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# Effect of Thai instrumental folk music on blood pressure: A randomized controlled trial in stage-2 hypertensive patients

Supap Im-oun[a], Praew Kotruchin[b,*], Pimchanok Thinsug[b], Thapanawong Mitsungnern[b], Panor Techa-atik[a], Chatlert Pongchaiyakul[c]

[a] Accidental and Emergency Nursing Department, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, Thailand
[b] Department of Emergency Medicine, Faculty of Medicine, Khon Kaen University, Thailand
[c] Department of Internal Medicine, Faculty of Medicine, Khon Kaen University, Thailand

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ABSTRACT

*Background:* From epidemiologic data, half of hypertensive patients did not achieve the target blood pressure with pharmacotherapy, partly due to poor compliance. Music therapy is an adjunctive therapy which was proved effective for blood pressure reduction. We aimed to investigate the effect of Thai instrumental folk music listening on blood pressure in Thai hypertensive patients.

*Design, setting and subjects:* A randomized controlled trial, conducted in the stage-2 hypertensive patients at Srinagarind Hospital, Khon Kaen, Thailand.

*Methods:* One hundred-twenty participants were randomized to music listening group and control group (1:1). The music listening group was assigned to listen to Thai instrumental folk music once a day for one month.

*Outcome measures:* The primary and secondary outcome measures were home blood pressure (Day 0th and 30th) and office blood pressure (Day 0th and 120th), respectively.

*Results:* Home systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the music listening group were significantly reduced compared with baseline (−9.5 ± 7.1 mmHg (95%CI −11.43, −7.64) and −6.1 ± 5.7 mmHg (95%CI −7.51, −4.53), respectively). Both home SBP and DBP at day 30th of the music listening group were significantly lower than in the control group (−6.0 mmHg (95%CI −8.58, −3.40) and −3.15 mmHg (95%CI −5.20, −1.09), respectively), while the differences of office SBP and DBP between two groups were not significant.

*Conclusion:* This study demonstrated that Thai instrumental folk music listening was effective for SBP and DBP reduction in stage-2 HT patients. This therapy can be used as an alternating approach simultaneously with pharmacological treatment.

This trial was registered retrospectively after completion to ClinicalTrials.gov registration number: NCT03381820.

**What is known about the topic?**

- Poor control hypertension is associated with increased risk of fatal and non-fatal cardiovascular events. Unfortunately, due to low adherence and compliance of antihypertensive drugs, only 50% of patients achieved the blood pressure target. Existing studies have shown that music therapy was a promising adjunctive approach for blood pressure lowering. However, the effect of music therapy on systolic blood pressure and diastolic blood pressure was inconsistent among studies.

**What this study adds?**

– The results from this study demonstrated the favorable outcome of the Thai instrumental folk music listening for lowering the SBP and DBP in patients with stage-2 hypertension. It proves that music listening therapy is effective and safe as an adjunctive approach with pharmacological treatment, especially at the present time when lower BP target (< 130/80 mmHg) has been proposed by the latest hypertension guidelines for primary and secondary prevention of cardiovascular event.

* Corresponding author at: Emergency Medicine Department, Khon Kaen University, Mitraparp road, Muang, Khon Kaen, 40002, Thailand.
*E-mail address:* kpraew@kku.ac.th (P. Kotruchin).

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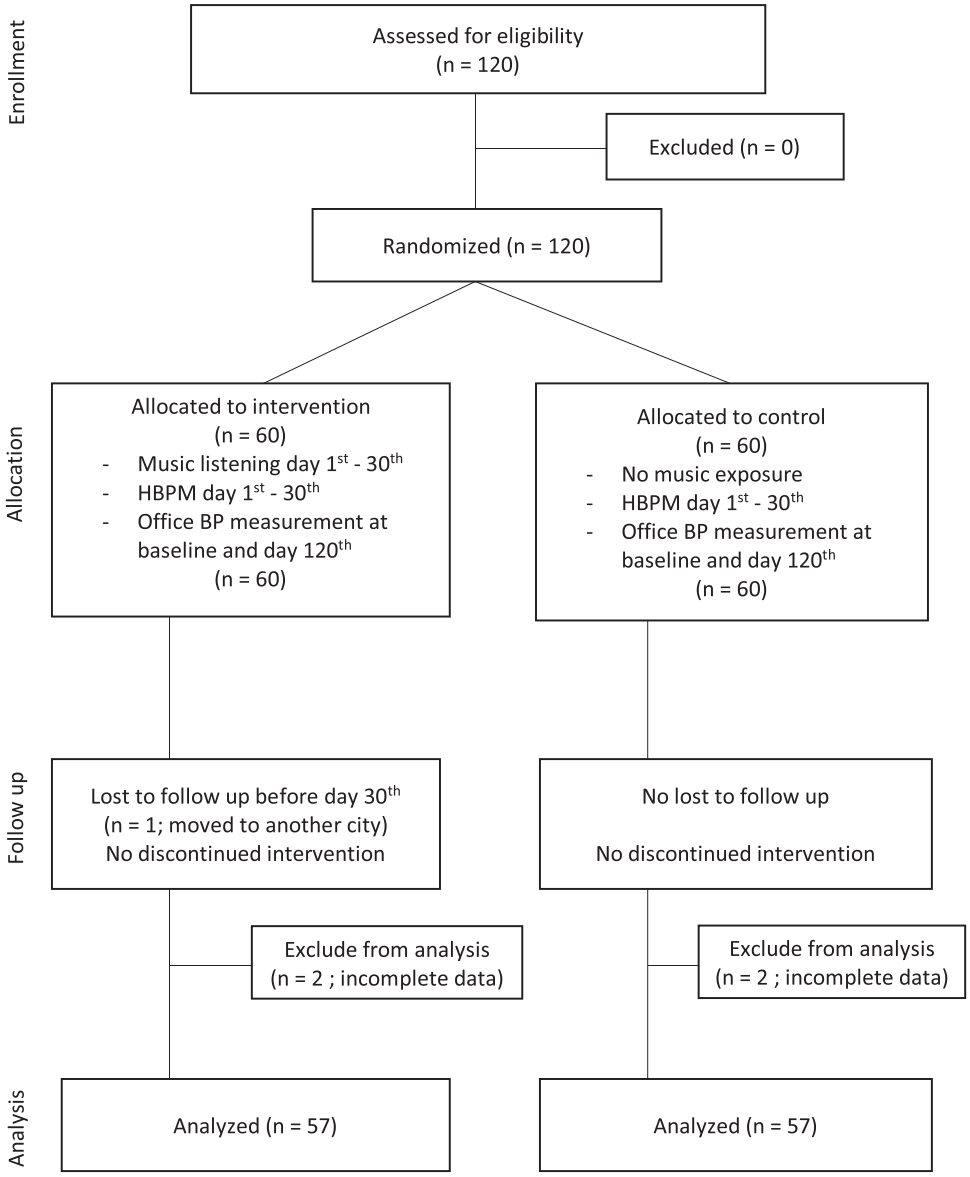


**Fig. 1.** *Consort diagram.* The Flow diagram of the progress through the phases of a parallel randomized trial of two groups.

## 1. Introduction

Poor control hypertension (HT) is associated with increased risk of fatal and non-fatal cardiovascular events.[1] However, due to low adherence and compliance of anti-HT drugs, only 50% of patients achieved the blood pressure (BP) target.[2] Existing studies have shown that the complementary therapy, namely, music therapy was a promising adjunctive approach for BP lowering. Previous studies reported that music therapy had a favorable effect on BP control.[3–5] However, the effect of music therapy on systolic BP (SBP) and diastolic BP (DBP) was inconsistent among the studies. A few systematic reviews and meta-analysis also stated a strong heterogeneity among the included studies.[3–6] Furthermore, although there were randomized-control trials that conducted in HT patients, most trials enrolled elderly patients with relatively lower BP at baseline.[7]

From the national health survey data, rate of uncontrolled HT (BP > 140/90 mmHg) in Thailand was very high (88%) for those undergoing conventional treatment.[8] Recently, the 2017 American College of Cardiology/American Heart Association Hypertension Guidelines recommends a lower BP target (≤130/80 mmHg) for primary and secondary prevention of cardiovascular events in adults.[9] According to the new BP target, the rate of uncontrolled HT is rising despite the available pharmacological therapy. Therefore, non-pharmacological intervention as the adjunctive therapy is necessary.

Thai instrumental folk music is unique and easy to familiarize. The melody is pleasant to the ear, outstanding with its rhythmic tinkling sound and representing a valuable cultural heritage. Therefore, it could be a good adjunctive treatment for hypertensive patients. The purpose of the current study was to conduct a well-controlled randomized trial to compare the effect of Thai instrumental folk music listening to an active control group on home BP and office BP in the individuals with stage-2 HT (BP > 140/90 mmHg).

## 2. Materials and methods

### 2.1. Study design and settings

This study was a parallel group, randomized controlled trial conducted at Srinagarind Hospital, a tertiary-care university hospital, located in Khon Kaen province in the Northeastern region of Thailand during 1st November 2015 to 31st May 2016. The ethical committee of Khon Kaen University approved the study protocol. The informed

consent was performed in all participants before enrollment. This trial was registered retrospectively after completion to ClinicalTrials.gov registration number: NCT03381820. The authors confirm that all ongoing and related trials for this intervention are registered.

### 2.2. Participants

The eligible participants were adults aged between 40 and 80 years old who were diagnosed stage-2 HT (defined by office SBP ≥140 mmHg and/or DBP ≥90 mmHg at first hospital visit) and were on stable anti-HT drugs for at least 3 months before enrollment. Pregnant women, white-coat HT, secondary HT and hearing loss or blind participants were excluded from the study.

### 2.3. Sample size calculation

Sample size for comparing means of SBP and DBP with repeated measures was calculated. We determined a significant level of 0.025 and 80% power of the test. Using the mean and S.D. of the control group and the intervention group of 140.9 ± 26.4 mmHg and 130.1 ± 28.1 mmHg, respectively.[10] The expected difference of SBP between the intervention group and control group was 10 mmHg.[10] Total numbers of participants were 156 (78 participants for each group).

### 2.4. Study protocol

#### 2.4.1. Randomization

Eligible participants who had already given inform consents were randomized into the intervention group (music listening group) or control group by block randomization (block of four (1:1), generated by a computer program) (Fig. 1). The investigators who involved in enrolling participants had no access to the randomization lists. Each randomization number was kept in the opaque-sealed envelope. The envelope was drawn and opened by the treatment investigators after history taking and physical examination were done. The treatment investigators and participants knew the results of randomization but the statistical-analyses investigator was blinded.

#### 2.4.2. Conventional treatment

Both participants in the music listening group and control group received anti-HT medication according to the standard HT guideline's recommendations.[9] Lifestyle modification to reduce BP was taught individually. The booklets about salt restriction, daily exercise, stress management and weight control were provided. Every participants were informed to take regular anti-HT medication even though the data about compliance was not collected.

#### 2.4.3. Thai instrumental folk music listening intervention

The Thai instrumental folk music was composed and edited by an experienced professor of Folk Music Department, Faculty of Arts, Khon Kaen University. It was slow-instrumental, 60–80 beats per minute and ranged between 40–60 dB. The entire music was 32 min length. The participants who were randomized into music listening group were assigned to listen to the music (MP3 format) once a day, by using earphones, from day 1st to day 30th at any time of day that was suitable with their lifestyles but not at the time of BP measurement. The study nurse made a phone call to check for compliance at 6O'clock in the evening every day. During day 31st–120th, the participants did not listen to the given music. The participants in the control group were requested not to listen to any kinds of music during day 1st to day 30th to control the possible effect of other music on the BP.

#### 2.4.4. Blood pressure measurement

Blood pressure level at the first HT diagnosis was collected from electronic medical records (Health Object, Srinagarind Hospital) for assessing the eligible criteria. After enrollment, the participants in both music listening group and controlled group were assigned to monitor home BP monitoring (HBPM) by using validated, Thai FDA-approved automatic BP devices (TD-3140B) from day 1st to day 30th (primary outcome). The study nurse trained every participants until they were able to do BP measurement correctly and confidently. HBPM was performed by the participants 2 times a day (in the morning before anti-HT drug administration and in the evening before dinner). At each time, 2 BP measurements were taken at 1-min intervals with the participant in a sitting position after 5 min of rest, and the average BP was recorded in a notebook, which was brought to the investigators at day 30th for statistical analyses.

The office BP was measured using an upper arm cuff oscillometric BP device (DINAMAP Pro 300, GE healthcare). The appropriate cuff size for individual arm circumference was used. Two BP measurements were taken at 1-min intervals with the participant in a sitting position after 5 min of rest, and the average BP was recorded. The baseline BP was measured before the randomization was done. The follow up BP was measured at day 120th (secondary outcome).

#### 2.4.5. Follow up

Participants were scheduled for follow up at day 30th and day 120th. At day 120th the office SBPs and DBPs were measured as described above. Data of anti-HT medication prescribed to patients at day 120th were collected from electronic medical records.

#### 2.4.6. Adverse event monitoring

All participants were informed to report minor and major adverse events that happen after the enrollment. For minor adverse events, each participants was informed to take note in a personal diary that was given after the enrollment and contact the study nurse as needed. For major adverse events, all participants were informed to contact the investigators by phone immediately. Participants who have life-threatening adverse events considered by the treatment investigators are to be withdrawn prematurely from the study for safety reason.

### 2.5. Statistical analysis

All analyses were based on intention-to-treat principle. Baseline characteristics data were shown as mean ± standard deviation (SD) or percentage. The $\chi 2$ test of independence was used to compare between groups for categorical variables. The Paired-T test was used to compare BP level within each group before and after the music intervention, and the analysis of covariance (ANCOVA), adjusted for baseline BP, was used to compare the BP level at day 30th and 120th between intervention and control groups. A probability value $< 0.025$ was considered statistically significant. All statistical analyses performed with STATA 10.1 registered for Khon Kaen University.

## 3. Results

Total of 120 participants were recruited. One hundred and fourteen participants were analyzed (57 participants in each group). Within 6 participants who were not included for analysis, five were unable to do HBPM regularly and one was lost to follow up (Fig. 1). There were prominent of females in both group. More than 60 percent of participants were below 60 years old. Mean age was 51.5 ± 8.5 and 51.8 ± 9.1 years old in music listening group and control group, respectively. Baseline home and office SBP and DBP of the music listening group were higher than the control group. Most participants had taken ≥1 antihypertensive drugs at baseline in both groups (Table 1).

After 30 days of the intervention in the music listening group, the mean difference of home SBP and DBP between day 30th and baseline were statistically significant, all $p < 0.01$ (−9.5 ± 7.1 mmHg (95%CI −11.43, −7.64) and −6.1 ± 5.7 mmHg (95%CI −7.51, −4.53), respectively). Regarding the office BP, the mean difference of both SBP

**Table 1**
Baseline characteristics.

| Measures | Music listening group N = 57 | Control group N = 57 | *p* |
|---|---|---|---|
| Age, y | 51.5 ± 8.5 | 51.8 ± 9.1 | 0.87 |
| Female, % | 57.9 | 64.9 | 0.56 |
| BMI, kg/m$^2$ | 24.7 ± 3.1 | 24.3 ± 3.6 | 0.56 |
| Occupation, n (%) | | | |
| Farmer | 2 (3.5) | 0 | |
| Merchant | 8 (14.0) | 5 (8.8) | |
| Housework | 9 (15.8) | 3 (5.3) | |
| Self-employed | 6 (10.5) | 7 (12.3) | |
| Government officer | 16 (28.1) | 30 (52.6) | |
| No occupation | 16 (28.1) | 12 (21.1) | |
| Current smoker, % | 14.0 | 17.0 | 0.87 |
| Alcohol drinking, % | 26.3 | 32.1 | 0.65 |
| Family history of hypertension, % | 61.4 | 57.4 | 0.81 |
| Diabetes, % | 22.8 | 29.6 | 0.55 |
| Hyperlipidemia, % | 38.6 | 46.3 | 0.53 |
| Number of current anti-HT medication, n (%) | | | |
| 0 | 5 (8.8) | 5 (8.8) | |
| 1 | 28 (49.1) | 29 (50.9) | |
| 2 | 19 (33.3) | 17 (29.8) | |
| > = 3 | 5 (8.8) | 6 (10.5) | |
| Baseline home SBP, mmHg | 137.3 ± 9.0 | 129.8 ± 10.7 | < 0.01 |
| Baseline home DBP, mmHg | 84.6 ± 8.1 | 76.1 ± 9.0 | < 0.01 |
| Baseline office SBP, mmHg | 142.5 ± 9.1 | 140.5 ± 8.5 | 0.22 |
| Baseline office DBP, mmHg | 87.3 ± 9.0 | 79.4 ± 12.2 | 0.03 |

and DBP between day 120th and baseline were also statistically significant, all $p < 0.01$ ($-10.8 \pm 19.0$ mmHg (95%CI $-15.84$, $-5.73$) and $-5.9 \pm 12.7$ mmHg (95%CI $-15.84$, $-5.74$), respectively). While in the control group, the mean difference of home SBP and DBP between day 30th and baseline were not statistically significant ($1.1 \pm 10.5$ mmHg (95%CI $-1.69$, 3.87) and $-0.2 \pm 5.5$ mmHg (95%CI $-1.24$, 1.68), respectively). Similarly, the mean difference between office SBP and DBP between day 120th and baseline were also not statistically significant ($-2.9 \pm 17.5$ mmHg (95%CI $-7.56$, 1.74) and $-3.02 \pm 18.2$ mmHg (95%CI $-7.89$, 1.81), respectively) (Fig. 2).

After adjusted with baseline BP, both home SBP and DBP at day 30th were significantly lower in the music listening group than in the control group, all $p < 0.01$ ($-6.0 \pm 1.3$ mmHg (95%CI $-8.58$, $-3.40$) and $-3.2 \pm 1.0$ mmHg (95%CI $-5.20$, $-1.09$), respectively). However, there was no significant difference of the office SBP and DBP at day 120th between both groups, although the mean office SBP of the music listening group was lower than in the control group ($-5.8 \pm 3.0$ mmHg (95%CI $-11.77$, 0.17)).

At the end of the study, titration of the anti-HT medication during 120 days of follow-up was not different between both groups. Majority of patients had no change in prescription (79.5% and 86% in music listening and control group, respectively), 5/54 (9.3%) and 3/57 (5.3%) needed up-titration, and 3/54 (5.6%) and 3/57 (5.2%) need down-titration, in music listening and control group, respectively. Three patients (5.6%) in music listening group and 2 patients in control group could stop medication, and there was no statistical difference between two groups. There was no adverse event reported throughout the study period.

## 4. Discussion

The main findings of the present study is that the Thai instrumental folk music listening is effective for lowering both home and office BP. After 30 days of the music listening, there were 9.5 and 11-mmHg reduction of home and office SBP, respectively. There was also 6-mmHg reduction of both home and office DBP. The results are statistically and clinically significant.

Hypertension is a global burden. It is a leading cause of death and disability-adjusted life years.[11,12] In stage-2 HT patients, a combination of different class of anti-HT drugs was recommended for target BP achievement.[9,13] However, it was not uncommon that most patients had low adherence and compliance, partly due to intolerability of medication side effects.[14–16] Therefore, alternative treatment, i.e., music therapy has been investigated as an adjunctive treatment.

The present study provides a strong support for the effectiveness of Thai instrumental folk music listening for BP lowering in patients who were diagnosed stage-2 HT. The results of this study is in good agreement with a study of Bekiroglu et al., which found beneficial effect of the 28-day Turkish classical music listening on both SBP (128.17 mmHg vs 115.17 mmHg, pre and post music intervention, respectively) and DBP (77.50 mmHg vs 70 mmHg, pre and post music intervention, respectively), all $p < 0.01$.[7] However, in the Turkish study, when compare SBP at day 28th between the intervention group (music exposure 25 min) and the control group (rest for 25 min), there was no significant difference (115.17 mmHg vs 114.67 mmHg, $p = 0.382$). This results are different from the present study which found significant difference of both SBP and DBP at day 30th between intervention and control groups. This can be explained by the different management of the control group between these two studies. In the Turkish study, resting for 25 min before BP measurement in the control group can result in BP reduction due to systemic vasodilatation.[17] Therefore, the control group was not completely control from BP lowering intervention. In the present study, the control group and the intervention group were informed to rest equally for 5 min before BP measurement. Therefore, the difference of BP between the intervention and control group was more pronounced.

Tang et al. studied the effect of audio relaxation program in elderly HT patients (mean age 85 years old) and found that 12-min Revitalizer II (audio relaxation program) and 12-min Mozart music can both reduce SBP and DBP at 5 min after the program ended.[8] But when followed for 1 and 3 months, there was no significant difference of SBP and DBP from baseline due to poor compliance (54–66%). This is inconsistent with the results of the present study which showed the beneficial effect of the music listening intervention through day 30th. The advantage of the present study is having the study nurse scheduled a daily phone call to the participants to remind them of the music listening and BP measurement.

A meta-analysis of the classical music therapy highlighted $-6.58$ mmHg reduction in SBP (95% CI: $-9.38$ to $-3.79$, $p < 0.05$) in music group, however, there was no significant difference in DBP.[3] The present study exhibited a larger magnitude of SBP reduction within the music group (mean reduction of $-9.5 \pm 6.7$ mmHg) as well as the significant reduction of DBP. This might explain by the different in types of the music intervention used among studies. Folk music in the present study may lead to some advantages over classical music due to patient's familiarity with the melody, instruments and rhythm. According to a trial that determined the efficacy of familiar music during colonoscopy, patients who listened to self-selected music during procedure had lower anxiety, heart rate and blood pressure.[18] Another systematic review on music therapy for relieving anxiety and pain suggested the slow music, 60–80 beats per minute with a minimum of 30-min length,[19] which similar to the music used in this study.

For long-term outcome, we measured office SBP and DBP at day 120th (90 days after the music intervention stopped) to investigate the legacy effect of music listening for BP reduction. The office SBP and DBP at day 120th were significantly lower from baseline in the intervention group, but not in the control group. However, there was no significant difference of the SBP and DBP between two groups. Since the present study did not control the confounding factors during long term follow up, there may be some factors such as food consumption, daily activities and stress presented as confounding factors in both intervention and control groups. The future study with more rigid long term protocol is required to prove the possible legacy effect of music listening therapy.

How music modulates BP remains imprecise. There are several

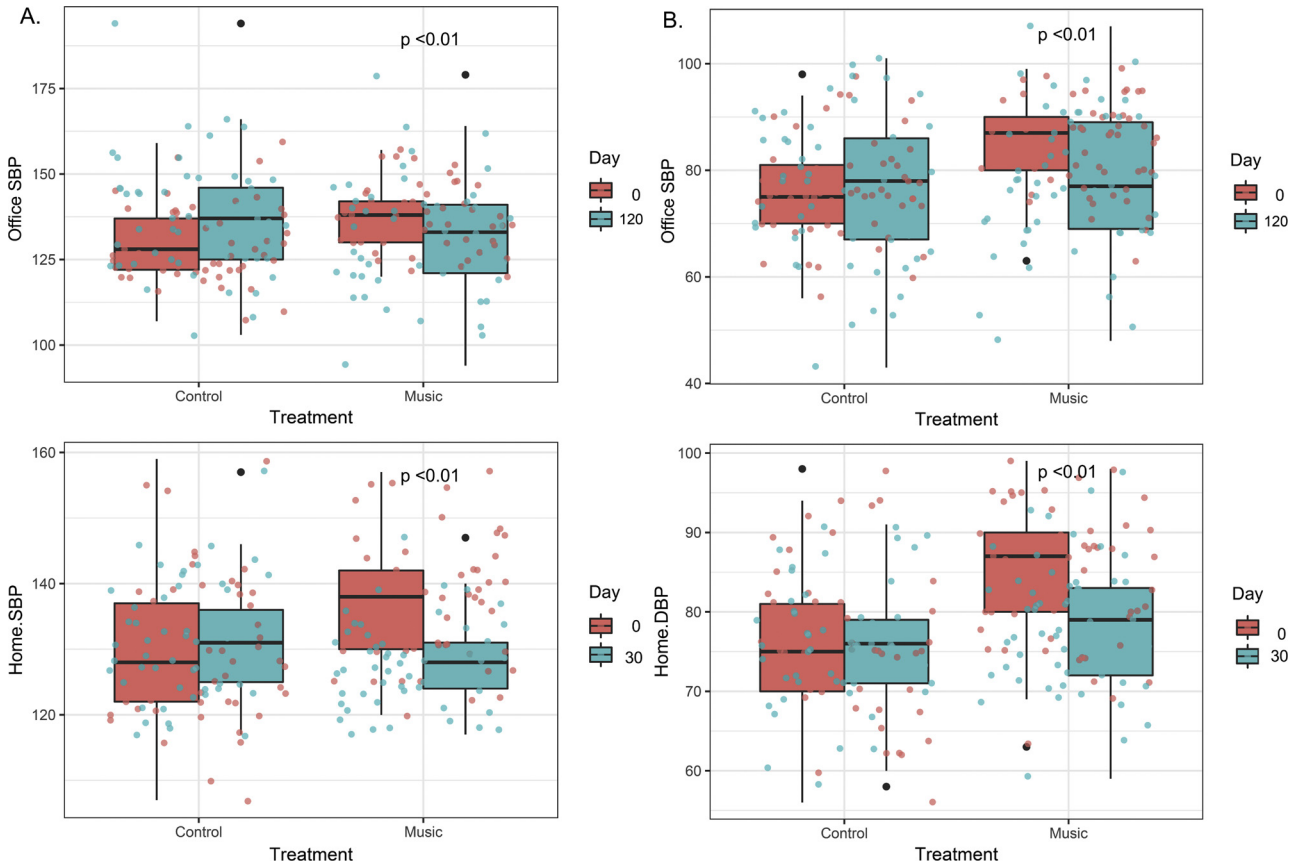


**Fig. 2. A**. *Systolic blood pressure (SBP) box plots*. The box plots show means of office SBP at day 0 (orange) and day 120th (green) and home SBP at day 0 (orange) and day 30th (green) of the intervention (music) and the control group (control). In music group, the mean difference of home SBP between day 0 and day 30th and office SBP between day 0 and day 120th were statistically significant. In the control group, the mean difference of home SBP between day 0 and day 30th and office SBP between day 0 and day 120th were not statistically significant. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

**B**. *Diastolic blood pressure (DBP) box plots*. The box plots show means of office DBP at day 0 (orange) and day 120th (green) and home DBP at day 0 (orange) and day 30th (green) of the intervention (music) and the control group (control). In the music group, the mean difference of home DBP between day 0 and day 30th and office DBP between day 0 and day 120th were statistically significant. In the control group, the mean difference of home DBP between day 0 and day 30th and office DBP between day 0 and day 120th were not statistically significant.

accountable mechanisms of music for BP reduction. In general, listening to music provided physical and mental relaxation.[20] The releasing of endorphins and the feeling of well-being was induced by listening to music by triggering psychological response on the limbic system.[21,22] Thoma et al., described the mechanism of music on vital signs and hormones. They found that music lessened the degree of psychological stress response by measuring the salivary cortisol.[23] In addition, the plasma catecholamine and plasma renin activity were also decreased after listening to music, explaining the lower sympathetic tone that involved both heart rate and blood pressure.[4]

The strength of this study was that we measured both home BP and office BP for the primary outcome. This study monitored short-term effect of music listening by HBPM which was unique and advantageous. Since, HBPM has better correlation with future CV events than office BP. Furthermore, it represents BP without external stress and eliminates the white-coat phenomenon which is caused by the environment of hospital.[24] However, the present findings should be interpreted in the context of potential limitation. Firstly, the number of participants were lower than the calculated sample size due to study period limitation. Second, the data were obtained from participants in Khon Kaen, Thailand, among whom; cultures and backgrounds were different from other ethnicity and data on lifestyles including salt intake, exercise and stress were not collected and analyzed. Third, participants and doctors were not blinded and may lead to the Hawthorne effect and intervention bias. Finally, the major focus of this study was on the reduction of BP level, not on the hard CV outcomes, further study might be necessary to determine the effect of music listening on the future CV risk reduction.

## 5. Conclusion

Thai Instrumental folk music listening was effective for SBP and DBP reduction in patients with stage-2 HT. The participants in the present study reported no adverse event during the study period. This brings to the conclusion that music listening therapy is effective for BP reduction, easy to apply and the most importantly, it is physically and mentally safe.

This therapy can be used as an alternating approach simultaneously with pharmacological treatment for achieving target BP in HT patients.

## Conflict of interest statement

The authors declare that there is no conflict of interest regarding the paper entitled “Effect of Thai instrumental folk music on blood pressure; a randomized controlled trial in stage-2 hypertensive patients”.

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