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# The Use of the RESPeRATE Device to Lower Blood Pressure in Inner City Obese Adolescents and Children: A Pilot Feasibility Study

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# **Abstract**

The RESPeRATE device was tested for feasibility of use in a population of overweight and obese children and adolescents (n = 10) in San Francisco, CA. After a 2-week and then a 2-month period, participants were interviewed on their frequency of use and attitudes towards the device. A high percentage stated that they enjoyed using the device at 2 months (90 %) and 80 % stated that they would recommend use to a friend or relative. Future studies are needed to assess the efficacy of the RESPeRATE device in lowering blood pressure and helping with weight loss/weight management in obese and overweight children.

#### **Keywords**

Stress; Ob	esity; Children	; Alternative medic	eine	

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Conflict of interest None.

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# 1 Introduction

The RESPeRATE is a device used to lower blood pressure (BP) through controlled breathing. Studies have shown it to work as an effective tool to combat high BP in adults [1–3]. An advantage to using the RESPeRATE device in efforts to lower BP is the lack of side-effects commonly seen when using drugs to control high BP. RESPeRATE has also been found to be effective in adults with resistant hypertension [4]. The machine works by strapping a sensor that monitors rate of breathing around the chest and headphones that play calming music synchronized with the user's breath. The user synchronizes breathing with the music to slow the rate of breathing.

Previous studies have evaluated the effectiveness of the RESPeRATE device on BP in adults. Given the increasing prevalence of hypertension among children due to the rise in pediatric obesity [5], it is necessary to find additional non-pharmacologic treatment approaches that could be used by children, as part of the primary behavioural change approach to treat hypertension in children [6]. This study investigates acceptance of the RESPeRATE device by children at high risk for hypertension and obesity. Additionally, we hypothesized that the RESPeRATE device would reduce stress and slow breathing to potentially target stress-related eating.

# 2 Methods

All participants were enrolled in the San Francisco Healthy Lifestyles Clinic (HLC) at San Francisco General Hospital (SFGH) where they received dietary and behavioral interventions to facilitate weight loss. Subjects were selected by one of the authors (CTT) based on desire to lose weight and potential compliance. All participants were obese with a body mass index (BMI) 95th percentile for age-sex using Center for Disease Control (CDC) growth curves [5]. Each participant first completed a background survey with questions about food consumption, physical activity, nutritional knowledge, and environment and behavior as part of the intake process at HLC. Height, weight and BP were measured at this time and BMI was calculated using weight and height measurements. After completing the interview, participants were given a RESPeRATE device and asked to wear the device for about 10 min per day. Children were given minimal instruction on how to use the device.

Study subjects were instructed to use the device daily at home, and a follow-up questionnaire was conducted 2 weeks later. As part of the follow-up interview, participants were asked questions from a structured questionnaire including ones about how often, where, at what time they used the device and whether they enjoyed using the device and if they would recommend it to family/friends. Additionally, participants were asked openended questions about whether they experienced any difficulties using the device and how they would recommend improving the experience. All subjects had the opportunity to ask any questions about using RESPeRATE during the follow-up interview at 2 weeks. Nine of the 10 participants completed the 2-week interview.

A final interview was conducted approximately 2 months after the child was first recruited into the study. During this interview, the participant was asked through the use of structured

questionnaire about what he or she liked and disliked about the RESPeRATE device as well as opinions about using the device in the future. Similar to the 2-week interview, participants were asked where, when and how often they used the device as well as if they would be interested to continue to use the RESPeRATE. After completion of the 2-month interview, the participant returned the device to the researcher, but the family was given information about where they could purchase the RESPeRATE if interested. BMI and blood pressure measurements were extracted from the medical record for those participants who completed the study. Nine had a BMI measurement and seven had a blood pressure measurement at completion of the study. The study was approved by the Institutional Review Board (Committee on Human Research) at the University of California, San Francisco.

# 3 Results

Ten children ages 6–14 (mean age was  $10.0 \pm 2.5$ , range 7–14) were recruited to participate and all ten completed the study in 2009. One dropped out before the 2 week interview based on logistical difficulties in participating. Nine participants completed the 2 week interview and ten completed the 2 month interview. Six of the eight participants were male and four were female. Race/ethnicity was self-identified as Latino/Hispanic in nine and Pacific Islander in one.

The mean participant BMI at the start of the study was  $30.3 \pm 7.6$  and post-study (for 9 out of 10 children measured) was  $30.8 \pm 7.2$  (Table 1). The mean systolic blood pressure at baseline was  $113.8 \pm 15.1$ , diastolic was  $56.2 \pm 5.6$  and at follow-up systolic was  $113.3 \pm 17.3$  and diastolic was  $61.4 \pm 8.8$  (for the seven children who had blood pressure measured at follow-up) (Table 1). Two children had a high blood pressure reading at baseline and these same children had a high blood pressure reading again at the end of the study. One additional child had a high blood pressure reading at follow-up (Table 1). Three indicated that they sometimes or always ate when they felt sad or stressed out. Patterns of use of the RESPeRATE were as follows at the 2-week time point: 44.4 % used the device every day with 88.9 % using the device for 10 min as instructed. Six participants used the RESPeRATE in the evening, and the other four used it in the afternoon (n = 3) or morning (n = 1).

Overall, the participants viewed the RESPeRATE device favorably with 77.8 % responding to the question "Did you like using the RESPeRATE device" as "Yes" (6/9) or "Mostly" (1/9) after 2 weeks of use. A similar percentage said that they would recommend RESPeRATE to a relative or friend (77.8 % or 6/9). Most (7 of 10) stated that the device was "very easy" or "easy" to use; only one participant stated that it was hard. At 2 weeks, six felt that using the device helped them feel more relaxed and less stressed.

At the 2 month time-point, nine (90 %) responded that they liked using the RESPeRATE "very much" or "somewhat", and eight (80 %) stated they would recommend it to a friend or relative. Six (60 %) used the device every other day during the prior 6-week period, and three (30 %) used it daily. Eight (80 %) hope to use it again.

# 3.1 Qualitative Results

The open-ended questions asked after 2 weeks and 2 months of use included the following benefits of use and concerns and suggestions for changes to the device.

#### 3.2 Positives

Many participants noted that the device helped them relax. One commented that "If you're nervous, you feel better once you use it." Two liked the music, one stating the "music was exciting and relaxing."

The majority felt that the RESPeRATE helped reduce stress and promote relaxation. Common responses after using the instrument were "feeling more relaxed than I used to", "practicing breathing was relaxing", and "It calmed me down".

# 3.3 Concerns and Complaints

The two most common complaints about the RESPeRATE were that the music got boring after frequent use and that the device had operational issues. Negative comments included "Having to do it everyday got boring", it had "weird music", and the music was "creepy." One subject complained about the lack of variety in the choice of music, stating "It sounds the same all the time"; another concluded with the suggestion that "Maybe they should change it (the music) to something that has more beat".

Operational issues included problems getting it to start easily and having a hard time strapping the belt on. One participant reflected on the experience stating that "It takes a lot of time to put it on, use it and put it away."

# 4 Discussion

Overall, the subjects viewed the RESPeRATE device favorably. Most enjoyed the experience and hoped to continue to use the device in the future. We did not find any significant changes in BMI or BP in the pre- and post-study measurements, although our sample size was small and not powered to evaluate the impact of use on lowering BP measurements or BMI. In this population of growing children, however, we did not find any increases in BMI measurements over a 2 month period. It is possible that the RESPeRATE helped to temper stress-related eating, which may be an explanation for maintenance of BMI. Another shortcoming of our study design, however, was lack of a control group, so it is possible that any maintenance in BMI levels could be attributable to the impact of the Healthy Lifestyles clinic at SFGH on this population.

As this is the first study using the RESPeRATE with children, further research should be conducted on the relationship that the device has on blood pressure and BMI in high risk obese and overweight children. Our qualitative results suggest that the device can be easily applied in older, high-risk, inner-city children with minimal instruction, although some may benefit from more instruction on use of the belt and how to turn the device on/off. Additionally, more diverse listening choices should be offered to children. While mind body interventions are being tested in obese adults [7, 8], futures studies are needed in this direction for children.

# **Acknowledgments**

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 Table 1

 Sociodemographic and health characteristics of participants and patterns of RESPeRATE use

	Mean (±SD) or percentage % (N/total)		
Variable			
Sociodemographics			
Age	$10.0 \pm 2.5$		
Male	60 (6/10)		
Latino/latina	90 (9/10)		
Pre and post-intervention health specifics			
Pre-intervention body mass index (BMI)	$30.3 \pm 7.6$		
Post-intervention BMI	$30.8 \pm 7.2$		
Pre and post intervention			
BMI 95th percentile	100		
Pre-systolic blood pressure	113.8 ± 15.1		
Pre-diastolic blood pressure	$56.2 \pm 5.6$		
Post-systolic blood pressure	$113.3 \pm 17.3$		
Post-diastolic blood pressure	$61.4 \pm 8.82$		
Pre-intervention hypertension	20 (2/10)		
Post-intervention hypertension	42.8 (3/7)		
Eating and lifestyle questions			
Do you eat when you are feeling sad or	stressed out?		
Always	10 (1/10)		
Sometimes	20 (2/10)		
Never	70 (7/10)		
2 week questions			
How often did you use the RESPeRATE			
In the last 2 weeks?			
Every day	44.4 (4/9)		
Every other day	22.2 (2/9)		
1× per week	22.2 (2/9)		
How long did you use the RESPeRATE for	or?		
10 min	88.9 (8/9)		
30 min	11.1 (1/9)		
Did you like using the RESPeRATE?			
Yes/most of the time	77.8 (7/9)		
Would you recommend RESPeRATE to a			
Yes	66.7 (6/9)		
2 month questions			
Do you like using the RESPeRATE?			
Yes (very much) or yes (somewhat)	90 (9/10)		
Would you recommend RESPeRATE to a relative or friend?			
Yes	80 (8/10)		

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No

	Mean (±SD) or percentage % (N/total)			
How many times a day did you use the RESPeRATE device in the last 6 weeks?				
A few times a day	10 (1/10)			
Once a day	30 (3/10)			
Every other day	60 (6/10)			
Would you like to use the RESPeRATE device again in the future				
Yes	80 (8/10)			
Maybe	10 (1/10)			

10 (1/10)

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