

Blood Pressure Study

Title: Smartphone app-guided inspiratory muscle strength training for lowering systolic blood pressure

Principal Investigator: Matthew Rossman, PhD

Location: Main CU Boulder Campus



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Goals of this Clinical Trial:

- Determine if 6 weeks of at-home breathing training (inspiratory muscle strength training, IMST) guided by a smartphone app yields similar results to IMST delivered in a supervised research setting when it comes to:
 - Decreasing systolic blood pressure (top number in a blood pressure reading)
 - Improving blood vessel function
 - Improving breathing muscle strength

Why is this research important?

Many adults have high systolic blood pressure (SBP; the top number in a blood pressure measurement), which can increase the risk of having a heart attack and other heart problems. Regular exercise can help improve SBP; however, most adults do not or cannot exercise enough to lower SBP. IMST (inspiratory muscle strength training) is one proposed way to lower SBP. Recent studies have found that ~5 minutes a day of IMST can lower blood pressure; however, these studies involved regular attendance at the research clinic. It is unknown if IMST lowers SBP when performed without research team instruction and monitoring.

Who is eligible to participate?

We are looking for individuals:

- 18 years or older
- Who have a systolic blood pressure (top number) between 120-160 mmHg
- Who own an Apple or Android smartphone
- Who are willing to perform breathing exercises 5-10 min/day, 6 days/week, for 6 weeks

We will further assess your eligibility once you complete this screening [form](#).

What do I receive for participating?

- Payment for your time (up to \$165 USD)
- Reimbursement for travel (current federal rate)
- Results from the tests we perform: blood work, blood pressure, artery stiffness, etc.
- PowerBreathe breathing trainer (pictured here)



What happens at the screening visits?

Once we review your screening form, you will be invited to partake in screening visit #1 where we will explain the study to you and perform some tests to see if you qualify for the study. This can either be done completely in-person or on two separate days, one over Zoom and one in-person at our facility on the main CU Boulder Campus. The entire visit takes ~1 hour. If it seems like you may qualify after screening visit #1, you'll be invited in for screening visit #2.

The screening process entails:

Visit 1

- Informed consent (review of the study and the risks/benefits)
- Paperwork
- Height and weight measurement
- Blood pressure and heart rate measurement

Visit 2

- Blood pressure and heart rate measurement
- Blood draw

You'll need to fast (no food or drink except water) for 5 hour prior to these visits.

What happens during the study?

This study requires ~11 hours of your time over the course of ~9 weeks.

If you qualify for the study, you will be invited to take part in baseline testing which entails:

- Blood vessel function and artery stiffness measures (performed with an ultrasound and pressure sensor on the surface of your skin)
- At-home blood pressure monitoring
- Questionnaires about your activity, sleep, etc.

You'll then be randomly assigned to one of two groups: clinic-based or app-based. Participants in both groups receive a PowerBreathe Plus IMST breathing trainer, an at-home blood pressure monitor, and perform 6 weeks of IMST (5-10 min/day, 6 days/week).

After completing 6 weeks of IMST, we will invite you in for post-testing, where we will repeat the same measures performed at baseline so we can see if any of your variables changed.

If you are in the clinic-based group, you will come to our facility once a week during those 6 weeks for a supervised training session. The other 5 sessions during each week will be performed unsupervised.

If you are in the app-based group, we will help you download an app on your phone, and the app will guide you through 6 weeks of IMST.

FAQs

Q: Where are you located?

A: Our facility is located on the main CU Boulder Campus in the Ramaley West Extension. We are directly south of the Student Rec Center. You can click [here](#) for an exact location.

Q: Where can I park?

A: We offer parking close to our facility in Lot 380. Parking is free for the duration of your visits to our facility. If you require assistance getting from your car to our facility, we have golf carts we can use to help transport you.

Q: I have some vacations coming up. Can I still be in the study?

A: We are flexible and can accommodate most vacation schedules. Please note: you'll need to be able to access the app if you are in the app-based group and be able to come into our facility once a week for 6 weeks if you are in the clinic-based group. For both groups, you'll need to be able to perform the IMST training 6 days/week while on vacation. Please communicate any upcoming vacations to us early on.

Q: How long are you taking participants for?

A: We are enrolling participants on an ongoing basis. If you have an extended trip coming up, we can schedule you to undergo screening after your trip.

Q: Should I stop taking my medications or change my diet/exercise routine for this study?

A: Unless instructed by your provider, you should continue taking all medications as prescribed. We may ask you to refrain from consuming over-the-counter supplements before your visits, but this is only for non-prescribed supplements. ***We ask that you inform us of any lifestyle changes during the course of the study, including changes in medications/supplements (doses included!), exercise routine, and diet, as these could potentially impact our measurements.***

Q: How is payment received?

A: You will be paid at the end of the study in the form of a check mailed to you ~1 month after you complete it. If you would prefer, we are happy to pay you throughout the study.

Q: I'm uncomfortable with having an individual of the opposite sex perform certain measurements on me. Can you still accommodate me?

A: Your comfort and safety is our first priority. We can make adjustments in our staffing to ensure you feel comfortable. The same thing goes for any measurement--if you are uncomfortable with us performing any measurement, we can adjust to ensure your comfortability. Before each visit, we will send you in-depth details of the measurements and verbally obtain your consent to perform each measurement. You can opt out at any point in time.