**Effects of a Home-Based Breathing Training on Menopausal Symptoms Among Community Postmenopausal Women**

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**Purpose:** This is a prospective, triple-blinded and randomized controlled trial (clinicaltrial.gov identifier - NCT 03082040) examining the effects of a home-based breathing training assisted with biofeedback on menopausal symptoms and autonomic functions among community menopausal women in Taiwan.

**Methods:** Participants, aged from 45 to 64, reporting cessation of menstrual cycles with natural causes for more than 12 consecutive months and scored with any menopausal symptoms on the Greene Climacteric Scale (GCS) were eligible for participation. Participants were randomly assigned to either an intervention group or a waiting-list control group. The intervention group underwent a home-based slow breathing assisted with biofeedback device 20 minutes twice daily for 4 weeks, and participants in the control condition will participate the same breathing training after a four-week waiting period. The primary outcome measures are menopausal symptoms using the Greene Climacteric Scale (GCS). The secondary outcome measures are autonomic functions expressed by blood pressure, heart rate and time-domain heart rate variability. Data were collected before breathing training (baseline), week 4, and week 8. All analysis were by Intention to treat.

**Results:** A total of 324 community women were screened, and 54 postmenopausal women with mean age of 56.09±4.31 year-old participated. Postmenopausal psychological symptoms were positively associated with somatic and vasomotor symptoms ($r=.45$ and $r=.69$, respectively, all $p<.001$) but not associated with autonomic functions (all $p>.05$). Results of the regressions indicated that hot flashes were associated with increased anxious and depressed symptoms ($β=.366$, $p=.007$ and $β=.449$, $p=.001$, respectively) whereas somatic symptoms also result in more anxious and depressed symptoms ($β=.617$ and $β=.711$, respectively, all $p<.001$). Adjusting for baseline pNN50, hot flashes and somatic symptoms, the intervention group (n=24) showed significant decreased menopausal symptoms, including the total scores, anxious, depressed and psychological symptoms, after the four-week breathing training ($p<.001$, $p=.009$, $p=.001$ and $p=.002$, respectively) and keep descending after a four-week follow-up but without statistical significance (all $p>.05$). The waiting-list controls (n=30) also showed significant decreased menopausal symptoms in total scores, anxious, depressed and psychological symptoms after the same four-week breathing training ($p<.001$, $p=.002$, $p<.001$ and $p<.001$, respectively). Pooled participants (n=52) with the four-week breathing training also showed decreased menopausal symptoms, in all factor domains (all $p<.01$). No significant results were found on any autonomic functions, neither in the intervention group nor the waiting-list controls (all $p>.05$).

**Conclusion:** We confirm that a four-week home-based breathing training assisted with biofeedback has a beneficial impact on menopausal symptoms, especially the anxious and depressed symptoms, among community menopausal women. Our home-based breathing training is recommended to popularize for community menopausal women to practice at home.

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**Title:**
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**Keywords:**
autonomic functions, menopausal symptoms and slow breathing
Abstract Summary:
This is a prospective, triple-blinded and randomized controlled trial with a crossover design. Our results confirm that this four-week home-based breathing training assisted with biofeedback has a beneficial impact on menopausal symptoms, measured by the Greene Climacteric Scale, among community menopausal women in Taiwan.

Content Outline:
Introduction

1. The majority of menopausal women experience not only physical changes but emotional symptoms.
2. Postmenopause may be at increased risk for autonomic dysfunction and cardiovascular disease.
3. Slow breathing is widely applied to provide relaxation and improve autonomic functions.

Purpose

1. To examine the effects of a home-based breathing training assisted with biofeedback on menopausal symptoms and autonomic functions among community menopausal women.

Methods

1. Design: a prospective, triple-blinded and randomized controlled trial
2. Participants:
   1. Aged from 45 to 64, reporting cessation of menstrual cycles with natural causes ≥ 12 consecutive months
   2. Greene Climacteric Scale (GCS) scores ≥ 1
3. Measurement:
   1. Menopausal symptoms: GCS
2. Autonomic functions (blood pressure, heart rate and time domain heart rate variability): ProComp Infiniti

4. Study groups:
   1. Intervention group: Participants were trained with a home-based slow breathing assisted with biofeedback device 20 minutes twice daily for 4 weeks.
   2. Waiting-list control group: Participants in the control condition participated the same breathing training after a four-week waiting period.

5. Data collections: baseline, week 4, and week 8.

Results

1. Fifty-four postmenopausal women with mean age of 56.09 ± 4.31 year-old participated.

2. Menopausal symptoms:
   1. Hot flashes and Somatic symptoms were associated with anxious and depressed symptoms.
   2. Adjusting for baseline pNN50, hot flashes and somatic symptoms,
      ▪ The intervention group (n=24) showed significant decreased menopausal symptoms, including the total scores, anxious, depressed and psychological symptoms, after the four-week breathing training and keep descending after a four-week follow-up but without statistical significance.
      ▪ The waiting-list controls (n=30) also showed significant decreased menopausal symptoms in total scores, anxious, depressed and psychological symptoms after the same four-week breathing training.
      ▪ Pooled participants (n=52) with the four-week breathing training also showed decreased menopausal symptoms, in all factor domains.

3. Autonomic functions:
   1. No significant results were found on any autonomic functions.

Conclusions

1. We confirm that a four-week home-based breathing training assisted with biofeedback has a beneficial impact on menopausal symptoms among community menopausal women.

2. Our home-based breathing training is recommended to popularize for community menopausal women to practice at home.

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