

Blood Pressure Study

Title: Inspiratory muscle strength training for lowering systolic blood pressure and improving endothelial, cerebrovascular, and cognitive function

Principal Investigator: Matthew Rossman, PhD

Location: Main CU Boulder Campus



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Goals of this Clinical Trial:

- Determine if 3 months of at-home breathing training (inspiratory muscle strength training, IMST) improves the following variables to the same extent as traditional exercise (e.g., walking briskly):
 - Systolic blood pressure (top number in a blood pressure reading)
 - Blood vessel function
 - Brain function

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, but we are curious if the improvements seen with IMST are similar, better, or worse than the improvements seen with standard exercise (e.g., walking briskly). If successful, this study will help identify a safe, effective, low-burden way to reduce blood pressure and decrease the risk of developing other heart problems.

Who is eligible to participate?

We are looking for individuals:

- 50 years or older (*if applicable, postmenopausal > 1 year*)
- Who have a systolic blood pressure (top number) between 115-160 mmHg
- Who are willing to perform breathing exercises 5-10 min/day OR walk 25 min/day for 6 days/week over the course of 3 months

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

What do I receive for participating?

- Payment for your time (up to \$400 USD)
- Reimbursement for travel (current federal rate)
- Meal vouchers for visits > 3 hrs
- 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. If it seems like you may qualify after screening visit #1, you'll be invited in for screening visit #2. You will need to fast (no food or drink except water) for up to 5 hour prior to these visits.

Visit 1 (~2 hrs)

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

Visit 2 (~1.5 hrs)

- Blood pressure and heart rate measurement
- Exercise stress test (heart health)
- Physical exam (by physician)
- Ankle-brachial index (checks for artery disease)

What happens during the study?

This study requires ~23.5 hours of your time over the course of ~5 months.

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 a ultrasound and pressure sensor on the surface of your skin)
- Blood draw
- At-home blood pressure monitoring
- Brain function (assessed with tests administered on an iPad)
- Bone mineral density and body composition (DEXA scan)
- Exercise testing (VO2 max test: how much oxygen your body consumes while exercising)

You'll then be randomly assigned to one of two groups: IMST or aerobic exercise. During your first two weeks, you'll come to the lab for 1 supervised session. After you feel confident in performing IMST OR walking while using the heart rate monitor, you'll come to the lab once every other week for the rest of the 3-month period.

For 6 days/week over 3 months:

- The IMST group will be given the IMST breathing trainer and trained to perform IMST 5-10 min/day.
- The aerobic exercise group will be given a heart rate monitor and asked to walk 25 min/day.

After completing 3 months of IMST or walking, we will invite you in for post-testing, where you will repeat the same measures performed at baseline so we can see if any of your variables changed.

~6 weeks after completing post-testing, you'll be invited to the lab for follow-up testing, where we will see if any of the changes we saw from baseline to post-testing were sustained even without performing IMST for 6 weeks.

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 perform the IMST training 6 days/week OR walk 25 min/day, 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: Do I have to stop my current exercise routine (if I have one) to participate?

A: Nope! We would like to maintain your current exercise routine and live your life as you normally do. The walking or breathing exercises would be [in addition to](#) your current routine.

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.