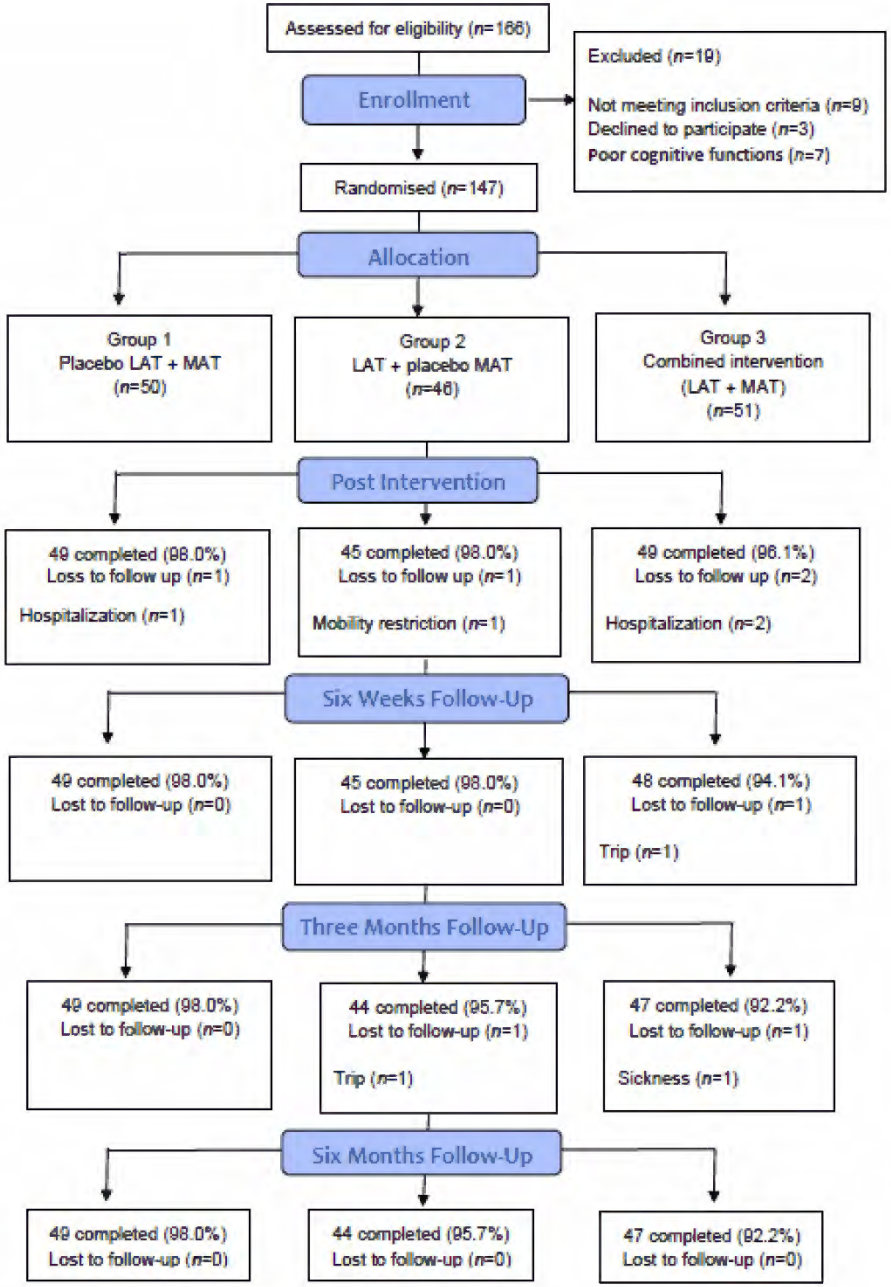


Fig 4: Flowchart of recruitment

Treatment Effect

- The differences in the primary and secondary outcomes of the three groups across different time points were compared through GEE model analysis, adjusted for age.
- In general, no significant differences were detected in the outcome measures (including PSQI, sleep parameters measured by actigraphic monitoring, SF-12 and PHQ-9) among the three groups.
- However, within-group comparisons indicated significant differences in all of the subjective measures, including PSQI, SF-12 (physical and/or mental components) and PHQ-9 for individual groups over time.
- When the sleep conditions were evaluated by actigraphic monitoring, significant differences in 'wake after sleep onset' (minutes) and 'sleep efficiency' (%) were only detected in subjects in Groups 1 and 3.
- The completers' analysis showed consistent findings on the primary and secondary outcomes of the trial.

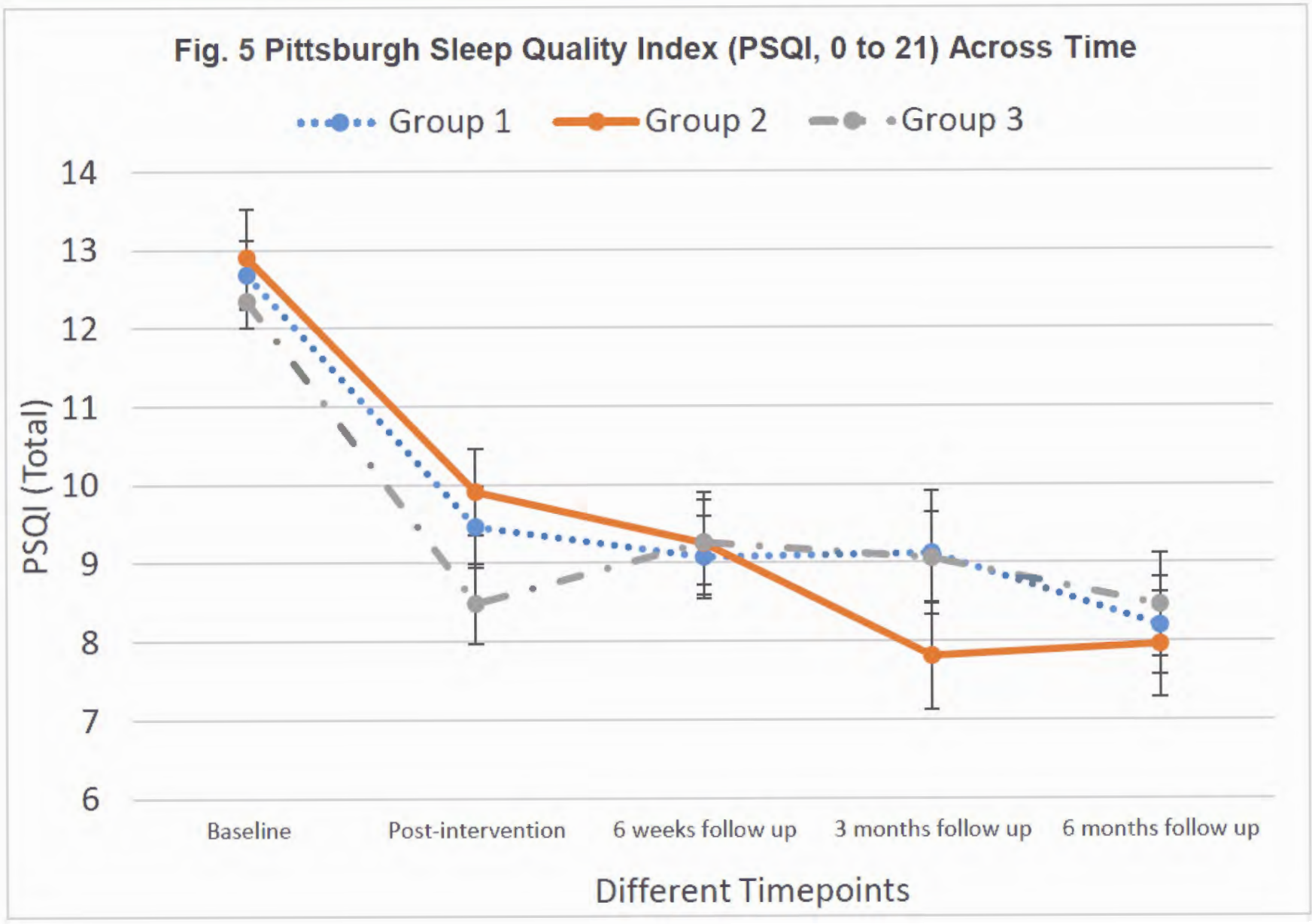


Fig. 5 Pittsburgh Sleep Quality Index (PSQI, 0 to 21) Across Time
Group 1
Group 2
Group 3
14
13
12
11
10
9
8
7
6
PSQI (Total)
Baseline
Post-intervention
6 weeks follow up
3 months follow up
6 months follow up
Different Timepoints

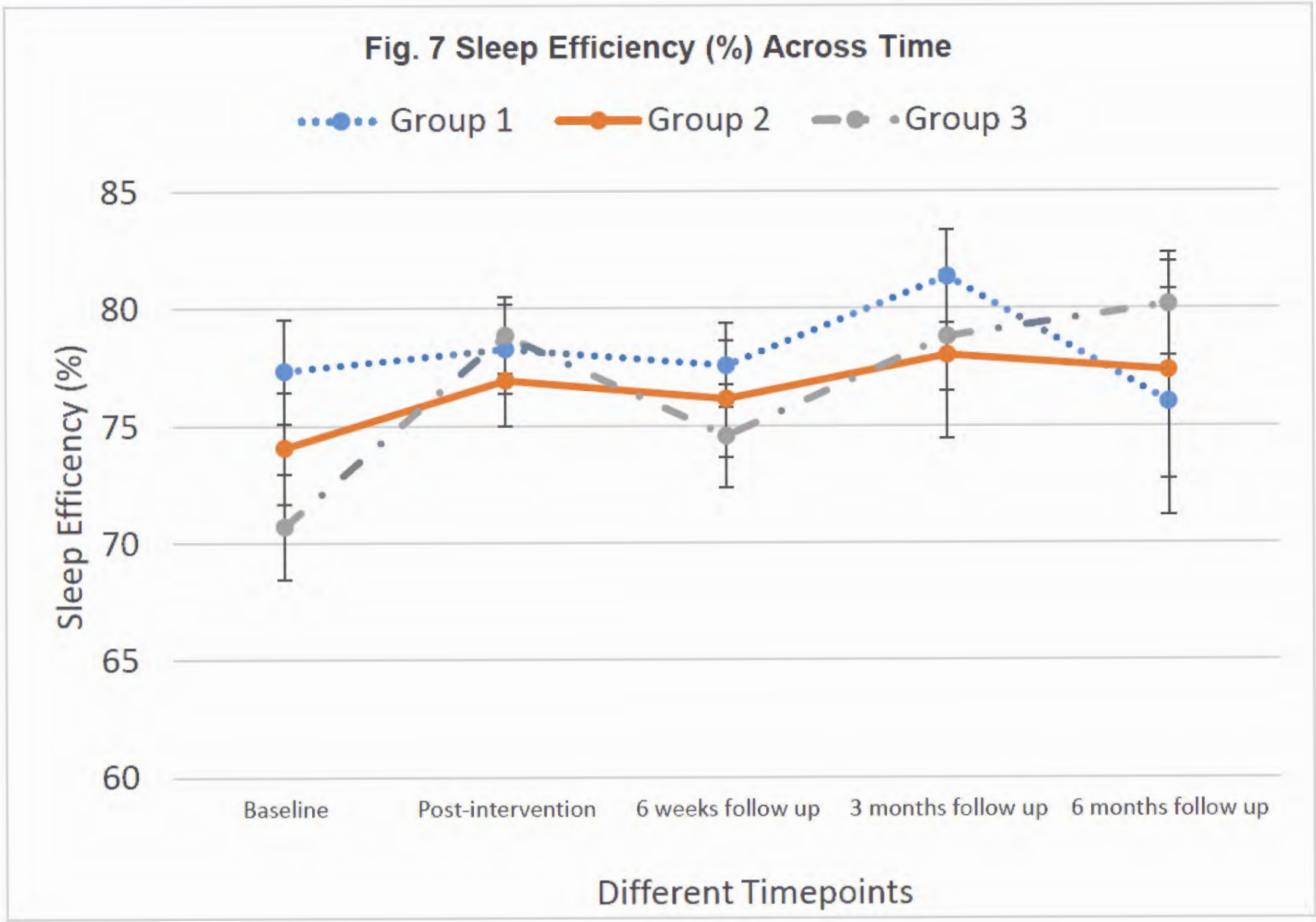


Fig. 7 Sleep Efficiency (%) Across Time
Group 1
Group 2
Group 3
85
80
75
70
65
60
Sleep Efficency (%)
Baseline
Post-intervention
6 weeks follow up
3 months follow up
6 months follow up
Different Timepoints

Conclusions

- This study provides valuable information regarding the therapeutic effect of different protocols using MAT, LAT or their combination.
- The treatment effects of the three protocols were comparable. Within-group comparisons indicated significant improvements in all of the subjective measures for individual groups over time. Such measures include sleep condition measured by PSQI, HRQOL (both physical and mental components of SF-12) and depression status.

- When the sleep conditions were evaluated by objective measures using actigraphic monitoring, significant deduction in the awakening time after sleep onset and increase in sleep efficiency were detected in subjects who received MAT (i.e. Groups 1 and 3) but not in those who received LAT alone.
- The combined MAT and LAT approach did not show any advantage over MAT alone.
- The findings indicate that a longer therapeutic course and more frequent administration of LAT may be considered in future trials to achieve the optimal treatment effect.
- In general, AT could be considered as a non-invasive approach with minimal adverse effects for managing sleeping problems among elders.

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Q&A