https://doi.org/10.1016/j.sleep.2018.07.025

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Effects of Zero-time Exercise on inactive adults with insomnia disorder: A pilot randomized controlled trial

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Number of tables: 4
Number of figures: 1
Total number of words: 4,931 (excluding title page, abstract, keywords, acknowledgements, and references)

Conflict of interests: All authors declared that there is no conflict of interest.

Author contributorship: WFY, THL and AYKL conceived and designed the trial. THL and AYKL established the zero-time exercise protocol. KPS and YYH reviewed the sleep hygiene education instructions and trained the instructor. AKYL and YTC performed the zero-time exercise and sleep hygiene education training courses, respectively. YMY conducted the assessments. WFY and YMY analysed the data and drafted the manuscript. THL, AYKL, and LMH revised the manuscript. All authors approved the final version accepted for publication.

Abstract

Objective: To evaluate the feasibility and clinical effects of a lifestyle-integrated exercise, namely zero-time exercise (ZTEx), on improving insomnia in inactive adults with insomnia disorder.

Methods: In this pilot randomized controlled trial, 37 physically inactive adults (mean age: 49.9 years; SD: 13.6 91.9% female) fulfilling the diagnostic criteria of insomnia disorder recruited from the community were randomized to ZTEx training or sleep hygiene education (SHE) groups. Subjects in the ZTEx group (n = 18) attended two 2-hour training lessons to learn ZTEx and practiced daily for 8 weeks. Subjects in the SHE group (n = 19) attended two lessons of the same schedule and duration. The primary outcome measure was the Insomnia Severity Index (ISI).

Results: The ZTEx group had lower ISI scores than the SHE group, with large between-group effect size of 0.93 to 1.10 at week 2, 4, 6, and 8, but the difference became non-significant at week 8, suggesting the loss of efficacy 2 months after the training. For secondary outcomes, no significant between-group differences were found in sleep parameters by sleep diary or objective actigraphy. The adherence to ZTEx training course was satisfactory, with 83% of the group completing two sessions and 78% of practicing ZTEx for 5 days or more per week during the 8-week intervention period.

Conclusion: The simple and brief ZTEx training showed high acceptability and exercise compliance and first evidence of efficacy in reducing insomnia severity in inactive adults with insomnia disorder. Fully powered confirmatory trials with longer follow-up are justified.

Trial registration number: ClinicalTrials.gov, #NCT03155750

Keywords: Lifestyle-integrated exercise; Sleep; RCT; Sedentary; Physical activity; Actigraphy.

INTRODUCTION

Around 9% to 15% of adults have insomnia symptoms with daytime functioning impairment [1]. Hong Kong is the most Westernized and urbanized city in China, and according to the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition) (DSM-5), the prevalence of insomnia was 10.8% [2]. Patients with insomnia experience negative consequences resulting in heavy social and economic burdens [3].

A recent meta-analysis of 66 clinical trials showed that regular physical exercise has small beneficial effects on total sleep time, sleep efficiency, sleep onset latency, and sleep quality, with small to medium effect size (Effect size, ES ranged 0.25-0.74) [4]. Another systematic review of 13 randomized controlled trials (RCTs) found that resistance exercise showed small-to-moderate effects on improving sleep quality or insomnia symptoms (ES, ranged 0.26 – 0.6) [5]. However, the previous trials focused on healthy subjects or poor sleepers, but not subjects with insomnia diagnosis [4].

To date, only four RCTS on subjects fulfilling well-defined insomnia criteria reported positive effects of exercise on relieving insomnia [6-9]. These studies examined the effects of brisk walking [6, 7], regular and acute aerobic exercise [8, 9]. However, these studies were limited by small sample size, and lacked essential sleep measures in insomnia trials. Moreover, the exercise was intensive and participants were required to commit additional time and effort in order to be eligible for the trials. Therefore, it is not surprising that our survey showed only 6.1% of adults who met the diagnostic criteria of insomnia used exercises to alleviate insomnia, which was lower than that of taking Chinese herbal medicine (23.0%), prescribed medications (17.6%) and even alcohol (8.4%) [10].

Lack of time is the most frequently reported barrier that prevents people from initiating and/or maintaining exercise, followed by financial cost, limited access to facilities, and dislike of performing vigorous exercise [11]. The lifestyle-integrated approach of incorporating exercise into daily activities has been proposed to overcome the barriers of exercise, such as climbing stairs rather than using an elevator. Integrating exercise into daily routine is simple and requires less time and cost, and serves as a lower-entry level exercise than conventional vigorous exercise [12]. An RCT in Belgium showed that lifestyle-integrated physical activity program had similar effects to structured exercise program for improving physical fitness in sedentary older adults [13]. However, at 2-year follow-up the structured exercise group showed a decrease in cardiorespiratory fitness, muscular fitness, and functional performance but the

lifestyle physical activity group did not. The lifestyle-integrated physical activity program was suggested to have higher compliance in the long run as they did not require extra access to facilities[13]. The lifestyle-integrated exercise may be a useful intervention to increase physical activity level in individuals with insomnia. However, to our knowledge, there were no studies on lifestyle-integrated exercise interventions for insomnia disorder.

Since 2015, in the Hong Kong citywide project titled “FAMILY: A Jockey Club Initiative for a Harmonious Society” (the FAMILY Project), a lifestyle integrated exercise - "Zero-time Exercise" (ZTEx) has been created to promote the incorporation of simple exercises into daily life and habituated activities through a series of train-the-trainer workshops to conduct various community-and family-based ZTEx programs for community participants [14]. ZTEx refers to simple movements and stretching, which is of low intensity and can be increased to moderate intensity. ZTEx does not require extra time (hence zero-time), money, and equipment (3 Zeros) and can be done anytime, anywhere and by anybody (3As) [14]. ZTEx has been designed for easy integration into daily routines. Examples include raising both legs above the ground with simple movement, stretching or foot pedaling when people are sitting while waiting, reading, watching TV or commuting; upper-body movements and stretching while doing sedentary work, standing and walking. ZTEx is attractive to busy people and those who believe that they are too busy to start exercising. Preliminary data of an intervention study on 53 social service workers found that after a two-session (total 4 hours) ZTEx training workshop, there were significant increases in the number of days of having exercise while sitting and standing at 3-month follow-up [15].

The present pilot RCT aimed to examine the feasibility of offering a ZTEx training program to improve sleep problems in inactive adults with insomnia disorder using sleep hygiene education as the control and to derive preliminary evidence of effectiveness. We hypothesized that subjects who receive an 8-week ZTEx training program would have better improvement in insomnia symptoms, as measured by the insomnia severity index (ISI), compared with subjects who received sleep hygiene education.

METHODS

Design

A two-armed, assessor-blinded RCT was conducted to assess the effectiveness of ZTEx training using sleep hygiene education (SHE) as the control in an intervention period of 8 weeks. Participants were randomly assigned to ZTEx training or SHE at a 1:1 ratio. A computer-

generated randomization list with a random block size of 4 to 6 was prepared. The group allocation was enclosed in sequentially numbered, opaque and sealed envelopes. Both ZTEx training and SHE sessions were held in a classroom at the School of Nursing, Hong Kong Polytechnic University. Research ethics approval was obtained from the local ethic review board (HSEARS20170405002). The trial was registered in ClinicalTrials.gov (ClinicalTrials.gov identifier: #NCT03155750) and all the study procedure followed the protocol in the register. This RCT was conducted and reported following CONSORT.

Subjects

Subjects with insomnia were recruited through recruitment posters at universities, social network agencies, and advertisements of a radio program from June to September 2017. Eligible subjects (1) were adults aged 18–65 years; (2) were Chinese Hong Kong residents capable of Cantonese or Putonghua communication; (3) fulfilled the DSM-5 diagnostic criteria of insomnia disorder (primary insomnia) according to a validated diagnostic tool, Brief Insomnia Questionnaire (BIQ) [16], which included difficulties in falling asleep, difficulties in staying asleep, or early morning awakening associated with clinically significant impairment in daily living for at least 3 months; (4) scored at least 10 points in the ISI, which is an optimal cutoff (86.1% sensitivity and 87.7% specificity) for detecting insomnia cases in the community sample [17]; (5) were willing to provide informed consent and comply with the trial protocol; (6) were ambulant and independent in daily activities; and (7) had either less than 150 min of moderate physical activity or 75 min of vigorous physical activity per week, or an equivalent combination of both [18].

Individuals were excluded if they (1) their insomnia might be due to specific medical conditions, side effects of medication intake, or other sleep disorders; (2) they used medication or psychotherapy for insomnia or other psychiatric disorders; (3) they had psychiatric disorders screened by DSM-IV structural clinical interviews, including generalized anxiety disorder, major depressive disorder, posttraumatic stress disorder, and psychosis; (4) they had impaired cognitive functioning for providing consent or understanding instructions (scored <22 in Hong Kong Montreal Cognitive Assessment); (5) they were shift workers; (6) their body mass index was 27.5 or above [19]; and (7) they had unsafe conditions and were not recommended for exercising by physicians.

Instructors

The ZTEx instructor was a registered nurse and a registered polysomnographic technologist (AYK Lai) with experience of teaching ZTEx in the community. SHE was taught by another registered nurse (LYT Chan) who had received training for delivering sleep hygiene by a clinical psychologist (FYY Ho).

Intervention

Subjects attended two 2-hour sessions of ZTEx training or SHE in a small group size of 5 to 7 to ensure the mastery of training contents, within-group interaction, and sufficient contact time with the instructor. The two sessions were held with one week in between. Subjects were instructed to practice ZTEx, follow sleep hygiene procedure daily during the 8 weeks of the trial period, and record their practice on an exercise logbook or sleep hygiene logbook. Subjects in the SHE group (controls) received ZTEx training after the 8-week assessment as compensation and vice versa.

ZTEx training

Training materials were developed by Lam *et al*. (2016), and each subject was provided with a handout with step-by-step illustrations. **Table 1** summarizes the training content. The first session (2 hours) aimed at motivating subjects for behavioral changes and promoting the mastery of ZTEx. The consequence of physical inactivity (risk perception), self-efficacy of doing ZTEx, and the association between behavior and positive outcomes were covered. The group training of ZTEx was offered with examples, explanation of specific purposes and benefits (see Appendix 1 for the details). Subjects were invited to set realistic goals, plan possible actions, and incorporate physical exercises into daily routine activities with the assistance of instructors; for examples, starting simple exercises while sitting or standing during waiting, watching TV, commuting or doing sedentary work. We demonstrated 10 different types of ZTEx such as simple stretching, and limb movements while sitting, standing or walking, and requested that they practice these activities with us.

During the second session (2 hours; 1 week after the first session), the subjects shared experiences and barriers in doing ZTEx. Any positive changes were highlighted, and possible suggestions were discussed. The mastery of ZTEx in the subjects was inspected using a pre-designed checklist, and any discrepancy of technique was corrected. At the end of the session, the instructor provided a summary of the course and answered queries regarding ZTEx.

Treatment fidelity

The subjects' mastery of ZTEx was evaluated by the course instructor using a fidelity checklist, which consisted of three domains: frequency, strength, and techniques of ZTEx. Any barriers of practicing ZTEx identified were discussed. Phone contact by research assistant was provided to subjects for further queries regarding ZTEx.

Control intervention (SHE)

The treatment duration and frequency of SHE group were the same as that of ZTEx training (two 2-hour sessions, 1 week apart, **Table 1**). Each subject had a training handout (8 pages) about activity schedules and sleep hygiene instructions. The instructor introduced basic facts about sleep and insomnia; enhanced the understanding of own sleep habit through the Sleep Hygiene Practice scale [20], Caffeine Knowledge quiz [21], and impact of poor sleep hygiene on maintaining sleep problems; and illustrated a role-model example of sleep–wake schedule. Sharing of sleep problems and possible solutions were encouraged.

During the second session, the course content and home practice experience of subjects were reviewed. Local statistics regarding insomnia were shown and the rationale of each instruction was discussed. Participants completed a "true/false" quiz regarding some facts of sleep for testing the understanding on sleep hygiene instructions of subjects. A course summary and Q&A session were arranged at the end of the session. Additional details regarding the content of the SHE course can be found in our previous study in which SHE was used as a control group [22].

Telephone follow-up

During the 8 weeks of trial period, research assistants made a 2-minute follow-up call twice a week in both groups to enhance the compliance and to remind recording their practice in their logbook. The research assistants were aware of the group allocation but they did not perform outcome assessment.

Outcome assessments

The ISI, the primary outcome, was assessed at baseline and weeks 2, 4, 6, and 8. The objective outcomes of sleep parameters and handgrip strength were assessed at baseline and week 8. Other assessments including Hospital Anxiety and Depression Scale (HADS), 20 itemed Multidimensional Fatigue Inventory (MFI-20), Short-Form Six-Dimension (SF-6D), moderate and vigorous intensity physical activities level were performed at baseline, week 4

and week 8. Outcome assessments were measured by an assessor who was blinded to the group allocation. The acceptance of training course and adverse events were assessed by instructors who were not blinded to the group allocation.

Subjective measures

Primary outcome measure

The ISI is a validated, self-reported scale, ranging from 0 to 28, with seven items rating the severity of insomnia symptoms and the associated daytime impairment in a 5-point Likert scale [23]. The Chinese version of ISI used in this study demonstrated good internal consistency (Cronbach alpha=0.83) in our previous study[24].

Secondary outcome measures

The 7-day standardized sleep diary recorded the daily bedtime and wake time, from which the total time in bed (TIB) was calculated [25]. Subjects were required to estimate sleep-onset latency (SOL), wake after sleep onset (WASO), and total sleep time (TST), and sleep efficiency (SE) was then estimated (TST/TIB ×100%). The HADS, a 14-item self-rated questionnaire, evaluated the severity of depressive and anxiety symptoms [26]. A score of 8 or higher in depression or anxiety subscales indicates the presence of depressive/anxiety symptoms. A validated Chinese HADS with Cronbach's alpha of 0.86 was used [27]. The severity of fatigue was assessed by the 20-item multidimensional fatigue inventory (MFI-20)[28]. The MFI-20 score ranged from 20–100 with a cut-off of 61 or above indicating severe fatigue. Sufficient validity and reliability of the Chinese version MFI-20 were reported (Cronbach's alpha of 0.89 and test–retest reliability of 0.73) [29].

Objective measures

Actigraphy

Actigraphs (Motionlogger Micro Watch; Ambulatory Monitoring, Inc., Ardsley, NY, USA), a watch-like accelerometer–microprocessor device, measure physical movements that estimate the wake and sleep states based on the association between movement and wakefulness/sleep [30]. To collect objective sleep outcome data, subjects were asked to wear an actigraph on their non-dominant wrist prior to their bedtime for 7 consecutive days. Evidence supporting wrist actigraphy as a valid objective measure in studying insomnia was found, and it has been shown to be highly accurate for estimating sleep parameters [30].

Handgrip strength

Muscle function is a key indicator of the physical fitness of an individual, especially the muscle strength of handgrip [31]. The strength of sitting isometric handgrip was assessed with a hand dynamometer (Jamar Plus Digital Dynamometer; Sammons Preston, Bolingbrook, IL, USA) in the sitting position with the feet of the subjects flat on the floor. Maximal power was applied for 3 seconds (absolute handgrip strength) with the forearm and wrist in the neutral position and flexed at the elbow at 90° [32].

BMI

Body weight was measured with the subjects wearing minimal clothing and no shoes. Height was measured with a stadiometer. Body weight (kg) of each participant was divided by the squared height (m^2) to calculate BMI.

Assessment of physical activity level

Subjects were instructed to recall the time spent on both moderate and vigorous intensity physical activities (MVPA) in the past 7 days. Definitions involving the intensity of activities were provided as follows: “moderate-intensity activities are associated with higher heart rate, quicker breathing than usual, and sweating, whereas vigorous intensity activities entail significantly higher heart rate, quicker breathing, and excessive sweating.” Examples were provided as well. The estimated duration of moderate and vigorous intensity activities was computed with a 2:1 ratio as a self-reported weekly physical activity level.

Assessment of quality of life

The quality of life of an individual was measured using the six-level preference-based assessment derived from the health survey SF-36 as SF-6D [33]. A reliable and feasible Chinese version of SF-6D was adopted for the cost-utility analysis, which included physical and social functioning, role participation, mental health, bodily pain, and vitality [34]. The Chinese SF-6D showed good test–retest reliability and an intraclass correlation of 0.79[34].

Assessment of acceptability and compliance

Attendance to training courses was recorded and subjects were asked about their willingness of learning more about ZTEx or sleep hygiene instructions using a 10-point scale question ranging from 1 to 10. These data were used to assess the acceptability of using lifestyle-integrative exercises as an intervention for insomnia.

An exercise logbook was provided to each participant for recording daily practice, frequency, and time spent on ZTEx during the 8 weeks of study to assess treatment compliance.

Subjects in the SHE group received a logbook for recording their daily compliance of sleep hygiene instructions by yes/no questions. Compliance of both groups was assessed with identical follow-up procedures.

Assessment of credibility

Credibility regarding the rationale of the delivered treatment and its efficacy to alleviate insomnia symptoms was measured using the 4-item Credibility of Treatment Rating scale (CTRS)[35]. CTRS was scored with a 6-point Likert scale, in which a higher score indicates higher expectancy toward the treatment.

Data analysis

A sample of at least 12 per group in a pilot RCT provided sufficient methodological experience to conduct a fully powered study [36]. Taking into account a dropout rate of 25%, 16 subjects per group were needed. We planned to include a total sample of 32 subjects, with 16 in each group.

All data were entered and analyzed with SPSS 23.0 (IBM Corp., USA). Wrist actigraphy was assessed using Action-W software (Ambulatory Monitoring, Inc., Ardsley, NY, USA). The between-group differences in ISI scores and secondary outcomes were compared by the linear mixed effects model between the two groups (ZTEx training vs. SHE) by time-point (from baseline to week 8) interaction effect. Within-group differences were analyzed by repeated measures with linear mixed effects model. An intention-to-treat analysis was conducted, and the mixed-effect model, assuming random effect, was used to deal with missing data. Both the within-group and between-group effect size (ES) was computed according to Cohen's *d* with difference in means divided by the pooled standard deviations. Effect size was considered as small, ES = 0.2, medium, ES = 0.5, and large, ES = 0.8 [37]. A positive sign was used to denote a superior effect in the ZTEx training group than the SHE comparison group for between-group effect size, and to indicate superior effect at post-treatment compared to the baseline for within-group effect size. Bonferroni correction was applied for adjusting multiple time-point comparisons using a conservative threshold of $P<0.0125$ for the primary outcome (four time points) and $P<0.025$ for some of the secondary measures (HADS, MFI-20, SF-6D, and physical activity level; two time points). Completer analysis was performed by including only the subjects who complied with the intervention protocol, defined as having ZTEx or

following the sleep hygiene instruction for at least 5 days per week, as recorded by the logbook during the intervention period (up to week 8).

RESULTS

Characteristics of recruited participants

All enrolled participants received face-to-face screening for eligibility, and 37 subjects were randomized. Two subjects were lost at week 8 (5.4%). The CONSORT diagram is shown in **Figure 1. Table 2** shows that recruited subjects were mainly female (91.9%) with a mean age of 49.9 years (SD = 13.6) and a BMI of 22.1 (SD = 2.8). The mean duration of insomnia was 7.3 (SD = 7.5) years. Only a few of them had used exercise as an intervention for insomnia (8.1%) before participation. The average duration of their moderate-to-vigorous activities was 22.0 min (SD = 41.0) weekly. The mean score of ISI was 15.7 (SD = 3.9), and about half of the subjects had moderate-to-severe insomnia (ISI scored ≥15; 54.1%). The ZTEx group did not substantially differ from the SHE group, except for education.

Treatment acceptability, fidelity, and treatment compliance

The ZTEx group rated an average of 8.6 (SD = 1.1) out of 10 for the acceptability of ZTEx training. They had high treatment compliance (15 of 18 subjects in the ZTEx group completed the two sessions). All subjects in the ZTEx group completed the fidelity check and all subjects in SHE group passed the tests about sleep hygiene instructions. Of the 18 subjects in the ZTEx group, 17 returned their exercise logbooks. Fourteen practiced ZTEx 5 days or more in a week with an average of 34.3 min per day during the 8-week intervention period. Subjects in the ZTEx group were asked to set a goal for weekly time spending on doing ZTEx at the beginning of ZTEx training, and 10 of the 18 subjects successfully achieved their goal at week 8. For the SHE group, 14 of the 19 subjects returned the sleep hygiene logbooks. During the consecutive 8 weeks of observation, 11 subjects followed eight or more sleep hygiene instructions for at least five out of seven nights.

Effectiveness

<u>Primary outcome of insomnia symptom severity</u>

Table 3 shows significant group-by-time interactions. Compared with the SHE group, ZTEx group had a significantly greater reduction of insomnia symptom severity with large effect size at all four assessment time points (week 2: ES = 0.93, P=0.001; week 4: ES = 1.10,

P=0.002; week 6: ES = 1.09, *P*=0.008; week 8: ES = 0.96 *P*=0.03). The differences remained significant after Bonferroni correction for multiple time comparison points (*P*<0.0125), except at week 8 (**Figure 2**). In the completer analysis, the results did not alter at week 2, 4, and 6 but only the differences at week 4 remained significant after Bonferroni correction.

Secondary outcomes

Sleep diary and actigraphy

No significant between-group difference was observed between the ZTEx and SHE groups in SOL, WASO, TST, and SE measured by sleep diary or actigraph in all study visits (**Table 3**).

Emotion, quality of life, fatigue, activity level, physical health, and BMI

Table 4 shows no significant between-group difference in HADS anxiety and depression scores, MFI-20, SF-6D utility score, time spending on moderate and vigorous intensity activities, and BMI throughout in all study visits. The ZTEx group showed a significantly higher grip strength of the dominant hand than the SHE group with moderate effect size at week 8 (ES=0.56, *P*=0.04).

Treatment credibility

No significant differences were found in the "confidence in effectiveness," "confidence in recommending to others," "perception of treatment rationale," and "likelihood of relieving other complaints" between ZTEx and SHE groups.

DISCUSSION

This is the first RCT to examine the effects of a simple and innovative lifestyle-integrated Zero-Time Exercise training on reducing insomnia severity. We included both subjective and objective sleep outcome measures, which are regarded as essential measures in insomnia trials [38]. We have demonstrated that training inactive subjects with insomnia to perform a lifestyle-integrated exercise – ZTEx through two 2-hour training sessions by briefly trained healthcare professionals was feasible. The brief ZTEx training showed preliminary evidence on improving the perceived severity of insomnia symptoms and related daytime impairment as measured by ISI across the 4 time points and increasing the grip strength of the subjects' dominant hand. The severity of insomnia, according to the ISI original cutoff, was improved from a moderate to severe level of insomnia (ISI score ≥ 15) at baseline to a subthreshold clinical insomnia (ISI score 8-14) at week 4 to 8. Significant within-group

improvements with moderate within-group effect size were observed in the sleep-diary-derived SOL and WASO at both week 4 and 8. At week 8, ZTEx also showed significant within-group improvements with moderate within-group effect size in HADS-Anxiety and MFI-20 scores, and a large effect size in self-reported moderate-to-vigorous activity level. Because of the small sample size, the statistical power was limited to detect significant differences in sleep parameters and other secondary measures.

Our effect size of ISI improvement was large and comparable to those of other intensive exercises. An RCT examined whether achieving the minimal activity level of 150 minutes of moderate-intensity physical activity a week, as suggested by the World Health Organization, was enough to improve sleep in physically inactive subjects with primary insomnia. The subjects in the treatment group (n=20) were instructed to walk briskly for a 4-week training period in their chosen setting, distributed over 5 days and monitored by a pedometer. After 6 months with brisk walking (≥5 days/week), the subjects in intervention group had a significantly decreased insomnia symptom severity, measured by ISI (between-group ES = 0.78), compared to subjects usual lifestyle control (n=21)[7]. Another 4-arm RCT on subjects with primary insomnia (n=12 in each group) found moderate-intensity aerobic exercise for 30 minutes significantly improved SOL, sleep onset latency, total wake time, and increased TST and SE by polysomnography (between-group ES on different sleep parameters ranging from 0.13 to 0.68) [8]. In contrast, we did not find any improvement in actigraphy at week 8. The subjective improvements found in our study were not corroborated by the objective measure. This inevitably weakened the confidence of our findings. On the other hand, our effect size was inferior to that of a 16-week aerobic physical activity program in sedentary older adults with primary insomnia found by an RCT, in which aerobic exercise routine (walking, cycling, or treadmill) in combination with SHE (n=10) was compared to non-physical recreational activity plus SHE (n = 7). Their results showed that the exercise group had a significantly greater improvement in Pittsburgh Sleep Quality Index score (ES =2.5), but the dropout rate was as high as 29.4% [9]. The exercise interventions tested by others are more intensive than ours and require participants to commit much extra time and effort with probably lower acceptance and adherence.

After the ZTEx training, the grip strength of the participants significantly increased. The self-reported weekly moderate-to-vigorous physical activity level in the ZTEx group (171.7 min) appeared to be higher than the SHE group (71.3 min) at week 8 but was not significant. The findings have provided suggestive evidence that our ZTEx training on helping

participants to change their physically inactive lifestyle to a relatively more active lifestyle can result in significant improvement in some health indicators (such as grip strength). Although insomnia, poor sleep quality, and prolonged sleep duration were found to be consistent predictors of weaker grip strength [39, 40], they might be the results of less frequent exercise (<3 times per week) in people with sleep complaints. Hence, whether the greater increase of grip strength could be attributed to either improvement of insomnia symptoms or the enhanced physical activity level, or both should be further studied.

According to the behavior change wheel framework by Michie *et al*.[41], sufficient conditions of behavioral change involve three essential conditions, namely, capability (one's physical and psychological capacity to engage in the target activity), opportunity (the factors that lie outside an individual that make or prompt the behavior happen), and motivation (the brain processes that energize and direct behavior). Interventions that aim to change specific behavioral patterns should be designed to target these three essential components. The ZTEx program aims to change the inactive habits of subjects by using a lifestyle-integrated approach to incorporate very simple exercise which does not need extra time into habitual daily routines. Such approach can increase one's capacity and opportunity to change inactive behavior and should be more acceptable to inactive people who usually lack time and dislike vigorous exercises as the first step, as reflected by a moderate effect size in subjects' increase in their perceived rationale of the training. ZTEx uses a foot-in-the-door strategy to overcome barriers of increasing physical activity. In addition, the ZTEx training is brief, easy to conduct, understand and practise. It can therefore be readily disseminated in the community. Based on the train-the-trainer approach of building capacity in the communities, training from experts to key stakeholders or volunteers to deliver ZTEx intervention for subjects with insomnia may relieve the cost and manpower burden in the health sector, resulting in efficient and effective utilization of available resources [42]. We had conducted 36 train-the-trainer workshops for about 900 trainees, including community leaders, teachers and social service workers and volunteers during April 2015 to March 2017. The trainees acted as trainers and successfully implemented and/or helped to conduct community and family based ZTEx programs for about 55,000 community participants. The trainees and community participants reported significant increases in physical activity and ZTEx, and improvements in well-being [43].

In the ZTEx group, the severity of insomnia decreased at week 4, but the increase in MVPA at week 4 was minimal. Hence, the improvement in ISI at week 4 may not be attributed to change in MVPA but other factors. We would like to point out that ZTEx consists of

movements ranged from low to moderate intensity. It is possible that, at the beginning, the subjects only engaged in low intensity ZTEx which was not reflected in MVPA as it only counted physical activity that was at least in moderate intensity; and such low intensity ZTEx might lead to subjective sleep improvement in inactive subjects. Another possible factor is that, during the training, we have highlighted the benefit of exercise and negative consequences of physical inactivity on sleep and health. The subjects may become more sensitive to note their change in sleep after starting to change their inactive behavior by doing ZTEx. Further study with moderator analyses may help to confirm the relationship between exercise intensity and sleep improvement.

Limitations

This study had several limitations. First, we promoted this trial as a study on exercise intervention for insomnia for inactive people during subject recruitment. Thus, the subjects who were interested in this study might have higher motivation to change their inactive behavior such that they might have a higher expectation of the intervention and exercise compliance. Second, our sample consisted of a high proportion of female subjects (91.9%) and exclusion of other psychiatric comorbidities which may limit the generalizability of the results. On the other hand, we did not assess subjects' menopausal status which may affect their sleep. This is especially the case when our sample was potentially for menopausal age. Third, the study was limited by the lack of objective measure of activity level. The physical activity level was assessed by self-report measures. Objective measures of physical activity, including pedometers and accelerometers, can be included to verify the exercise compliance of subjects. Finally, we did not use polysomnography for excluding participants who might be potential sufferers of sleep apnea and other possible sleep disorders. Relatively loose selection criteria for subject recruitment from the community were used so that the findings could be made more generalizable.

In conclusion, our simple and brief ZTEx training showed high acceptability and exercise compliance and first evidence of efficacy in reducing insomnia severity in inactive adults with insomnia disorder. Further fully powered trials are necessary to determine the effectiveness and compliance of ZTEx using a longer follow-up and compare it with more intensive exercise.

Acknowledgements

We are grateful to all the participants of this study. Thanks to Ms. Yim-Tung Cheng, Ms. Wing-Man Cheung, Mr. Chun-Pong Fong, Ms. So-Wan Lau, Ms. Wai-Yi Law and Ms. Nga-Shan Li for helping with study logistics.

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Figure 1. Trial flowchart

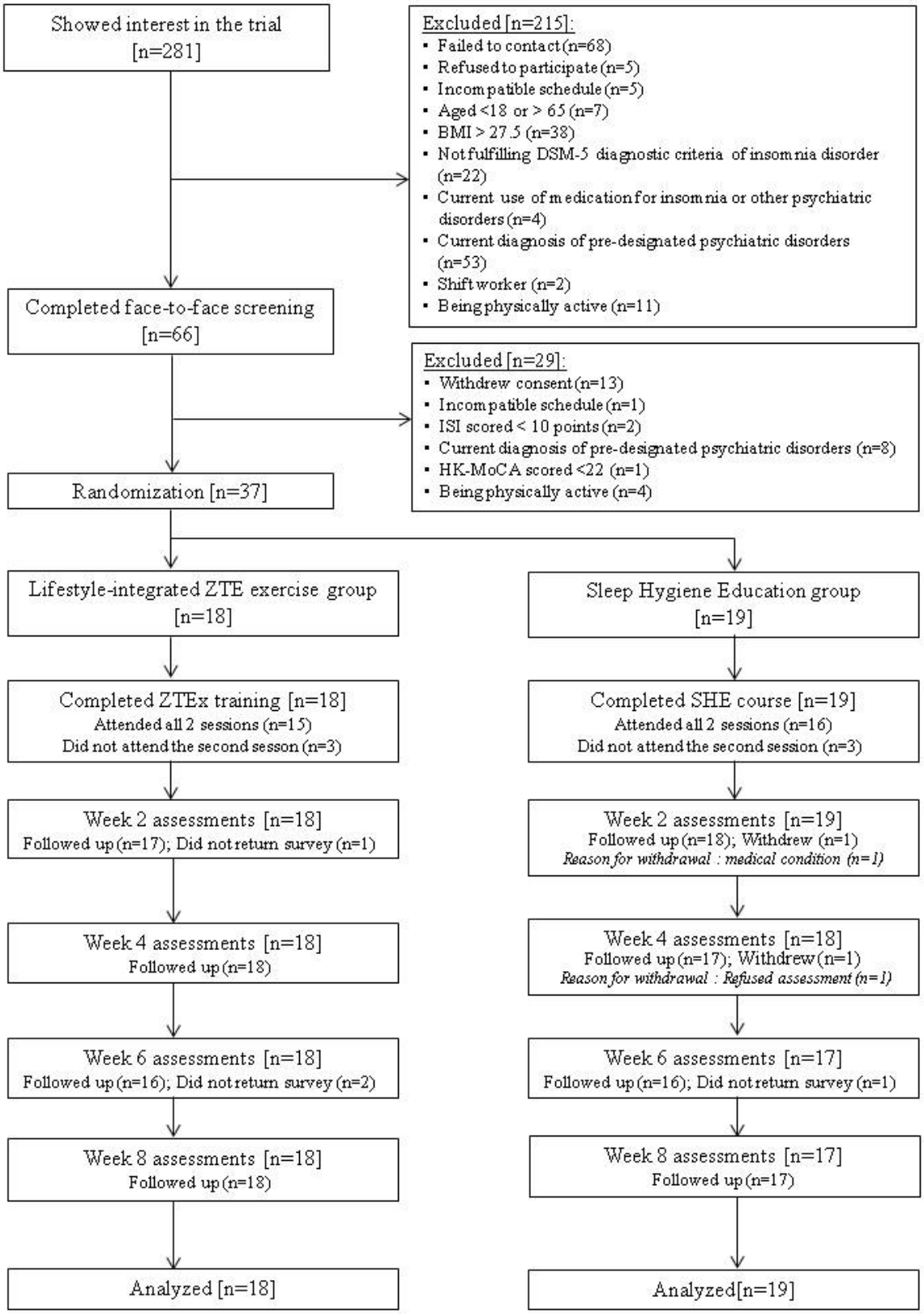
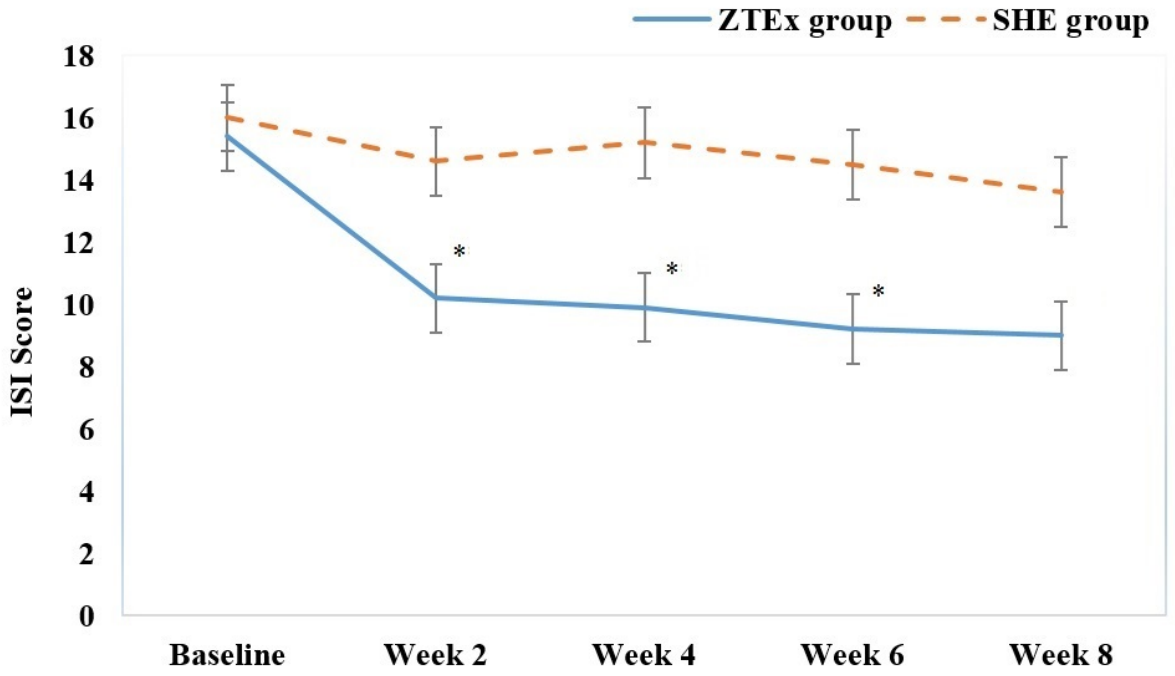


Figure 2. Changes in Insomnia Severity Index (ISI) score in the ZTEx group and the SHE group across study time points



* P < 0.0125, the significance threshold after Bonferroni correction.

Table 1. Contents of training sessions

Lifestyle-integrated Zero-time Exercise (ZTEx)	Sleep Hygiene Education (SHE)
Session One: Technique training, knowledge and motivation enhancement session 1. Enhance the participants' perception of the positive effects of exercise on sleep and the harmful effects of physical inactivity (10 min); 2. Introduce the importance of healthy living habits (healthy eating, physical activity, positive emotions) and personal well-being (10 min); 3. Enhance their knowledge, self-efficacy and outcome expectations in relation to ZTEx (10 min); 4. Group training of ZTEx (30 min); * Break (10 min); 5. Invite them to set realistic goals and plan for prac**ticin**g ZTEx (20 min); 6. Fidelity checking (15 min); 7. Conclude with a brief summary and key statements (15 min)	*Session One: Knowledge about sleep and sleep hygiene* 1. Share experience of sleep problems (15 min); 2. Introduce the basic facts about sleep and insomnia (15 min); 3. Enhance the participants' understanding of their sleep habits through completing the Sleep Hygiene Practice Scale (SHPS) and Caffeine Knowledge Quiz (30 min); * Break (10 min); 4. Explanation of how poor sleep hygiene impacts the maintenance of their sleep problems (20 min); 5. An ideal activity scheduling illustrated by a role-model (10 min); 6. Conclude with a brief summary and key statements (20 min).
Session Two: Booster session 1. Ask the participants about their experience of and barriers against doing ZTEx (10 min); 2. Discuss the barriers they encountered, and explore solutions with them (10 min); **3.** Highlight any positive changes they reported (10 min); 4. Group practice of ZTEx (30 min); * Break (10 min); 5. Remind them of the negative consequences of physical inactivity (15 min); 6. Remind the participants to note the positive changes that come with doing ZTEx regularly (15 min); 7. Conclude with a brief summary and key statements (20 min).	*Session Two: Booster session* 1. Review the content of the first session (15 min); 2. Discuss the barriers they encountered and explore solutions with them (30 min); 3. Facts and statistics about insomnia (true / false test) (15 min); * Break (10 min); 4. Reinforce learning by completing the SHPS (30 min); 5. Conclude with a brief summary and key statements (20 min)

Table 2. Socio-Demographic and Clinical Characteristics of Study Participants

Variables [a]	All sample (N=37)	ZTEx group (N=18)	SHE group (N=19)	*P*-value [b]
Age, years	49.9 ± 13.6	49.8 ± 13.5	50.0 ± 14.1	0.97
Female, % [c]	34 (91.9)	16 (88.9)	18 (94.7)	0.61
BMI, kg/m^2	22.1 ± 2.8	22.1 ± 3.1	22.1 ± 2.6	0.99
Marital status, %				0.36
Never married	13 (35.1)	5 (27.8)	8 (42.1)	
Married	24 (64.9)	13 (72.2)	11 (57.9)	
Education level, % [c]				0.048
Primary education or below	1 (2.7)	1 (5.6)	0 (0.0)	
Secondary education	17 (45.9)	5 (27.8)	12 (63.2)	
College or above	19 (51.4)	12 (66.7)	7 (36.8)	
Employment status, %				0.63
Employed	17 (45.9)	9 (50.0)	8 (42.1)	
Retired/Unemployed/Housewives	20 (54.1)	9 (50.0)	11 (57.9)	
Insomnia duration, years	7.3 ± 7.5	7.4 ± 7.8	7.2 ± 7.4	0.94
Clinical insomnia (moderate-high severity), % [d]	20 (54.1)	9 (50.0)	11 (57.9)	0.63
Previous use of sleep medication, % [c]	3 (8.1)	2 (11.1)	1 (5.3)	0.60
Use of exercise as treatment for insomnia, % [c]	3 (8.1)	2 (11.1)	1 (5.3)	0.60
Sleep parameters measured by sleep dairy				
SOL, min	55.5 ± 51.6	50.2 ± 32.0	60.6 ± 65.6	0.54
WASO, min	40.3 ± 33.2	36.0 ± 27.5	44.4 ± 38.1	0.45
TST, min	354.2 ± 56.7	363.1 ± 56.8	345.9 ± 56.7	0.36
SE, %	73.3 ± 11.2	76.4 ± 10.5	70.3 ± 11.3	0.10
Sleep parameters measured by actigraph				
SoL, min	17.9 ± 9.2	15.6 ± 6.1	20.0 ± 11.1	0.15
WASO, min	45.2 ± 28.1	41.5 ± 26.5	48.7 ± 29.9	0.44
TST, min	396.7 ± 58.2	389.2 ± 63.2	403.8 ± 53.8	0.45
SE, %	83.2 ± 8.1	83.3 ± 8.3	83.1 ± 8.1	0.95
ISI, 0-28	15.7 ± 3.9	15.4 ± 3.8	16.0 ± 4.1	0.70
HADS, 0-21				
Anxiety	7.3 ± 4.4	7.9 ± 4.8	6.7 ± 4.0	0.39
Depression	6.0 ± 4.0	6.8 ± 4.3	5.3 ± 3.7	0.24
MFI-20, 20-100	61.9 ± 11.0	60.4 ± 11.3	63.3 ± 10.7	0.43
SF-6D utility score, 0-1	0.693 ± 0.123	0.690 ± 0.110	0.696 ± 0.137	0.87
Handgrip strength (dominant hand), kg	22.9 ± 6.1	23.4 ± 6.7	22.5 ± 5.5	0.63
Weekly moderate-vigorous activity, min	22.0 ± 41.0	33.6 ± 48.0	11.1 ± 30.4	0.10
CTRS, 1-6 [e]				
Confidence in effectiveness	4.1 ± 1.1	4.0 ± 1.1	4.2 ± 1.2	0.68
Confidence in recommending to others	4.1 ± 1.0	4.1 ± 1.1	4.2 ± 1.0	0.77
Perception of treatment rationale	4.0 ± 0.9	3.9 ± 1.1	4.1 ± 0.7	0.72
Likelihood of relieving other complaints	4.1 ± 0.9	4.1 ± 1.0	4.1 ± 0.9	0.85

Abbreviations: BMI, Body Mass Index; CTRS, Credibility of Treatment Rating Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; MFI-20, 20-item Multidimensional Fatigue Inventory; SE, Sleep Efficiency; SF-6D, Short-Form Six-Dimension health survey; SHE, Sleep Hygiene Education; SOL, Sleep Onset Latency; TST, Total Sleep Time; WASO, Wake After Sleep Onset; ZTEx, Zero Time Exercise.

[a] Data are presented as mean ± standard deviation or number (%).

[b] Independent t-test or chi-square was used for comparison. As all differences were due to randomization (i.e. chance), P values are for reference only.

[c] Fisher exact test was performed.

[d] Insomnia severity index scored 15 points or above.

[e] Higher score indicated higher credibility towards treatment received.

Table 3. Insomnia Severity Index (ISI), sleep parameters derived from the 7-days sleep diary and actigraph across study time points

Outcomes	ZTEx group (N=18)		SHE group (N=19)		*P*-value [c]	Between-group ES (95% CI) [d]
	Estimated mean ± SE [a]	Within-group ES [b]	Estimated mean ± SE [a]	Within-group ES [b]		
Insomnia symptoms						
ISI score						
Baseline	15.4 ± 1.10		16.0 ± 1.07			
Week 2	10.2 ± 1.10	1.11*	14.6 ± 1.10	0.30	0.001	0.93 (0.23, 1.59)
Week 4	9.9 ± 1.10	1.18*	15.2 ± 1.13	0.17	0.002	1.10 (0.39, 1.77)
Week 6	9.2 ± 1.12	1.32*	14.5 ± 1.13	0.31	0.008	1.09 (0.38, 1.76)
Week 8	9.0 ± 1.10	1.37*	13.6 ± 1.12	0.50	0.03	0.96 (0.26, 1.62)
Sleep parameters derived by sleep diary						
SOL, min						
Baseline	50.2 ± 9. 56		60.6 ± 9.31			
Week 4	30.6 ± 9. 56	0.48*	48.5 ± 9.88	0.29	0.56	0.43 (-0.23, 1.07)
Week 8	23.6 ± 9.56	0.66*	52.5 ± 9.92	0.19	0.18	0.69 (0.01, 1.34)
WASO, min						
Baseline	36.0 ± 6.73		44.4 ± 6.55			
Week 4	21.1 ± 6.73	0.52*	22.5 ± 7.07	0.74*	0.53	0.05 (-0.60, 0.69)
Week 8	17.2 ± 6.73	0.66*	25.9 ± 7.05	0.62*	0.98	0.29 (-0.36, 0.93)
TST, min						
Baseline	363.1 ± 16.10		345.9 ± 15.68			
Week 4	382.5 ± 16.10	0.28	354.2 ± 16.57	0.12	0.59	0.40 (-0.26, 1.04)
Week 8	391.5 ± 16.10	0.42*	372.5 ± 16.24	0.38	0.91	0.27 (-0.38, 0.91)
SE, %						
Baseline	76.4 ± 2.85		70.3 ± 2.78			
Week 4	78.4 ± 2.85	0.17	75.3 ± 2.94	0.40	0.43	0.25 (-0.40, 0.89)
Week 8	82.6 ± 2.85	0.51	79.0 ± 2.97	0.69*	0.56	0.29 (-0.37, 0.93)
Sleep parameters derived by actigraph						
SOL, min						
Baseline	15.6 ± 2.09		20.0 ± 2.04			
Week 8	17.7 ± 2.09	-0.24	17.5 ± 2.29	0.26	0.14	-0.02 (-0.67, 0.62)
WASO, min						
Baseline	41.5 ± 6.32		48.7 ± 6.15			
Week 8	39.7 ± 6.32	0.07	34.4 ± 6.79	0.51*	0.14	-0.19 (-0.83, 0.46)
TST, min						
Baseline	389.2 ± 13.60		403.8 ± 13.24			
Week 8	379.2 ± 13.60	-0.17	394.5 ± 14.85	-0.15	0.98	-0.25 (-0.89, 0.40)
SE, %						
Baseline	83.3 ± 1.72		83.1 ± 1.68			
Week 8	83.3 ± 1.72	0.00	83.7 ± 1.90	0.08	0.83	-0.05 (-0.69, 0.59)

*, P-value reached a significant level after Bonferroni adjustment by repeated measures with linear mixed effects model for within-group comparison to the baseline measure.

Abbreviations: ISI, Insomnia Severity Index; SE, Sleep Efficiency; SHE, Sleep Hygiene Education; SOL, Sleep Onset Latency; TST, Total Sleep Time; WASO, Wake After Sleep Onset; ZTEx, Zero Time Exercise.

[a] Estimated mean and standard error from linear mixed-effects model.

[b] Within-group effect size was calculated by the mean difference compared to the baseline divided by a pooled standard deviation. Effect size was considered as small, ES = 0.2, medium, ES = 0.5, and large, ES = 0.8. A positive sign was used to indicate superior effect at post-treatment compared to the baseline.

[c] *P*-value for group by time interaction of mean score using linear mixed-effects models.

[d] Between-group effect size calculation was based on the between-group mean difference divided by a pooled standard deviation. Effect size was considered as small, ES = 0.2, medium, ES = 0.5, and large, ES = 0.8. A positive sign was used to denote a superior effect in the ZTEx group than the SHE group.

Table 4. Hospital Anxiety and Depression Scale (HADS), 20 itemed Multidimensional Fatigue Inventory (MFI-20), Short-Form Six-Dimension (SF-6D), weekly physical activity level, and grip strength across study time points

Outcomes	ZTEx group (N=18)		SHE group (N=19)		*P*-value [c]	Between-group ES (95% CI) [d]
	Estimated mean ± SE [a]	Within-group ES [b]	Estimated mean ± SE [a]	Within-group ES [b]		
HADS-Anxiety						
Baseline	7.9 ± 0.97		6.7 ± 0.95			
Week 4	6.6 ±0.97	0.32	6.0 ± 0.98	0.17	0.42	-0.14 (-0.79, 0.51)
Week 8	5.9 ±0.97	0.49*	5.8 ± 0.99	0.21	0.29	-0.02 (-0.67, 0.62)
HADS-Depression						
Baseline	6.8 ± 0.91		5.3 ± 0.88			
Week 4	5.9 ± 0.91	0.23	5.6 ± 0.92	-0.08	0.16	-0.08 (-0.72, 0.57)
Week 8	5.8 ± 0.91	0.26	5.2 ± 0.92	0.03	0.30	-0.15 (-0.79, 0.50)
MFI-20						
Baseline	60.4 ± 2.69		63.3 ± 2.61			
Week 4	58.1 ± 2.69	0.20	61.9 ± 2.73	0.12	0.75	0.33 (-0.33, 0.97)
Week 8	53.4 ± 2.69	0.61*	60.0 ± 2.77	0.28	0.30	0.56 (-0.11, 1.21)
SF-6D utility score						
Baseline	0.689 ± 0.028		0.696 ± 0.027			
Week 4	0.718 ± 0.028	0.24	0.707 ± 0.029	0.09	0.63	0.09 (-0.56, 0.73)
Week 8	0.732 ± 0.028	0.36	0.681 ± 0.029	-0.12	0.13	0.42 (-0.24, 1.06)
Weekly moderate-vigorous physical activity, min						
Baseline	33.6 ± 24.06		11.1 ± 23.42			
Week 4	41.1 ± 24.06	0.07	33.7 ± 25.51	0.21	0.75	0.07 (-0.58, 0.71)
Week 8	171.7 ± 24.06	1.35*	71.3 ± 25.52	0.56*	0.11	0.94 (0.24, 1.60)
Grip Strength (dominant hand), kg						
Baseline	23.4 ± 1.46		22.5 ± 1.42			
Week 8	25.1 ± 1.50	0.27	21.5 ± 1.47	-0.16	0.04	0.56 (-0.11, 1.21)

*, P-value reached a significant level after Bonferroni adjustment by repeated measures with linear mixed effects model for within-group comparison to the baseline measure.
Abbreviations: HADS, Hospital Anxiety and Depression Scale; MFI-20, 20-item Multidimensional Fatigue Inventory; SF-6D, Short-Form Six-Dimension health survey; SHE, Sleep Hygiene Education; ZTEx, Zero Time Exercise.

[a] Estimated mean and standard error from linear mixed-effects model.

[b] Within-group effect size was calculated by the mean difference compared to the baseline divided by a pooled standard deviation. Effect size was considered as small, ES = 0.2, medium, ES = 0.5, and large, ES = 0.8. A positive sign was used to indicate superior effect at post-treatment compared to the baseline.

[c] *P*-value for group by time interaction of mean score using linear mixed-effects models.

[d] Between-group effect size calculation was based on the between-group mean difference divided by a pooled standard deviation. Effect size was considered as small, ES = 0.2, medium, ES = 0.5, and large, ES = 0.8. A positive sign was used to denote a superior effect in the ZTEx group than the SHE group.