

AWARD NUMBER: W81XWH-16-1-0346

TITLE: Evaluation of HRV Biofeedback as a Resilience Building Intervention in the Reserve Component

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1. INTRODUCTION

The Evaluation of HRV Biofeedback as a Resilience Building Intervention in the Reserve Component study will test heart rate variability biofeedback-assisted resilience training (HRV-BART) versus relaxation breathing training to see if resilience (i.e., the ability to bounce back from adversity) and posttraumatic growth (PTG) can be increased. The study will include both non-patients and participants who meet screening criteria for posttraumatic stress disorder (PTSD) to see if HRV biofeedback can be used as a treatment supplement and potential resilience-building intervention. The specific aims of this study are to (1) develop a mobile app for use with the BART protocol; (2) examine the relationship between baseline HRV and resilience, mental health, substance use, stress and physical health measures; (3) examine how much military personnel with mental health symptoms have lower HRVs and resilience measures at baseline and change over time; and (4) find out how having other mental health issues may affect the impact of HRV-BART on resilience, coping, and PTG scale scores. The study team will recruit 200-500 Reserve Component service members (RCSMs) through behavioral health providers and inactive duty training activities as well as fire and police first responders from North Carolina. Participants will be randomized to receive a 1.5-hour group introductory training in either HRV-BART or relaxation breathing alone and be assessed on baseline HRV and mental and physical health questionnaires. Participants will then be provided with a phone app and Polar heart monitor strap for weekly practice and assessments and follow-ups at 3, 6, 9, and 12 months. We will look for changes in HRV, PTG, and resilience over time to determine the optimal length for each training. We will also determine training effectiveness for those with sleep disturbances, depression, anxiety, and/or PTSD. To date, we have received all IRB approvals, conducted a pilot test determining optimal data collection devices, developed the software and other programming needed for the study, developed all recruitment materials, recruited and tracked 329 participants as of July 31, requested an add on to extend data collection through September and begun data preparation and analysis. This study will provide the first data on the association between HRV and PTG and the ability to increase resilience and PTG scores through training. This will help us design and deliver programs to improve mental and physical well-being of RCSMs first responders and, ultimately, military medical readiness.

2. KEYWORDS:

Biofeedback, HRV, heart rate variability, posttraumatic stress disorder, PTG, resilience, stress, BART, relaxation breathing, reserve component, National Guard, first responders

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Aims and Tasks	Timeline		
Specific Aim 1: Develop and pilot test the Personal Health Informatics Toolkit (PHIT) platform for use with the Biofeedback-Assisted Resilience Training (BART) protocol.			
Major Task 1: Develop and Pilot Test the Physiological Data Collection Platform	Start	End	% Complete
Subtask 1: Prepare human studies protocol documents for pilot test and submit to local Institutional Review Boards (IRBs) and Department of Defense (DoD) Human Research Protection Office (HRPO) for approval	8/1/2016	4/1/2017	100%
Subtask 2: Develop data collection (DC) platform	8/1/2016	4/1/2017	100%
Subtask 3: Recruit community participants for pilot	8/1/2016	1/31/2017	100%
Subtask 4: Collect and analyze pilot test data	1/31/2016	2/31/2017	100%
Subtask 5: Modify platform as needed	2/31/2016	3/15/2017	100%
Subtask 6: Prepare pilot test report	3/15/2016	4/1/2017	100%
Milestone #1: Completed pilot test report		4/15/2017	100%
Milestone #2: Fully tested physiological data collection platform		4/15/2017	100%
Major Task 2: Prepare for Main Study DC	9/1/2016	12/8/2018	85%
Subtask 1: Prepare human studies protocol documents for main study and submit to IRBs and DoD HRPO for approval	12/1/2016	5/1/2017	100%
Milestone #3: All IRB and HRPO approvals received		5/1/2017	100%
Subtask 2: Develop and verify main study DC instruments	12/1/2016	5/1/2017	100%
Subtask 3: Develop and test DC software (PHIT adaptation) and study website	8/1/2016	4/1/2017	85%*
Milestone #4: Finalized DC platforms		6/30/2017	85%*
Subtask 4: Train data collectors for onsite DC	8/1/2017	10/1/2017	100%
Subtask 5: Secure final approval/schedules for DC sites	8/1/2016	10/1/2017	85%*
Subtask 6: Create study information documents and send to providers	9/1/2016	10/1/2017	85%*
Subtask 7: Train personnel and supervise phone calls to providers	6/1/2017	12/1/2017	100%
Subtask 8: Recruit and randomize military participants	6/7/2017	12/1/2017	85%*
Milestone #5: All data collection instruments/software ready for DC		10/1/2017	85%*
Milestone #6: Sample size requirement met		12/31/2017	85%*
Specific Aim 2: Examine the relationship between baseline HRV and resilience, mental health, substance use, stress and physical health measures.			
Major Task 3: Collect, Analyze, and Disseminate Baseline Data			
Subtask 1: Conduct HRV-BART or Paced Breathing training and collect baseline data	6/1/2017	12/1/2017	85%*
Subtask 2: Baseline dataset cleaning, analysis, and reporting	12/1/2017	9/30/2018	50%*
Milestone #7: Baseline technical report and 1 peer-reviewed journal article		9/30/2018	50%
Major Task 4. Follow-up Data Collection (weekly and 3, 6, 9 and 12 mos.)	6/7/2017	12/1/2018	
Subtask 1: Clean and prepare datasets for analysis	10/1/2018	5/31/2019	
Milestone #8: Cleaned and edited dataset		5/31/2019	
Subtask 2: Conduct analyses and prepare manuscripts/briefings	6/1/2019	7/31/2019	
Milestone #9: Analyses and manuscripts/ briefings for publication/presentation complete		7/31/2019	

*Completion status indicates additional data collection time requested on add on (mod dated 22 Aug 2018).

What was accomplished under these goals?

SPECIFIC AIM 1: DEVELOP AND PILOT TEST THE PERSONAL HEALTH INFORMATICS TOOLKIT (PHIT) PLATFORM FOR USE WITH THE BIOFEEDBACK-ASSISTED RESILIENCE TRAINING (BART) PROTOCOL.

Major Task 1: Develop and Pilot Test the Physiological Data Collection Platform

Subtask 1: Prepare human studies protocol documents for pilot test and submit to local Institutional Review Boards (IRBs) and Department of Defense (DoD) Human Research Protection Office (HRPO) for approval.

This task was completed in Year 1.

Subtask 2: Develop data collection (DC) platform

This task was completed in Year 1.

Subtask 3: Recruit community participants for pilot

This task was completed in Year 1.

Subtask 4: Collect and analyze pilot test data

This task was completed in Year 1.

Subtask 5: Modify platform as needed

RTI developers, in collaboration with UNC, met regularly via phone and in person regarding improvements to the data collection application.

Subtask 6: Prepare pilot test report

This task was completed in Year 1.

Milestone #1: Completed pilot test report

This task was completed in Year 1.

Milestone #2: Fully tested physiological data collection platform

Complete.

Major Task 2: Prepare for Main Study DC

Subtask 1: Prepare human studies protocol documents for main study and submit to IRBs and DoD HRPO for approval

This task was completed in Year 1.

Request for IRB renewal was submitted on 10 October 2017 and approved on 26 October 2017 (expiration 25 October 2018).

IRB amendments/modifications were required for the following:

- Broaden inclusion criteria to include veterans,
- Add a Spectra 12-02 Parker Laboratories 360 Electrode Gel tube in the participant's recruitment package for new participants to improve heart rate monitor connectivity,
- Change in principal investigator from Greg Lewis, PhD to Maria Davila, PhD,
- Request to allow Greg Lewis, PhD to remain on the study team as co-investigator at the University of Indiana via a reliance agreement between the UNC IRB and the UI IRB,
- Request approval for the privacy policy required by Google Play Store,
- Request approval to conduct phone follow-up with participants,
- Request to email participating first responders who had not been asked about veteran status in the baseline survey,
- Request to develop and administer a supplementary survey to these first responders to obtain veteran status,
- Extend data collection period, reduce the length of study and compensation for new participants,
- Surveys Month 3 and Month 6 modification,
- BART poster, contact card, briefing script, training script, and consent form modifications.

Milestone #3: All IRB and HRPO approvals received

IRB modification/amendment approval dates during Year 2 are listed below:

30 August 2017
14 September 2017
30 November 2017
3 January 2018
21 March 2018
6 August 2018

It was consistently determined that the study posed no more than minimal risk.

Subtask 2: Develop and verify main study DC instruments

Initially completed in Year 1, modification to surveys (1, 2, 3, and 3-6-9-12 months) and the consent form were required due to the addition of first responders and veterans to the study population. Study questionnaires were subsequently uploaded into the BART application.

Additionally, a supplemental survey (based on the 12-month questionnaire) was developed to capture veteran status for first responders as this variable was not captured in the initial survey for first responders. This supplemental survey was only administered at the 6-month time point to a small subset of the participants who fall into this category.

Subtask 3: Develop and test DC software (PHIT adaptation) and study website

The BART Study website is fully functional.

The BART mobile application became available for free download to study participants via the Apple App Store and the Google Play Store. Trouble shooting continued for both the Apple and Android platforms as issues were identified and resolved, and user experience enhancements were applied. Based on experience to date, several app revisions were made to keep participants incentivized to stay in the study.

An incentive payment algorithm was developed to track incentive payments and to manually distribute payments in the event a participant did not receive the incentive due (e.g., if training or survey criteria was incomplete or activity was conducted out of order).

Data specifications were created and modified to streamline data download from the app to appropriate analysis formats.

Milestone #4: Finalized DC platforms

Complete.

Subtask 4: Train data collectors for onsite DC

Additional data collectors were trained to accommodate increased training opportunities at various locations throughout NC, GA, and VA.

Subtask 5: Secure final approval/schedules for DC sites

Recruitment efforts continued with the Air Force, Marine Corps, Army, and Naval Reserve. The Army Reserve consented to make its Reservists available to the study in NC, VA, and GA and provided a directive to encourage participation in the study.

Subtask 6: Create study information documents and send to providers

This task was completed in Year 1. No modifications or further activity was required in Year 2.

Subtask 7: Train call center personnel and supervise phone calls to providers

Team members rather than call-center personnel were trained in Year 1 to conduct follow-up calls to interested providers.

Subtask 8: Recruit and randomize military and first responder participants

Recruitment activities over the last year have included phone, email, and in-person discussions with military, mental health care provider, veteran organization, and first responder (police departments, fire departments, and EMS/EMT) points of contact. Specific examples of these recruitment efforts are as follows:

- Drs. Hourani and Strange conducted an in-person Study briefing to the USARC Surgeon, COL Mary Reed, and the USARC Deputy Chief of Staff for Operations, Mr. William Hamilton. As a result, approval was granted to access USARC subordinate commands in North Carolina, Virginia, and Georgia. We identified POCs for several North Carolina USAR units and scheduled recruitment visits to those units.
- Efforts to access Navy Reservists in North Carolina required our team to seek approval from the U.S. Navy Bureau of Medicine and Surgery (BUMED). This request process began in early November 2017. While we have the approval of the Director of the Navy Human Research Protection Program Specialty Leader for Research Psychology, the BUMED legal staff have yet to provide approval.
- Because of Virginia's relative proximity to the majority of our team in North Carolina, in late January we began seeking approval to recruit participants from the Virginia Air National Guard and the Virginia Army National Guard. The initial responses from these organizations were positive; however, Virginia Army National Guard ultimately denied the request.
- Recruitment efforts were made with mental health providers in the Ft. Bragg, Charlotte, and Jacksonville, NC areas. Providers were asked to share or make study materials available to eligible clients.

Dr. Hourani was contacted by the Vermont Employee Assistance Program which expressed interest in a possible BART train the trainers program for their first responders. Because we did not have the IRB authority or a train-the-trainer protocol, we trained their mental health providers in paced breathing only under separate funding. Note that this experience will serve well in developing the train-the-trainer protocol for BART as a follow on to the present study.

Facebook and radio advertising were identified as relatively inexpensive options to improve visibility and awareness in the target communities. The radio advertisements were run in the Wilmington and Fayetteville, NC areas during the last two weeks of December 2017, and then subsequently modified to include veterans and run once more only in Fayetteville, NC. A Facebook advertisement was also run during the month of December and was run again for inclusion of veterans. Unfortunately, the providers, radio advertisements, and Facebook advertisements yielded little gain.

Milestone #5: All data collection instruments/software ready for DC

Both the Android and Apple (iOS) versions of the software app were uploaded to the Google Play Store and Apple App Stores for access by study participants. Updates were uploaded as necessary.

Milestone #6: Sample size requirement met

Due to interference between heart rate monitor and app technologies, only small groups or individuals rather than the originally planned larger groups can train simultaneously. As a result, data collection was slower than anticipated and we requested an add-on to extend data collection through September 2018. We have since scheduled additional data collection sessions for September which we will be conducting.

Specific Aim 2: Examine the relationship between baseline HRV and resilience, mental health, substance use, stress and physical health measures.

Major Task 3: Collect, Analyze, and Disseminate Baseline Data

Subtask 1: Conduct HRV-BART or Paced Breathing training and collect baseline data

Field data collection began in August 2017 and is continuing. The data collection teams varied in number (2-8 staff) depending on the anticipated number of possible participants at a given location. See below for specific data collection sites, number of participants recruited per site, and the cumulative recruitment numbers by date.

Due to an opportunity to include a considerable number of interested participants, data collection has been extended through September 2018. Originally participants were given a window of time to fill out specific surveys; however, this restriction was revised, and participants were given the option to fill out surveys indefinitely in an effort to collect as much data as possible.

Participants who had not uploaded data in the last 90 days were contacted by email to encourage participation and provide support if necessary. Those who did not respond to email were also contacted by phone. (Participants are not classified as a “drop out” until they have been inactive in the study for a full year.)

Date of enrollment	Location	# of participants	Accumulated
06/10/17	NOSCA, Army Reserve, Atlanta GA	4	4
08/26/17	Individual training - RTI, Durham NC	2	6
09/09/17	Air National Guard Base, Charlotte NC	18	24
10/07/17	NOSCA, Army Reserve, Atlanta GA	22	46
10/15/17	NOSCA, Army Reserve, Atlanta GA	6	52
11/04/17	Air National Guard Base, Charlotte NC	8	60
11/04/17	Stanly County Airport, Albemarle NC	10	70
11/09/17	Holly Springs Police Department, Holly Springs, NC	7	77
11/10/17	Holly Spring Police Department, Holly Spring NC	3	80
11/16/17	Holly Springs Police Department, Holly Springs, NC	1	81
11/17/17	Holly Springs Police Department, Holly Springs, NC	2	83
11/18/17	Individual training, Durham, NC	2	85
11/27/17	Morrisville Police Department, Morrisville, NC	6	91
11/30/17	Morrisville Police Department, Morrisville, NC	6	97
12/11/17	Morrisville Police Department, Morrisville, NC	4	101
12/14/17	Cary Police Department, Cary, NC	3	104
01/12/18	Cary Police Department, Cary, NC	3	107
01/05/18	Individual training (Reservist/First Responder), Smithfield, NC	1	108
01/12/18	Individual training (Reservist), Durham, NC	1	109
02/13/18	Cary Police Department, Cary, NC	3	112
03/12/18	Individual training (Veteran), Roanoke Rapids, NC	1	113
03/13/18	Group Training (First Responders), RTI	3	116
03/14/18	Individual Training (First Responder), Holly Springs, NC	1	117
03/15/18	Individual Training (First Responder), Raleigh, NC	1	118
03/19/18	Individual Training (Veterans), RTI	2	120
03/21/18	Individual Training (First Responder), RTI	1	121

Date of enrollment	Location	# of participants	Accumulated
03/22/18	Individual Training (First Responder), Morrisville, NC	1	122
03/25/18	Individual Training (Veteran), Atlanta Georgia	1	123
04/02/18	Group Training (Veterans), Fayetteville, NC	4	127
04/06/18	Group Training (First Responders), RTI	2	129
04/09/18	Individual Training (First Responder), RTI	1	130
04/10/18	Group Training (First Responders), Apex, NC	1	131
04/11/18	Group Training (First Responders), Apex, NC	6	137
04/13/18	Group Training (First Responders), Apex, NC	4	141
04/19/18	Group Training (First Responders), Apex, NC	2	143
04/26/18	Group Training (Veterans), Fayetteville, NC	2	145
04/27/18	Group Training (First Responders), Raleigh, NC	3	148
05/05/18	Army Reserve Unit, Ft. Eustis, VA	11	159
05/10/18	Individual, Goldsboro, NC	1	160
05/14/18	Individual Training, Wake Forest, NC	2	162
05/17/18	Individual Training, RTI	1	163
05/18/18	Individual Training, RTI	1	164
05/19/18	Army Reserve Unit, Virginia Beach, VA	29	193
05/20/18	Army Reserve Unit, Knightdale, NC	36	229
05/22/18	Individual Training, RTI	1	230
05/31/18	Individual Training, Beaufort, SC	1	231
06/10/18	Army Reserve Unit, Charlotte, NC	42	273
06/24/18	Army Reserve Unit, Alexandria, VA	38	311
06/24/18	Army Reserve Unit, Richmond, VA	18	329
08/22/18	Individual Training, MHSRS 2018	1	330

Subtask 2: Baseline dataset cleaning, analysis, and reporting

We managed the following subtasks:

- Set up a monthly routine to download data, check data quality, identify participants who are behind on submission of data, etc.
- Created several custom stored procedures for the BART study MS SQL Server database to allow for exporting raw Polar monitor inter beat interval (IBI) data and compute HRV datasets for QA review and interim statistical analyses.
- Created an automatic codebook generator which reads the BART app survey specification files (in XML) and produces a comma-separated list of all survey variables and their characteristics. This latter “pre-codebook” can then be imported into Excel and additional information added (i.e., alternate variable names, report labels, range check parameters) for use by the data analysis team and statistical reporting software.
- Developed the Statistical Analysis plan to ensure a systematic approach to data management and analysis. Performed quality checks on preliminary baseline data; prepared SAS dataset formats and labels; programmed composite variable algorithms. Prepared preliminary tables for demographic and key outcome variables. And, developed procedure to analyze and validate HRV data.
- Finished tools/applications to process the raw heart rate data (RR data). Developed application to convert stress game file and training file into individual Inter Beat Interval (IBI) files - week, session, task, and attempt number are noted per participant. Developed application to classify IBI files into Good, Edit, and Bad, and to edit IBI data classified as such. Developed application to derive HRV parameters and organize the data into a matrix suitable for statistical analysis. Finished the tool/application to summarize the processed HRV obtained by the BART app.
- Revised apps, data collection materials and questionnaires to accommodate expanded participant samples and reduced incentive opportunities (due to time constraints).
- Conducted preliminary data analyses and prepared poster presentations for Military Health System Research Symposium 2018 and other technical venues (see Appendix).

Major Task 4. Follow-up Data Collection (weekly and 3, 6, 9 and 12 mos.)

Subtask 1: Clean and prepare datasets for analysis

Performed quality checks on preliminary baseline and follow-up data; prepared SAS dataset formats and labels; programmed composite variable algorithms.

Subtask 2: Conduct analyses and prepare manuscripts/briefings

This task has not yet begun.

What opportunities for training and professional development has the project provided?

We provided opportunities for 2 junior staff to help develop and present posters at the American Psychological Association (APA) and Military Health System Research Symposium (MHSRS) annual meetings.

How were the results disseminated to communities of interest?

Bart HRV and app methodologies and preliminary results were disseminated at APA and MHSRS in August 2018 (see attached).

What do you plan to do during the next reporting period to accomplish the goals?

Complete baseline data collection scheduling and preparations
Complete recruitment
Complete at least one methodology and one baseline results paper for publication
Continue follow up data collection and processing
Continue statistical analyses and reporting

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Pending

What was the impact on other disciplines?

Pending

What was the impact on technology transfer?

- We determined that the Polar Strap device for the measurement of HRV was the most efficient and reliable of the three main devices tested.
- We designed, developed, and tested working software that provides the interface between HRV and smartphone technology.

What was the impact on society beyond science and technology?

Pending

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Minor changes were made to streamline data collection time when needed (e.g., allowing participants to complete the first baseline questionnaire at home rather on site). We broadened our participant base to include other first responders, such as firemen and policemen, and reduced the potential burden on the military. Minor questionnaire changes were made to accommodate the addition of these participants. Because of the add-on start date in August, newly recruited participants (those in September) will be followed up to 6 months.

Actual or anticipated problems or delays and actions or plans to resolve them

Thank you for the add-on funds to extend data collection and maximize sample size for analyses.

Changes that had a significant impact on expenditures

Thank you for the additional funds to extend participant recruitment. Increasing recruitment will increase sample size to permit more in depth statistical analyses of the data and allow for stronger conclusions.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to report.”

Publications, conference papers, and presentations

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers, and presentations.

An abstract entitled “Lessons Learned Integrating Heart Rate Data Collection for the Biofeedback-Assisted Resilience Training (BART) Study” was accepted for presentation at the 9th International Conference on Applied Human Factors and Ergonomics (AHFE 2018) in Orlando, FL in July 2018. No BART funds required.

An abstract entitled “Mobile technology for improving psychological resilience via heart rate variability biofeedback” was accepted for presentation at the UNC Digital Health Symposium in Chapel Hill, NC on 23 February 2018.

A focused technology session with examples from BART was presented at the International Field Directors and Technologies Conference on Integrating Wearable Sensor Technology with Survey Data Collection, Denver, Colorado, May 2018. No BART funds required.

The following four posters were presented at the Military Health System Research Symposium 2018 in Kissimmee, FL on August 2018 (see appendix):

1. Hourani, L., Morgan, J., Davila Hernandez, M., Lewis, G., Meleth, S., Kizakevich P, Eckhoff R, Ramirez D, Morgan T, Strange L, Lane B, Weimer B, Lewis A. Heart rate variability biofeedback as a resilience-building intervention in the Reserve Component and First Responders.
2. Morgan, J.K., Hourani, L.L., Lane, E. M., Morgan, T., Davila, M. The physiology of positive psychology: heart rate variability, posttraumatic growth, and coping styles in the military.
3. Kizakevich, P., Davila, M., Eckhoff R., Lewis, G., Watkins, R., Boyce M., Hourani, L. Mobile health technology for biofeedback assisted resilience training (BART).
4. Davila M., Kizakevich, P., Eckhoff, R., Lewis, G., Hourani, L. Building resilience via HRV biofeedback in the reserve component: evaluation of a mobile technology combined with a portable heart rate monitor.

Website(s) or other Internet site(s)

Study website: <https://bart.rti.org>

Technologies or techniques

- BART Phit 4 Duty app on iOS and Android platforms
- Battery of applications to process the raw IBI data into Heart Rate Variability (HRV) data

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

- Study recruitment/announcement video
- Recruitment materials and questionnaires

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Laurel Hourani, PhD, MPH
Project Role:	PI
Nearest person month worked:	10
Contribution to Project:	Directed and reviewed all study activities on the RTI site.
Name:	William Abb
Project Role:	Consultant
Nearest person month worked:	1
Contribution to Project:	Consulted on Citizen Soldier list for study recruitment.
Name:	Dr. Maria Davila
Project Role:	PI
Nearest person month worked:	7
Contribution to Project:	Directed and reviewed all study activities on the UNC site.
Name:	Dr. Greg Lewis
Project Role:	Co-Investigator
Nearest person month worked:	3
Contribution to Project:	Previous PI on the UNC site. Consulted on data analysis. Indiana University
Name:	Randy Eckhoff
Project Role:	Software Developer
Nearest person month worked:	6
Contribution to Project:	Led software development for mobile iOS app and the bart.rti.org website.
Name:	Paul Kizakevich
Project Role:	Biomedical Engineer
Nearest person month worked:	7
Contribution to Project:	Adapted the PHIT for Duty app as a foundation for implemented the BART study protocol, including questionnaires, physiological data analysis, HRV biofeedback, and incentive monitoring.
Name:	Marian Lane
Project Role:	Co-Investigator
Nearest person month worked:	2
Contribution to Project:	Assisted with provider recruitment
Name:	Amanda Lewis
Project Role:	Project Manager
Nearest person month worked:	6
Contribution to Project:	Managed weekly meetings; staffing changes; assisted with phone follow-ups; planned staff training days

Name:	Stephen Litavec
Project Role:	Programmer
Nearest person month worked:	1
Contribution to Project:	Assisted with app development and training
Name:	Sreelatha Meleth
Project Role:	Lead statistician
Nearest person month worked:	3
Contribution to Project:	Developed analysis plan, analyzed dropout rate, assisted with training
Name:	Jessica Morgan
Project Role:	Co-Investigator
Nearest person month worked:	3
Contribution to Project:	Assisted with data collection and analysis
Name:	Timothy Morgan
Project Role:	Co-Investigator
Nearest person month worked:	5
Contribution to Project:	Responsible for recruitment and logistics
Name:	Derek Ramirez
Project Role:	Analyst
Nearest person month worked:	1
Contribution to Project:	Assisted with data analysis
Name:	Rebecca Watkins
Project Role:	Software technician
Nearest person month worked:	1
Contribution to Project:	Assisted with software development of mobile iOS app and bart.rti.org website.
Name:	Belinda Weimer
Project Role:	Co-investigator
Nearest person month worked:	2
Contribution to Project:	Questionnaire development; e-mail follow-up; incentive tracking system

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Davila assumed PI responsibilities from Dr. Lewis who transferred to Indiana University.

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies, or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Appendix A. Abstracts/Poster presentations

Appendix B. Modification Extension (6 Months)

Appendix C. Quad Chart

Appendix A. Abstracts/Poster Presentations

Heart Rate Variability Biofeedback as a Resilience-Building Intervention in the Reserve Component and First Responders

Laurel L. Hourani, PhD, MPH,¹ Jessica Morgan, PhD,¹ Maria Davila Hernandez, PhD,² Greg Lewis, PhD,² Sree Meleth, PhD,¹ Paul Kizakevich, MS,¹ Randy Eckhoff,¹ Derek Ramirez, MA,¹ Tim Morgan, MA,¹ Laura Strange PhD, RN,¹ Becky Lane, PhD,¹ Belinda Weimer, MA,¹ Amanda Lewis¹

1. Background

Posttraumatic stress disorder (PTSD) has negative effects on service members in multiple facets of their lives. Increasing resilience can serve as a protective factor against PTSD and other associated mental health issues. Reserve Component members have a different set of stressors than their active duty counterparts, including balancing civilian employment with military service, varied access to medical and other services, and greater isolation from peers and military support systems. Creating evidence-based, portable resilience-building training using biofeedback or breathing techniques that can be learned in a single session and practiced at home will be particularly valuable to Reserve Component members as well as first responders.

This study involves developing an intervention based on heart rate variability (HRV) biofeedback for building resilience and supplementing PTSD treatment. HRV (i.e., variation in the time interval between heartbeats) is a measure of parasympathetic nervous system activity, with higher HRV indicating greater flexibility and ability to regulate emotional responses. PTSD is associated with reduced levels of both respiratory sinus arrhythmia (RSA) and low-frequency HRV (LFHRV). Hyperarousal and anxiety are thought to underlie this association. Reduction of physiological arousal during and/or shortly after trauma exposure may prevent or reduce the likelihood of psychological distress, including PTSD symptoms.

Biofeedback is a technique that allows an individual to receive feedback about internal physiological processes, and biofeedback training provides the opportunity to learn to manipulate these processes through this awareness. HRV biofeedback training has been shown to improve depression, anxiety, stress, and PTSD outcomes. However, questions remain about factors influencing HRV biofeedback's effectiveness and the subgroups for whom it works. This study begins to close these gaps.

Self-regulation can be enhanced by practice and conscious intervention through HRV biofeedback-assisted relaxation training (BART). In this way, HRV serves as both a measure of autonomic regulation and a promising target for any intervention to improve the resilience of individuals before or after a traumatic event. HRV-BART is the most logical, direct pathway to intervene and enhance physiological resilience.

The concept of resilience—the ability to rebound from adversity—has recently been a major focus in efforts to improve military well-being, and studies have associated it with various mental health outcomes in this population. An important aspect of this process is the return to a physiologic equilibrium indicated by higher resting HRV and a quicker return to resting heart rate following a stressor. Some studies have indicated that an increase in HRV is linked to resilience, though these studies have not measured it with standardized instruments. Therefore, the objective of this study is to create evidence-based, portable resilience-building training using biofeedback or relaxation breathing techniques that can be learned in a single session and practiced at home as a valuable tool for both Reserve Component and First Responders (fire and police officers).

2. Study Aims

1. Examine the relationship between HRV and resilience, mental health, substance use, stress, and physical health measures.
2. Examine individual differences in response to various BART training parameters (breathing speed, amount of practice, knowledge of and prior use of biofeedback and/or other complementary methods).
3. Examine the extent to which resilience and mental health symptoms are linked to HRV at baseline and how that relationship changes over time. Explore the interaction between comorbidities that may impact the effect of HRV-BART on resilience, coping, and posttraumatic growth (PTG) scale scores.

3. Methods

This 3-year longitudinal study entails adapting and developing an enhanced HRV biofeedback training protocol to test the effects of paced respiratory rates and frequency and length of at-home practice in a large sample of Reserve Component members and First Responders, including those who meet screening criteria for PTSD. Participants who volunteer participate in a 60-minute training session and complete survey assessments over the course of 1 year.

Self-Report Questionnaire Measures

Primary outcome data will be obtained through questionnaires with standard Connor-Davidson Resilience Scale (CD-RISC) scores, coping measures (Brief coping scale [COPE]), Perceived Stress Scale, Posttraumatic Growth Inventory (PTGI), and sleep problems (Sleep Disturbance Scale). Secondary outcomes include mental health (PCL-C; GAD-7; Center for Epidemiologic Studies Depression Scale [CES-D]), physical health (Short Form 12-item Health Survey [SF-12], TBI), and alcohol use problems (Alcohol Use Disorders Identification Test [AUDIT]). Covariates include combat and deployment, recent tobacco and caffeinated beverage use, age, education, use of other relaxation techniques, and interest in learning relaxation skills.

Procedure

- Participants are trained in one of two protocols:
 1. HRV biofeedback with paced breathing
 - OR
 2. Paced breathing only
- Participants provide weekly status updates on their resilience scores by mobile app.
- Data are analyzed at weekly intervals through the 6-week at-home practice period, and later at 3-, 6-, 9-, and 12-month follow-up intervals.
- Up to \$165 in Amazon gift cards are available to participants and free heart rate monitor.

Incentives

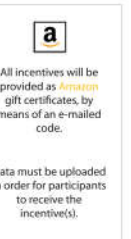
Time Period	Incentive \$ Value	Required Subject Activities
Baseline Assessments	\$25	HRV assessment + Baseline Survey Module 1 = \$15 Baseline Survey Module 2 = \$5 Baseline Survey Module 3 = \$5
Week 1	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Week 2	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Week 3	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Week 4	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Week 5	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Week 6	\$10	Practice at home (x3) Complete Brief Weekly Follow-Up Survey
Month 3	\$20	HRV assessment Quarterly Follow-Up Survey
Month 6	\$20	HRV assessment Quarterly Follow-Up Survey
Month 9	\$20	HRV assessment Quarterly Follow-Up Survey
Month 12	\$20	HRV assessment Quarterly Follow-Up Survey
Total	\$165	

Statistical Analyses

To examine the relationship between baseline HRV and our independent variables, we ran bivariate correlations at baseline to assess the associations between all variables of interest: HRV, PTG, resilience, hardiness, PTSD, depression, anxiety, stress, coping, and substance abuse. Simple moderation models will be run and significant results are modeled using simple slopes when appropriate. Analyses of variance are used to determine if groups assigned to different BART training parameters show significant differences in results at follow-up. Latent growth curve modeling will be used to assess the trajectories of each variable over time. We expect that the inclusion of biofeedback will increase the speed and magnitude of shifts in HRV parameters. Our first hypothesis and test results are shown below.

Hypothesis 1

We hypothesized that HRV will be positively associated with resilience, PTG, hardiness, coping, and physical health and that it will be negatively associated with PTSD, depression, anxiety, substance abuse, and stress.



4. Results

Results

Preliminary baseline data are based on 286 participants (132 PB and 154 BART). **Table 1** shows the demographic distribution of the PB and BART groups. Results indicate a significant positive correlation between coping scores and RSA at rest and between RSA recovery post stressor for both generalized anxiety ($r=.151, p=.02$) and PTSD checklist scores ($r=.173, p=.015$) and between LFHRV recovery post stressor and PTSD ($r=.14, p=.05$) and depression ($r=.13, p=.05$). (**Tables 2-5**).

Table 1. Frequency distribution of baseline sociodemographic variables by group

Component/Sample	PB	BART	Total
ARNG (%)	0 (0)	1 (0.88)	1
USAR (%)	65 (69.15)	80 (70.8)	145
USNR (%)	3 (3.19)	3 (2.65)	6
ANG (%)	19 (23.21)	15 (13.27)	34
USAFR (%)	1 (1.06)	3 (2.65)	4
USMCR (%)	6 (6.38)	11 (9.73)	17
First Responder (%)	38	41	286
Gender			
Female (%)	47 (36.15)	52 (33.99)	99
Male (%)	83 (63.85)	101 (66.01)	184
Age Group			
18-20 (%)	9 (6.92)	5 (3.29)	14
21-30 (%)	35 (26.92)	50 (32.89)	85
31-41 (%)	37 (28.46)	57 (37.5)	94
42+ (%)	49 (37.69)	40 (26.32)	89
Education			
High School or Less (%)	17 (12.98)	15 (9.87)	32
Some College (%)	28 (21.37)	42 (27.63)	70
College Grad (%)	86 (65.65)	95 (62.5)	181
Deployment			
Ever N (%)	63 (-73.26)	62 (-60.19)	125
Never N (%)	23 (-26.74)	41 (-39.81)	64
Missing	46	51	286

Table 2. Correlations between RSA differences, PTSD, depression, anxiety, substance abuse, and stress, Rho (p-val)

	PTSD	Depression	Anxiety	Substance Abuse	Stress
RSA_post_rest_diff	0.068 (0.34)	0.048 (0.47)	0.056 (0.40)	-0.130 (0.06)	0.056 (0.40)
RSA_post_stress_diff	0.173 (0.015)	0.13 (0.05)	0.151 (0.02)	-0.122 (0.08)	0.124 (0.06)

Table 3. Correlations between RSA differences, resilience, physical health, hardiness, and PTG, Rho (p-val)

	Resilience	Physical Health	Hardiness	PTG
RSA_post_rest_diff	-0.064 (0.36)	0.16 (0.02)	-0.045 (0.54)	-0.06 (0.36)
RSA_post_stress_diff	-0.09 (0.19)	0.14 (0.05)	-0.14 (0.05)	-0.08 (0.27)

Table 4. Correlations between LFHRV differences, PTSD, depression, anxiety, substance abuse, and stress, Rho (p-val)

	PTSD	Depression	Anxiety	Substance Abuse	Stress
LFHRV_post_rest_diff	0.04 (0.58)	0.07 (0.28)	0.01 (0.91)	-0.011 (0.86)	0.007 (0.91)
LFHRV_post_stress_diff	0.14 (0.05)	0.13 (0.05)	0.03 (0.58)	-0.13 (0.07)	0.06 (0.37)

Table 5. Correlations between LFHRV differences and resilience, health, hardiness, and PTG, Rho (p-val)

	Resilience	Physical Health	Hardiness	PTG
LFHRV_post_rest_diff	-0.135 (0.05)	0.18 (0.008)	-0.01 (0.87)	-0.006 (0.92)
LFHRV_post_stress_diff	-0.19 (0.007)	0.21 (0.003)	-0.12 (0.10)	-0.12 (0.08)

Figure 1. PCL scores by RSA

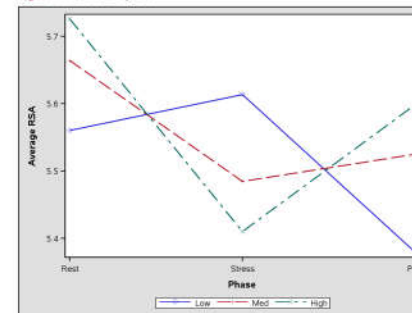
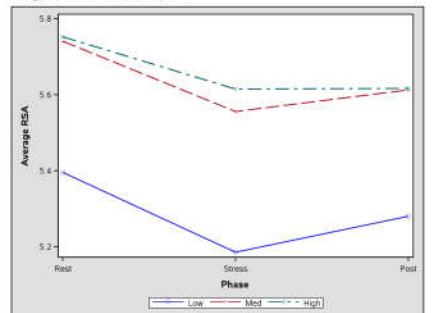


Figure 2. Resilience scores by RSA



5. Conclusion

This study will assess the potential of HRV biofeedback and optimal parameters as an adjunct treatment for PTSD-related symptoms and provide the first empirical examination of the association between HRV measures and the ability to increase resilience scores. Preliminary baseline data indicate biofeedback HRV training may help improve symptoms of PTSD and other mental health symptoms in these population groups.

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Jessica Kelley Morgan, PhD^{1*}; Laurel L. Hourani, PhD, MPH¹, Marian E. Lane, PhD¹, Timothy Morgan¹, Maria Davila, PhD²

1. Introduction

Background.

Accumulating evidence suggests that some people who experience adverse events are able to perceive positive psychological changes resulting from the cognitive work required to deal with the crisis (Morgan, Desmarais, Mitchell, & Simons-Rudolph, 2017; Tedeschi & Calhoun, 2004); this phenomenon is referred to as posttraumatic growth (Tedeschi & Calhoun, 1996).

Recent research in military Veterans suggests that the experience of posttraumatic growth has an effect on overall satisfaction with life, and buffers against deleterious effects of posttraumatic stress disorder (Morgan et al., 2017).



Prior work has also shown that positive emotions and coping styles may affect physiological responses to stressors (Tugade & Fredrickson, 2004; Tugade, Fredrickson, & Barrett, 2004). Whether posttraumatic growth affects post-trauma physiology is unknown.

Heart rate variability (HRV) is the variation of beat to beat intervals, also known as R-R intervals.

Higher HRV indicates better parasympathetic activity.

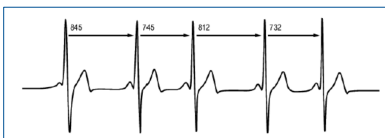


Figure 1. Variability in beat to beat intervals of heart rate.

2. Study Methods

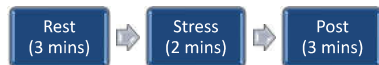
Participants and Procedures.

Military service members and Veterans were recruited to take part in a study on biofeedback-assisted resilience training using a mobile application.

Participants' heart rate variability was assessed using a Polar H7 sensor (Polar Electro Inc, Bethpage, NY) and a conductive fabric chest strap. This heart rate sensor provides beat-by-beat interbeat intervals and pairs wirelessly to mobile devices. Every two seconds, a physiological signal processing module was used to filter and derive, and display the average heart rate (HR), and three heart rate variability (HRV) measures across a 20-second epoch. Specifically, data from the sensor were inspected for artifact by an algorithm (adapted from Bertsone, Quigley, Jang, & Boysen, 1990 to work in real-time), then analyzed according to the Porges-Bohrer method to measure low frequency (LF-) and high frequency (HF-) HRV or respiratory sinus arrhythmia (RSA) (Lewis, Furman, McCool, & Porges, 2012).



2. Study Methods (continued)



HRV measures were assessed during a seated resting baseline (3 minutes), an Eriksen-Flanker task (2 minutes) and a recovery period (3 minutes). The Eriksen-Flanker task was used to create cognitive load and act as a stressor, and the HRV measures during and after the Eriksen-Flanker task therefore assessed physiological reactivity and recovery.



Figure 2. Heart rate variability biofeedback.

Measures

Posttraumatic Growth Inventory (Tedeschi and Calhoun, 1996). Posttraumatic growth was measured using the PTGI, a 21-item measure assessing the five domains of growth: increased appreciation in life, relating to others, new possibilities, spiritual change, and personal strength.

Coping styles were assessed using the Brief COPE (Carver, 1997). We examined three dimensions: positive reframing (items 12 and 17), planning (items 14 and 25), and active coping (items 2 and 7).

Statistical Analyses

We calculated mean RSA at each phase and assessed correlations between point estimates and posttraumatic growth and coping. We then examined associations between the slopes and difference scores with the coping styles and posttraumatic growth.

We plotted RSA over the three baseline phases (rest, stress, and post) by mean levels of posttraumatic growth and coping styles (medium) as well as high (+1 SD) and low (-1 SD).

3. Results

Recruitment is scheduled to end at the end of September 2018; currently enrolling Guard/Reserve Component and Veterans. Current sample size is 236. For the analyses presented, $N = 168$. Mean participant age is 35.67 years ($SD = 11.52$).

Sex		Education	
Female (%)	74 (44.3)	HS/GED	16 (7.7)
Male (%)	92 (55.1)	0-2 Yrs College	64 (30.9)
Component		4-Year Degree	42 (20.3)
ARMG (%)	1 (0.4)	Graduate Level	45 (21.8)
USAR (%)	145 (70.1)	Outcomes M (SD)	
USNR (%)	6 (2.9)	PTG	37.94 (12.1)
ANG (%)	34 (16.4)	Positive Reframing	5.5 (1.6)
USAFR (%)	4 (1.9)	Planning	6.0 (1.5)
USMCR (%)	17 (8.2)	Active Coping	5.9 (1.6)



3. Results (continued)

Findings indicated that the Eriksen-Flanker task produced increases in cardiovascular activity from baseline. These changes reflect task-induced cardiovascular arousal, which included increases in heart rate and decreases in RSA and LF-HRV. Results showed that higher reports of posttraumatic growth were associated with higher RSA during the resting phase and the stressor task at baseline. Posttraumatic growth was also positively associated with several styles of coping, including active coping, positive reframing, planning, acceptance, and religion. Similarly, several coping styles were related to baseline HRV measures. Positive reframing was associated with higher RSA during rest, stressor, and recovery periods, and LF-HRV at rest and stressor periods.

For posttraumatic growth, there were no significant differences within each phase, but there were significant differences for the slopes. Those high in posttraumatic growth showed a slight (nonsignificant) increase in HRV during the stressor, while those lower in PTG showed greater negative reactivity to the stressor and subsequent greater recovery. See Figure 3.

For active coping, planning, and positive reframing, those highest in these coping styles had the highest HRV across all three phases. See Figures 4-6.

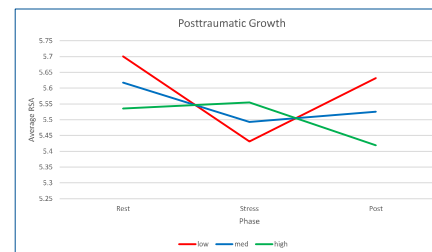


Figure 3. RSA by posttraumatic growth across phases.

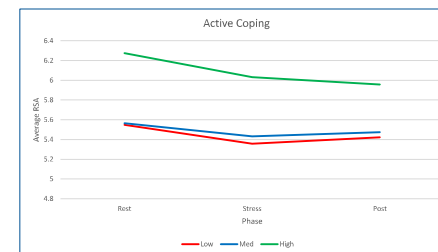


Figure 4. RSA by active coping across phases.



Figure 5. RSA by planning across phases.

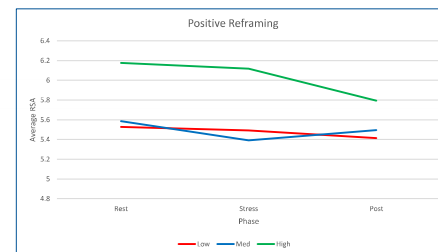


Figure 6. RSA by positive reframing across phases.

4. Discussion

Our findings demonstrate that beyond self-reported perceived psychological outcomes following trauma, the experience of posttraumatic growth is related to physiological states, both at rest and under negative emotional arousal. These results therefore have implications for researchers and clinicians alike. Through the intentional facilitation of posttraumatic growth and fostering positive reframing, military service members and Veterans may be able to affect their physiology and improve short- and long-term health outcomes.

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References available upon request.

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Research Topic Area *	Psychological Health & Resilience Young Investigator Competition? Yes <i>Qualifications: Primary authors and presenters must be residents, fellows, doctoral candidates and post-docs/individuals with a doctoral degree within five years of graduation from a terminal degree. Service academy cadets are also eligible for this presentation category. Previous winners are not eligible. Previous winners are those who have placed 1st, 2nd or 3rd at previous MHSRS meetings.</i> <i>Note: YI submissions not selected for a plenary presentation will be reconsidered for an oral or poster presentation under the Research Topic area selected.</i>	
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Abstract

Background. Accumulating evidence suggests that some people who experience adverse events are able to perceive positive psychological changes resulting from the cognitive work required to deal with the crisis (Morgan, Desmarais, Mitchell, & Simons-Rudolph, 2017; Tedeschi & Calhoun, 2004); this phenomenon is referred to as posttraumatic growth (Tedeschi & Calhoun, 1996). Recent research in military Veterans suggests that the experience of posttraumatic growth has an effect on overall satisfaction with life, and buffers against deleterious effects of posttraumatic stress disorder (Morgan et al., 2017). Prior work has also shown that positive emotions and coping styles may affect physiological responses to stressors (Tugade & Fredrickson, 2004; Tugade, Fredrickson, & Barrett, 2004). Whether posttraumatic growth affects post-trauma physiology is unknown. **Methods.** Military service members and Veterans were recruited to take part in a study on biofeedback-assisted resilience training using a mobile application. Participants' heart rate variability was assessed using a Polar H7 sensor (Polar Electro Inc, Bethpage, NY) and a conductive fabric chest strap. This heart rate sensor provides beat-by-beat interbeat intervals and pairs wirelessly to mobile devices. Every two seconds, a physiological signal processing module was used to filter and derive, and display the average heart rate (HR), and three heart rate variability (HRV) measures across a 20-second epoch. Specifically, data from the sensor were inspected for artifact by an algorithm (adapted from Berntson, Quigley, Jang, & Boysen, 1990 to work in real-time), then analyzed according to the Porges-Bohrer method to measure low frequency (LF-) and high frequency (HF-) HRV or respiratory sinus arrhythmia (RSA) (Lewis, Furman, McCool, & Porges, 2012). HRV measures were assessed during a seated resting baseline (3 minutes), an Eriksen-Flanker task (2 minutes) and a recovery period (3 minutes). The Eriksen-Flanker task was used to create cognitive load and act as a stressor, and the HRV measures during and after the Eriksen-Flanker task therefore assessed physiological reactivity and recovery. **Results.** Findings indicated that the Eriksen-Flanker task produced increases in cardiovascular activity from baseline. These changes reflect task-induced cardiovascular arousal, which included increases in heart rate and decreases in RSA and LF-HRV. Results showed that higher reports of posttraumatic growth were associated with higher RSA during the resting phase and the stressor task at baseline. Posttraumatic growth was also positively associated with several styles of coping, including active coping, positive reframing, planning, acceptance, and religion. Similarly, several coping styles were related to baseline HRV measures. Positive reframing was associated with higher RSA during rest, stressor, and recovery periods, and LF-HRV at rest and stressor periods. **Conclusions.** Our findings demonstrate that beyond self-reported perceived psychological outcomes following trauma, the experience of posttraumatic growth is related to physiological states, both at rest and under negative emotional arousal. These results therefore have implications for researchers and clinicians alike. Through the intentional facilitation of posttraumatic growth and fostering positive reframing, military service members and Veterans may be able to affect

	their physiology and improve short- and long-term health outcomes. The ability to train physiological responses will be discussed. References Berntson, G. G., Quigley, K. S., Jang, J. F., & Boysen, S. T. (1990). An approach to artifact identification: application to heart period data. <i>Psychophysiology</i>, 27(5), 586–598. Lewis, G. F., Furman, S. A., McCool, M. F., & Porges, S. W. (2012). Statistical strategies to quantify respiratory sinus arrhythmia: are commonly used metrics equivalent? <i>Biological Psychology</i>, 89(2), 349–364. https://doi.org/10.1016/j.biopsycho.2011.11.009 Morgan, J. K., Desmarais, S. L., Mitchell, R. E., & Simons-Rudolph, J. M. (2017). Posttraumatic stress, posttraumatic growth, and satisfaction with life in military Veterans. <i>Military Psychology</i>, 29(5), 434–447. http://dx.doi.org/10.1037/mil0000182 Tedeschi, R. G., & Calhoun, L. G. (1996). The Posttraumatic Growth Inventory: Measuring the positive legacy of trauma. <i>Journal of Traumatic Stress</i>, 9(3), 455–471. https://doi.org/10.1002/jts.2490090305 Tedeschi, R. G., & Calhoun, L. G. (2004). Posttraumatic growth: Conceptual foundations and empirical evidence. <i>Psychological Inquiry</i>, 15(1), 1–18. Tugade, M. M., & Fredrickson, B. L. (2004). Resilient individuals use positive emotions to bounce back from negative emotional experiences. <i>Journal of Personality and Social Psychology</i>, 86(2), 320–333. https://doi.org/10.1037/0022-3514.86.2.320 Tugade, M. M., Fredrickson, B. L., & Barrett, L. F. (2004). Psychological resilience and positive emotional granularity: Examining the benefits of positive emotions on coping and health. <i>Journal of Personality</i>, 72(6), 1161–1190. https://doi.org/10.1111/j.1467-6494.2004.00294.x
	Abstract Disclaimer
Learning Objectives *	** Use action verbs such as Describe, Define, Analyze to begin the description of each learning objective. A learning objective is one sentence. ** *1. Describe the phenomena of posttraumatic growth and heart rate variability in the military. *2. Analyze the associations between posttraumatic growth, coping styles, and heart rate variability under different conditions. *3. Conceptualize implications for training heart rate variability responses and facilitating posttraumatic growth in military populations.
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Mobile health technology for Biofeedback Assisted Resilience Training (BART)

Paul Kizakevich*, Maria Davila**, Randy Eckhoff*, Greg Lewis***, Rebecca Watkins*, Matt Boyce*, Laurel Hourani*

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Background

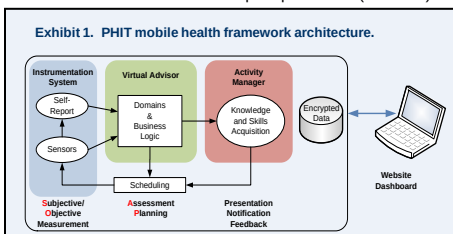
Psychological resilience, an individual's ability to recover from an adverse event and return to physiological homeostasis and mental well-being, is critical to minimize health effects such as sleep problems, substance abuse, post-traumatic stress disorder after a traumatic experience. In a study to evaluate resilience-enhancing methodologies, RTI and UNC researchers developed a mobile health app with stress relaxation elements and heart rate variability (HRV) biofeedback.

The objectives were to (1) develop an integrated mobile app with longitudinal health assessment and Biofeedback Assisted Resilience Training (BART); and (2) compare the efficacy of biofeedback-enhanced to simple paced breathing exercises in military, veteran, and civilian first-responder populations.

Methods

Personal Health Intervention Toolkit (PHIT)

The BART study app was implemented using RTI's PHIT toolkit, a reusable framework for mobile health research. The PHIT framework integrates multimodal data collection with an intelligent virtual advisor (IVA) that analyzes real-time data to recommend, tailor, and present domain-specific activities based on evidence-based rules and scripted processes (Exhibit 1).



Based on the clinical SOAP-notes paradigm, PHIT-based apps:

- Integrate self-reported and physiological sensor instruments,
- Analyze data via a scripted intelligent virtual advisor
- Tailor evidence-based self-help activities and interventions
- Reassess and fine-tune activities and interventions over time
- Monitor protocol adherence and automate incentive payments
- Hide the complexities of mobile software development, enabling researchers to focus on study aims and objectives

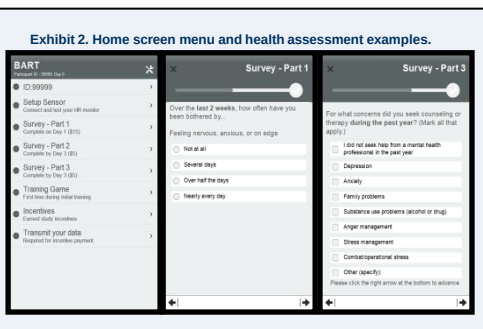
Data are stored on the device using an encrypted database, periodically uploaded to a secure server, and made available for analysis via a password-protected dashboard. Developing PHIT apps, instruments, IVA scripts, and intervention activities is straightforward yet the XML structures provide considerable power in customizing content, logic, scheduling, and interactivity.

PHIT's cross-platform design integrates a suite of health assessments with an expert system that recommends, tailors, and presents activities and interventions. The platform's simplicity supports development using XML, and its flexibility allows apps to collect health data from many different sources. Both iOS and Android versions are readily produced, with nearly identical user interfaces and function across operating systems.

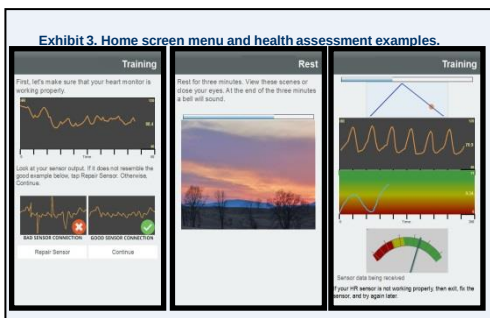
BART Mobile App

Built upon the PHIT toolkit, the BART app integrates subjective self-report baseline and outcome measures (i.e., stress, depression, sleep quality), a cognitive stressor, and four alternative resilience training regimens - 5 or 6 breaths/minutes paced breathing, with or without HRV biofeedback. Study participants use the BART app at least three times a week for resilience-building training over a 6-week training duration.

Required user actions, like health assessments, resilience training, and data uploads, are managed via a home screen task menu (Exhibit 2). Participant-reported outcome measures are made via brief questionnaires. As tasks are completed, an earned incentive table is updated. The menu is updated daily according to study protocol via the intelligent virtual advisor.



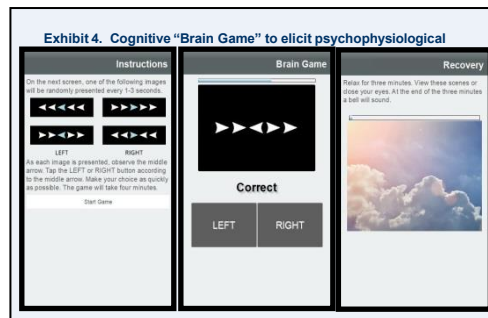
At the onset of each training exercise, the HRM is activated and a beat-by-beat heart rate is displayed to verify signal quality (Exhibit 3). For biofeedback of psychological arousal, BART captures beat-to-beat heart intervals from a Polar H7 heart rate monitor (HRM). Every two seconds, a physiological signal processing module is used to filter and derive, and display the average heart rate (HR), and three heart rate variability (HRV) measures across a 20-second epoch. The derived HR and HRV measurements are displayed as real-time waveforms for stress relaxation biofeedback, indicating movement to a more calm or more stressful state (Exhibit 3).



Three times each week for six weeks, each participant is asked to complete the BART protocol as shown in Exhibit 3, with a three minute resting baseline and a five minute resilience training segment. The four resilience training regimens are randomized via coding embedded in the Participant ID.

On study days 0 and 1, and after six weeks of training, participants also complete an augmented training regimen called the Training Brain Game (Exhibit 4). The Brain Game, a implementation of the Eriksen Flanker task, is designed to elicit psychophysiological stress under a controlled exercise as a way of evaluating resilience improvement over the six week duration.

The Brain Game begins with succinct participant instructions on performing the task. A series of stimulus screens are displayed with a field of arrows pointing to the left or right, including a central arrow that may be congruent or incongruent in direction with the bounding arrows. The Participant taps a left or right button below the stimulus as soon as possible to indicate the direction of the central arrow. After a four-minute duration, the BART app advances to a three-minute resting recovery phase.



Evaluation

An comparison of the four modes of resilience training is being conducted in a mixed population of military personnel, veterans, and civilian first responders. Recruitment and training are ongoing at multiple sites across multiple states.

Results

As this study is ongoing, the results are preliminary as of March 2018 and are presented merely to showcase features and capabilities of the BART app. This preliminary subset of study participants had the following demographics:

- Occupation**
 - 67 were military personnel
 - 48 were civilian first-responders
- Sex**
 - 28 were female
 - 69 were male
- Age**
 - 4 were 18-20 years of age
 - 33 were 21-30 years of age
 - 30 were 31-41 years of age
 - 28 were 42+ years of age

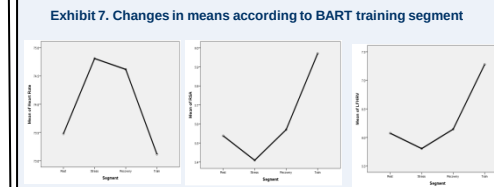
Descriptive statistics for Heart Rate and two HRV measures, Respiratory Sinus Arrhythmia (RSA) and Low Frequency HRV (LFHRV) are shown below (Exhibit 5) for these preliminary data. An analysis of variance comparing HRV means across the BART training segments is presented in Exhibit 6, along with plots of the HRV means in Exhibit 7. Although changes in these measures are quite small, they nonetheless are very significant ($P < .001$). Reduced parasympathetic activation during the Brain Game stressor task is indicated by the decrease in RSA, which returns to resting levels during recovery, and increases substantially during paced breathing training.

Exhibit 5. Descriptive statistics according to BART training

		N	Mean	Std. Deviation	Minimum	Maximum
Heart Rate	Rest	7498	73.480	12.3313	36.1	119.0
	Stress	1728	74.809	12.0278	48.1	117.0
	Recovery	1249	74.617	12.1457	44.4	111.0
	Train	16610	73.118	11.3636	28.2	119.0
	Total	27085	73.395	11.7280	28.2	119.0
RSA	Rest	7488	5.538	1.2553	.2	8.5
	Stress	1724	5.409	1.2601	1.0	8.5
	Recovery	1254	5.570	1.1963	.8	8.5
	Train	16639	5.970	1.1812	.2	8.9
	Total	27105	5.797	1.2279	.2	8.9
LFHRV	Rest	7377	6.075	1.3131	.3	9.7
	Stress	1722	5.805	1.2842	1.0	9.6
	Recovery	1250	6.145	1.2544	.7	9.6
	Train	16503	7.279	1.3725	1.2	10.0
	Total	26852	6.801	1.4762	.3	10.0

Exhibit 6. Analysis of variance

		Sum of Squares	df	Mean Square	F	Sig.
Heart Rate	Between Groups	6647.599	3	2215.866	16.137	.000
	Within Groups	3718679.508	27081	137.317		
	Total	3725327.106	27084			
RSA	Between Groups	1325.585	3	441.862	302.854	.000
	Within Groups	39540.084	27101	1.459		
	Total	40865.668	27104			
LFHRV	Between Groups	9905.345	3	3301.782	1823.795	.000
	Within Groups	48605.385	26848	1.810		
	Total	58510.730	26851			



Conclusions

Currently fielded for the BART research study, the BART app is being used to collect self-reported survey and HR sensor data for comparative evaluation of paced breathing relaxation training with and without HRV biofeedback. Preliminary *ad hoc* analyses indicate that the app acquires quality data for studying changes in psychophysiological stress according to mind/body activity states, including relaxation and cognitive stress conditions. No conclusion of efficacy, or non-efficacy, of the BART intervention should be drawn from these data. Once the study concludes, we plan on modifying the BART app for personal use outside of research with distribution via the Apple and Google app stores.

BART - A Mobile Application for Improving Psychological Resilience via Self-Administered Paced Breathing and Heart Rate Variability Biofeedback

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³ Indiana University, Bloomington, IN

Background: Psychological resilience, an individual's ability to recover from an adverse event and return to physiological homeostasis and mental well-being, is critical to minimize health effects such as sleep problems, substance abuse, post-traumatic stress disorder after a traumatic experience. In a study to evaluate resilience-enhancing methodologies, RTI, UNC, and IU researchers developed a mobile health app with stress relaxation elements, Bluetooth-based heart rate monitoring (HRM), and heart rate variability (HRV) biofeedback, and are evaluating efficacy in both civilian and military populations.

Methods: The BART research study app was implemented using RTI's PHIT toolkit, a reusable framework for mobile health research. The PHIT framework integrates multimodal data collection with an intelligent virtual advisor (iVA) that analyzes real-time data to tailor and request user activities based on evidence-based rules and scripted study requirements. BART integrates subjective self-report baseline and outcome measures (i.e., stress, depression, sleep quality), a cognitive stressor, and four alternative resilience training modes - 5 or 6 breaths/minutes paced breathing, each with or without HRV biofeedback. Study participants use the BART app at least three times a week for resilience-building training over a 6-week training duration. User actions, like health assessments, outcome measures, resilience training, and data uploads, are managed via a home screen task menu.

At the onset of each training exercise, the Polar H7 HRM is activated and beat-by-beat heart rate is displayed to verify signal quality. For biofeedback of psychological arousal, BART captures beat-to-beat heart intervals across 20-second epochs. Every two seconds a new epoch begins, a physiological signal processing module is used to filter and derive HRV, display the average heart rate (HR), and display three HRV measures. The derived HR and HRV measures are shown as continuous waveforms for stress relaxation biofeedback, indicating movement between calmer or stressful psychological status in real time. Three times each week for six weeks, each participant is asked to complete the BART protocol with a three-minute resting baseline and a five-minute resilience training segment. Periodically participants also complete an augmented training regimen called the Training Brain Game, an implementation of the Eriksen Flanker task, designed to elicit psychophysiological stress under a controlled exercise as a way of evaluating changes in resilience.

A comparison of the four modes of resilience training is being conducted in a mixed population of military personnel, veterans, and civilian first responders. Recruitment and enlistment is being conducted at multiple sites across multiple states. Since the studies is ongoing, the data presented herein are meant only to showcase features and capabilities of the BART app in the context of BART research paradigm.

Results: Preliminary descriptive statistics for Heart Rate and two HRV measures, Respiratory Sinus Arrhythmia (RSA) and Low Frequency HRV (LFHRV), were calculated as a quality check of BART app functionality. Changes in these measures were small, however significant ($P < .001$) between resting, stressor, and recovery phases. Reduced parasympathetic activation during the Brain Game

stressor task was indicated by a decrease in RSA, which later returned to resting levels during recovery, and increased substantially during paced breathing training.

Conclusions: The BART app is being used to collect self-reported survey and HR data for comparative evaluation of paced breathing relaxation training with and without HRV biofeedback. Preliminary ad hoc analyses indicate that the app acquires quality data for studying changes in psychophysiological stress according to mind/body activity states, including relaxation and cognitive stress conditions.

Supported in part by the U.S. Army Medical Research and Materiel Command (W81XWH-16-1-0346, W81XWH-16-1-0347, W81XWH-11-2-0129). The conclusions do not necessarily reflect the position or policy of the government, and no endorsement should be inferred.



Background

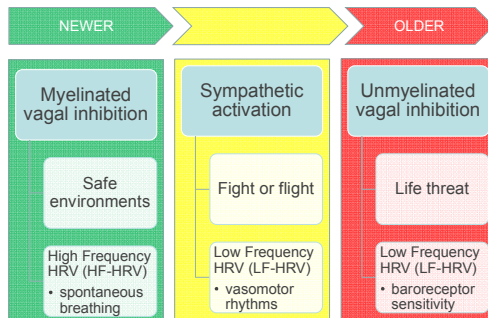
Psychological resilience is an individual's ability to recover from an adverse event and return to physiological homeostasis and mental well-being. An important aspect of this bouncing back process is the return to a physiologic equilibrium indicated by higher resting heart rate variability (HRV) and a quicker return to balanced sympathetic and parasympathetic 'drive' following a stressor.

The Biofeedback Assisted Resilience Training (BART) study evaluates a resilience-building intervention, through a mobile health app with stress relaxation elements and HRV biofeedback that pairs to a commercial of the shelf (COST) heart rate monitor (HRM).

Preliminary data analysis includes HRV data validation. We present the validation of the raw inter-beat interval data (RR) and the online processed HRV data, to answer:

1. Is the online HRV data reflecting the RR raw data?
2. Does the RR data reflect autonomic changes under physical and mental tasks?
3. Would the BART app be a suitable option to use HRV parameters as online indicators of neural regulation for research and treatment purposes?

Heart Rate Variability (HRV)



HRV Biofeedback

- Paced respiration at slower rates forces myelinated vagal activity to synchronize with blood pressure rhythms. Amplifies oscillations in heart rate around the paced frequency
- Practice can enhance an individual's ability to magnify HRV
- Visual **feedback** of HRV magnitude in real-time can facilitate learning the technique and motivate practicing.

Information

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office.

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Medical Research Program under Award No. W81XWH-16-1-0347. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

All human research activities were approved by the UNC Chapel Hill Biomedical IRB, #16-2312 and the USAMRMC (PR151616P), HRO Log No. A-19597.

Methods

The BART study collects data through a custom designed application (BART app) that is installed on the subject's personal phone/tablet. The study tracks each subject through self-report measures entered into the app and physiological signals (reported by the HRM). Heart rate data transmitted to the smart phone/tablet is stored and uploaded through secure transmission. The HRM (POLAR H7) is worn during study activities. Heart rate data is captured by the HRM and sent to the BART app via Bluetooth, the app collects RR data, process it into HRV and displays it online as Biofeedback.



Figure 1. POLAR H7, heart monitor placement.

Recruitment Protocol

1. Consent
2. Registration
3. Install BART app
4. Setup HRM
5. Training game
6. Survey 1

The study evaluates the pace respiration technique under two breathing paces: 5 or 6 breaths per minute, and with or without biofeedback.

Data collection proceeds in three phases:

- Baseline (Week 1): Surveys 1- 2- 3 and training game session.
 - Training game: rest (3 min), stress (4 min), post (3 min), and train (5 min).
- Regular practice (Weeks 1-6): weekly surveys and train session.
 - Train: rest (3 min) and train (5 min).
- Week 6: training game session.
- Follow-up (Month 3, 6, 9, and 12).

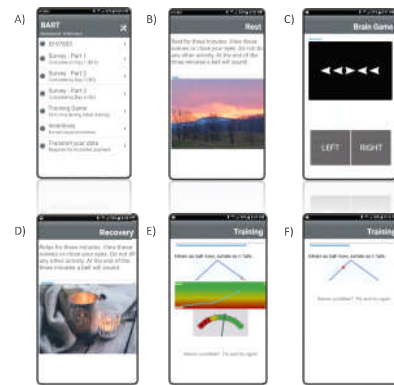


Figure 2. BART app windows: A) main, B) rest, C) Eriksen-Flanker challenge, D) post, E) train pace breathing with biofeedback, F) train pace breathing without biofeedback.

Results

The BART app collects raw heart rate data in the form of RR as well as processed HRV data. The RR data was process offline to derive HRV. For the analysis the following HRV parameters were used: heart rate (HR), heart period (HP), and biofeedback heart rate variability (BFHRV).

To evaluate validity of the data the next statistical analyses were performed:

- 1) Comparison of the two methods for HR and BFHRV parameters.
- 2) Evaluation on HRV parameters changes during the baseline; autonomic changes between rest, stress, post, and train.

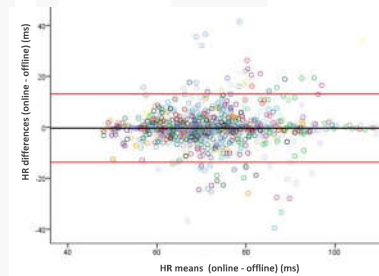


Figure 3. Bland-Altman plot of HR between online and offline analysis. For non-edited RR by participant for all sessions and tasks.

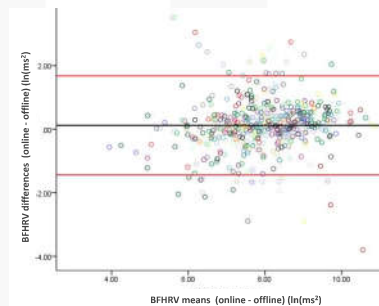


Figure 4. Bland-Altman plot of BFHRV between online and offline analysis. By participant for all sessions and train tasks.

- Data from 286 subjects (329 recruited), 36% female and 64% male.
- Since the offline process requires RR visual inspection and manual editing of artifacts, the HR data was separated in edited and non-edited to observed the convergence between the two methods. Edited data was not showing the same heart rate dynamics, meaning that the corresponding online data was not capturing accurate beat to beat heart rate. In consequence, HR data was analyzed using only non-edited RR.
- Repeated Measures ANOVA used the HRV data processed from offline RR.

Results

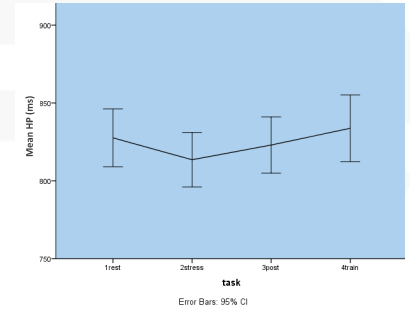


Figure 5. Repeated measures ANOVA for Heart Period (HP) across the 4 tasks, during the training session. There is an effect by task: $F(3,504) = 2.74$ $p = 0.04$.

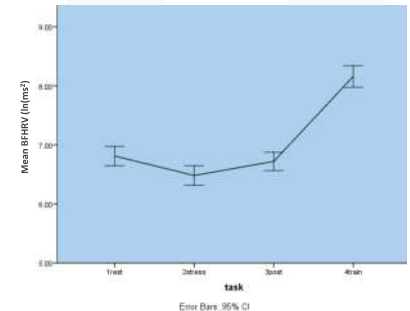


Figure 6. Repeated measures ANOVA for BFHRV across the 4 tasks during the training session. There is a strong effect by task: $F(2,18,366.84) = 296.14$ $p < 0.001$.

Conclusions

The software platform (BART app) and the HRM support remote data collection and intervention delivery needs.

The BART app acquires useful data to study changes in psychological stress according to mind/body activity states, and should be useful to compare alternative psychological resilience training paradigms.

Results show that the online and offline methods are measuring the same HRV parameters for the non-edited raw data, confirming synchrony while measuring online beat to beat heart rate.

Results from the baseline session show that the offline method captured the different HRV changes. Reduced parasympathetic activation during the stress is indicated by decrease in BFHRV, which returns to resting levels during post. The effect of pace breathing substantially increase BFHRV during the train task.

Offline edited data will be used to improve the online editing algorithm, by evaluating the current auto RR editing tool and setting recursive algorithms that will flag and manage abnormal heartbeats or sensor artifacts.

References

- [1] Connor, K. M., & Davidson, J. R. (2003). Development of a new resilience scale: The Connor-Davidson resilience scale (CD-RISC). *Depression and anxiety*, 18(2), 76-82.
- [2] Porges, S. W. (2007). The polyvagal perspective. *Biological psychology*, 74(2), 116-143.
- [3] Lehrer, P. M., & Gevirtz, R. (2014). Heart rate variability biofeedback: how and why does it work? *Frontiers in psychology*, 5, 756.

Building resilience via heart rate variability biofeedback in the Reserve Component: evaluation of a mobile technology combined with a portable heart rate monitor.

Authors:

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Psychological resilience is an individual's ability to cope with stress [1]. This ability to recover from an adverse event and return to physiological homeostasis and mental well-being, is fundamental to minimize health effects such as sleep problems, substance abuse, and PTSD. An important aspect of this bouncing back process is the return to a physiologic equilibrium indicated by higher resting heart rate variability (HRV) and a quicker return to resting heart rate following a stressor.

The physiological and psychological recovery is linked through a theoretical perspective (polyvagal theory) that emphasizes the hierarchical organization of the human autonomic nervous system (ANS). The ability to self-regulate is mediated by controlling both the parasympathetic (rest and restoration) and the sympathetic (stress) branches of the ANS [2]. Trauma can lead to triggering hyperarousal through the stress response or system shut-down, which can leave the autonomic system in a chronic state of reduced parasympathetic inhibition. Self-regulation, typically a subconscious process, can be enhanced by practice and conscious intervention through HRV biofeedback-assisted relaxation training.

HRV a measure of parasympathetic nervous system activity, is defined as the variation in the time interval between heartbeats, with higher HRV indicating greater flexibility and ability to regulate emotional responses. Resilience is linked with higher resting HRV [3]. Thus, HRV serves as both a measure of autonomic regulation and a promising target for any intervention to improve resilience.

The Biofeedback Assisted Resilience Training (BART) study evaluates a resilience-building intervention, through a mobile health app with stress relaxation elements and HRV biofeedback that pairs to a commercial of the shelf (COST) heart rate monitor (HRM).

The study is on its recruitment, data collection and preliminary data analysis stage. Preliminary data analysis includes HRV data validation. This abstract presents the validation off the raw inter-beat interval data (RR) and the online processed HRV data to answer:

- 1) Is the online HRV data reflecting the RR raw data?
- 2) Do the HRV and RR data reflect autonomic changes under physical and mental tasks?
- 3) Would the BART app be a suitable option to use HRV parameters as online indicators of neural regulation for research and treatment purposes?

The BART study collects data through a custom designed application (BART app) that is installed on the subject's personal phone/tablet. The study tracks each subject through self-report measures entered into the app and physiological signals (reported by the HRM). Heart rate data transmitted to the smart phone/tablet is stored and uploaded through secure transmission. The HRM is worn during study activities, the subjects are asked to practice 3-times per week for the first 6-weeks. Data collection

proceeds in three phases: Baseline (Week 0), Regular practice (Weeks 1-6), Follow-up (Month 3, 6, 9, and 12). Sessions on weeks 0 and 6 include a stress test, these sessions are structured as: 3-min Baseline (rest), 4-min stress test (stress), 3-min recovery (post), and 5-min pace breathing training (train). Training sessions on weeks 1 to 6 are pace breathing training only, structured as: 3-min rest and 5-min train.

The study was approved by the UNC IRB # 16-2312 and the USAMRMC, "Evaluation of HRV Biofeedback as a Resilience Building Intervention". The IRB authorized the recruitment of 500 subjects from the reserve component, national guardsmen, military veterans, and first responders. As of January 2018 ninety-eight subjects have been recruited. The gender mix was 29% female and 71% male. Age group division was 4% from 18-20, 34% from 21-30, 31 % from 31-42, and 29% older than 42; 2% did not provide age. Subjects self-identified as White or Caucasian (70%), Asian (4%), Black or African American (14%), American Indian or Alaskan Native (1%), 11% did not report race.

The BART app collects raw heart rate data in the form of inter-beat intervals (RR) as well as processed HRV data as heart rate (HR), biofeedback heart rate variability (BFHRV), low frequency heart rate variability (LFHRV), and high frequency heart rate variability or respiratory sinus arrhythmia (RSA). The RR is collected online, the HRV data is processed online from the RR data. To evaluate validity of the data the following statistical analyses were performed:

- 1) Comparison of the two methods for all HRV parameters from week 0 to 5. Bland & Altman and scatter plots will be used to compare and contrast both methods.
- 2) Evaluation on HRV parameters changes during the training session on week 0, autonomic changes between rest, stress, post, and train.

B-A plots between the online and post-hoc-RR analyses for the different HRV parameters (HR, BFHRV, LFHRV, and RSA) from weeks 0 to 5 indicate excellent agreement and minimal bias between the different measures. For the LFHRV and RSA, the B-A plots suggest that error magnitude is slightly larger for larger values, the LFHRV differences and RSA differences are larger on the positive right side of the B-A plots and closer to zero on the left side. For the four HRV parameters, 95 % of the differences are between the confidence intervals.

The linear regression from weeks 0 to 5 between online and post-hoc-RR for HR is in convergence ($y = .98x + .63$) displaying a high correlation R^2 of .78. For BFHRV while not in convergence ($y = .93x + .49$) indicates a high correlation R^2 of .86. For the LFHRV parameter ($y = 1.08x + .63$) differs from the unity but shows a high correlation R^2 of .80. While RSA is in convergence ($y = 1.02x + .34$) displays a moderate correlation R^2 of .67.

The analysis of variance comparing means of the HRV parameters (HR, BFHRV, LFHRV, and RSA) across the BART training tasks (rest, stress, post, and train) for week 0, show small but very significant changes ($p < .001$). Both methods are able to track the HRV changes from rest to stress back to post and further to train. Changes obtained by the BART-app on HR and RSA reflect a similar, attenuated response across time when compared to the post-hoc-RR outputs. Both methods track the moderate changes of BFHRV and LFHRV.

The BART app and software platform developed in conjunction with the HRM function sufficiently to support the data collection and intervention delivery needs for the BART study, and evaluate the efficacy of the intervention for resilience building. BART app acquires useful data for studying changes in psychological stress according to mind/body activity states, and should be useful in comparing efficacy among alternative psychological resilience training paradigms, such as the use of real-time HRV biofeedback.

Results from Week 0 to Week 5 show that both methods are measuring the same HRV parameters, confirming that the BART app, the sensor, and the software platform are working in synchrony while measuring online beat to beat heart rate data remotely.

Results from training session on W0 show that both methods captured the different HRV changes, reduced parasympathetic activation during the stress is indicated by the decrease in RSA, which returns to resting levels during post, BFHRV and LFHRV increase substantially during train. HR effect is opposite as expected.

Differences between methods on these preliminary results will be used to improve the app algorithms, by evaluating the current auto RR editing tool and setting recursive algorithms that will flag and manage abnormal heartbeats or sensor artifacts.

References

- [1] Connor, K. M., & Davidson, J. R. (2003). Development of a new resilience scale: The Connor-Davidson resilience scale (CD-RISC). *Depression and anxiety*, 18(2), 76-82.
- [2] Porges, S. W. (2007). The polyvagal perspective. *Biological psychology*, 74(2), 116-143.
- [3] Lehrer, P. M., & Gevirtz, R. (2014). Heart rate variability biofeedback: how and why does it work?. *Frontiers in psychology*, 5, 756.



Lessons Learned Integrating Heart Rate Data Collection for the Biofeedback- Assisted Resilience Training (BART) Study

Randall P. Eckhoff

Paul N. Kizakevich

Dr. Laurel Hourani, PhD

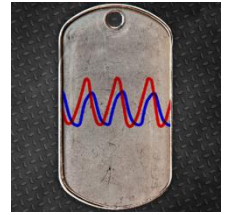
Dr. Maria Davila, PhD

Dr. Gregory Lewis, PhD



Biofeedback Assisted Resilience Training

- Enhance psychological resilience using paced breathing with biofeedback
- Heart rate variability biofeedback, cognitive stressor game, survey data collection



Polar H7



BART
Participant ID - 99999, Day 0

- Participant ID - 99999
Day:0 Week:1 Trainings:1 of 3+
- Survey - Part 1
Complete on Day 1 (\$15)
- Survey - Part 2
Complete by Day 3 (\$5)
- Survey - Part 3
Complete by Day 3 (\$5)
- Training Game
Required for +GAME incentives
- Incentives
Earned study incentives
- Transmit your data
Required for incentive payment

Instructions

On the next screen, one of the following images will be randomly presented every 1-3 seconds.

LEFT

RIGHT

As each image is presented, observe the middle arrow. Tap the LEFT or RIGHT button according to the middle arrow. Make your choice as quickly as possible. The game will take four minutes.

Start Game

Training

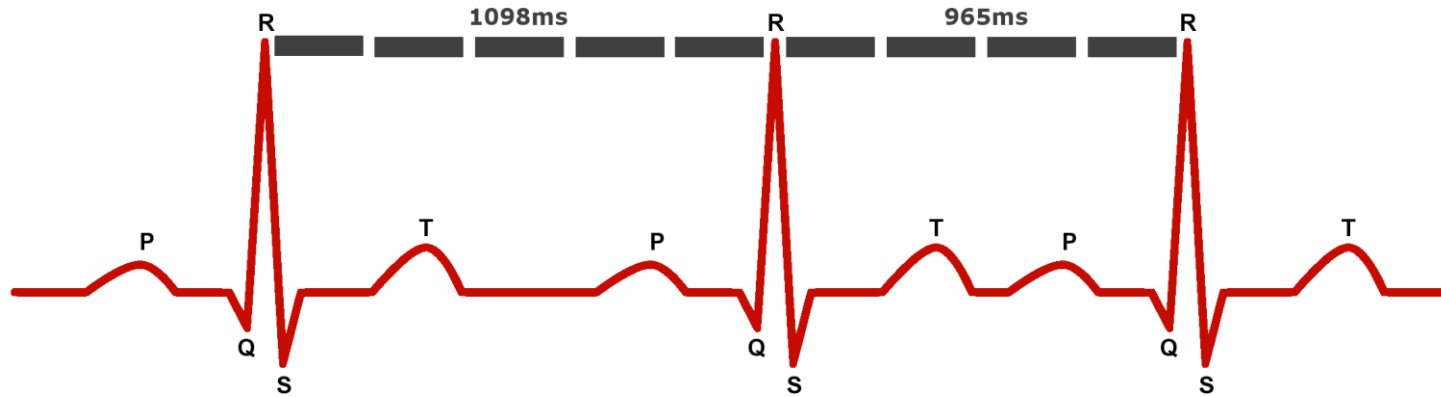
Sensor data being received

If your HR sensor is not working properly, then exit, fix the sensor, and try again later.

Requirements

- Need a heart rate monitor from which we can measure heart rate variability (HRV)
- Participants bring their own device (iOS/Android, phone/tablet)
- Study training
 - Tell participants about the study
 - Consent them, assign participant ids, hand out HR monitor
 - Download and set up app
 - Perform 1 HRV training exercise
- How many in each training session?
 - Reserves- 1 to 2 hours to train potentially many people on their reserve weekend
 - First responders- local police and fire, much smaller training size

Which heart rate monitor?



HRV measures the change in time between heart beats (RR interval)

Chest strap

- Measures heart rate electrically
- Works well moving and at rest
- Most send RR data

vs.

Wrist band

- Measures blood volume pulse
- Has issues with wrist movement
- Most do NOT send RR data

What did we do?

- Participant bring their own heart rate monitor not an option
- Validated 3 different chest strap monitors against ECG
- Provided monitor for each study participant on training day

Bring your own device

Different Bluetooth chipsets

Android versions

- API 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 (forthcoming)
- Manufacturer variations (Samsung, Google, Motorola, LG, ASUS, etc.)
- Cell provider variations (Verizon, AT&T, Sprint, T-Mobile, etc.)

iOS Versions

- iOS 6.0, 6.1, 7.0, 7.1, 8.0, 8.1, 8.2, 8.3, 8.4, 9.0, 9.1, 9.2, 9.3, 10.0, 10.1, 10.2, 10.3, 11.0, 11.1, 11.2, 11.3, 12 (forthcoming)
- Manufacturer variations - none
- Cell provider variations - none

What did we do?

- All team members tested, especially those with different phones
- Reached out to employees outside project
- Maintained test matrix



How do you train large groups?

Bluetooth devices are geared towards individuals and private use

Large group setting

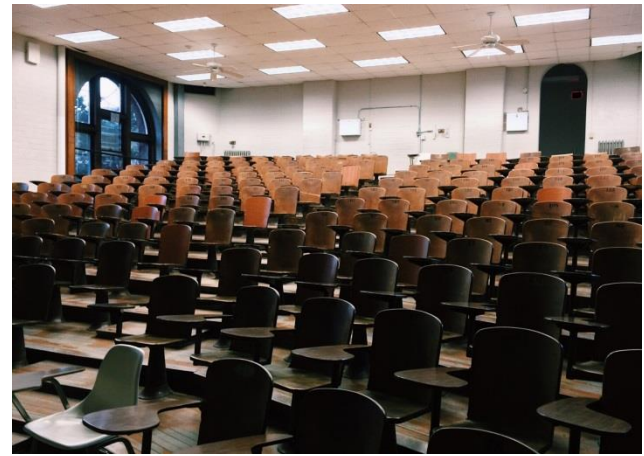
- Bad for Bluetooth
- Imagine 25 study participants with 25 heart rate monitors
- Gyms- picking up other's people heart rate data
- From a list of 25 monitors, someone will pick the wrong one

Surroundings

- New construction with state of the art everything
- 12 - 15 different Bluetooth devices when testing

What did we do?

- Staggered training of 3 - 5 participants at a time with more trainers
- Smart scanning- look for a heart rate monitor, not any BT device
- Couldn't control location and had to lengthen scan for HR monitors

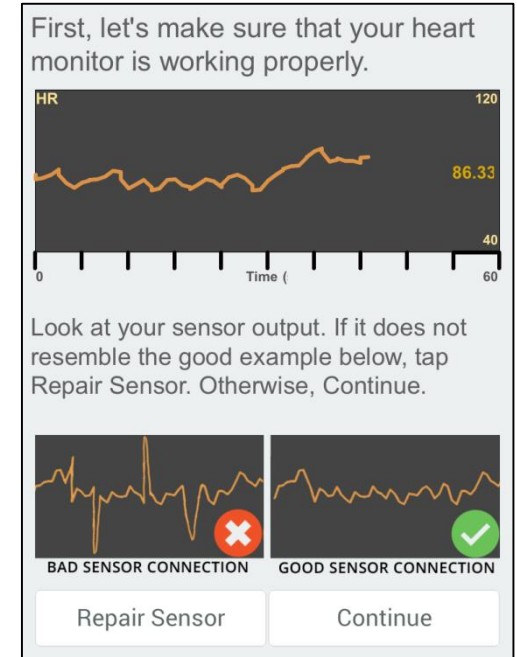


User Experience

How does user know what good HR data looks like?

What did we do?

- Before each training, connected to sensor to get sample data and compare bad vs. good
- During app setup (1) progress bar, (2) sensor validation, (3) data confirmation
- Sensors do stop working. Provide new sensor and reconfigure app with new sensor.



Scan for your sensor

Scanning for sensor

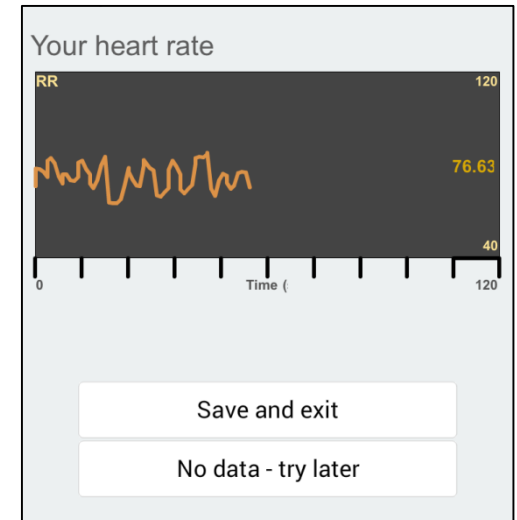
Stop scan and exit

Scan again

Sensor found.

Polar H7 EC99371D

Continue



iOS and Android



Their implementations are different. We wrote a high-level layer above iOS and Android to simplify our own development.

But...

- iOS allows for levels of asynchronous discovery
- Android, everything is synchronous
- Very frustrating to context switch between the different operating systems

What did we do?

- Include your software engineers early
- Wrote test software isolating Bluetooth connectivity code
- Regression test as new versions become available

An explosion of data

Do you save it all as it is reported?

0, 782, 894, 822, 901, 854, 811, 792, 849

Just offsets?

0, 782, 112, -72, 79, -47, -43, -19, 57

- Why save it all if you are just processing it into something else?
- Mobile app starts using more local storage and more upload bandwidth
- One run of a test may not yield a lot of data. But 20 minutes 3 times a week for a year long longitudinal study?
- And don't forget your reporting dashboard and data extracts

What did we do?

- Saved offsets
- Having all data allowed for backend validation of HRV formula during QA. Kept during the study “just in case”.
- Wrote specialized HRV data extract queries separate from the rest of the data



Security and Privacy

More data to protect

Potential for hacking Bluetooth and NFC



What did we do?

- Stressed doing the training at home where one would naturally find a quiet place the study required
- Had an application pin so as not to depend on a device pin. IRB also had input on this to protect participant privacy

An abstract graphic of a globe on the left side of the slide. The globe is composed of a grid of thin blue lines. Overlaid on this grid are numerous curved and straight lines of varying thicknesses, some ending in small circles, creating a network-like or orbital pattern. The lines are primarily in shades of blue and grey.

delivering **the promise of science**
for global good



Randy Eckhoff
reckhoff@rti.org

Appendix B. Modification Extension (6 Months

Application Cover Memo

Cover memo prepared by Maria Davila Hernandez on 07/18/2018 at 03:23 PM

We are requesting approval to modify the protocol of the study by reducing the total length of the study from one year to six months for participants recruited after the approval of this amendment. Participants recruited up to June 30th 2018 will perform the length of 1 year initially established.

The initial six months of the protocol will remain as submitted, the last two follow-ups will be eliminated, Month 9 and Month 12.

We estimate that the shortening of the protocol will not affect the statistical results during the first six months of data collection. On the contrary it will help to reach the 500 recruitment mark.

These changes do not increase risk to participants.

The modification is reflected on the following documents: consent form, incentives, advertisement material, and surveys for Month 3 and Month 6.

Post Approval Submissions

Modification Information

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

1. Provide a brief non-technical summary of any changes you will be making to the study (i.e., study application, project personnel, and/or study documents.) The text you enter here will be reproduced in the IRB approval document, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50-100 words. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

We are requesting approval to modify the protocol of the study by reducing the total length of the study from one year to six month for participants recruited after the approval of this amendment. Participants recruited up to June 30th 2018 will perform the length of 1 year initially establish.

The initial six month of the protocol will remain as submitted, the last two follow-up will be eliminated, Month 9 and Month 12.

Compensation for new participants will be reduce from \$175 to \$135, since they will not be completing requirements corresponding to Month 9 and Month 12 (\$20 each, for a total of \$40 less).

We estimate that the shortening of the protocol will not affect the statistical results during the first six months of data collection. The aims of the study will not be affected by this modification. By the contrary it will help to reach the 500 recruitment mark.

These changes do not increase risk to participants.

The modification is reflected on the following documents: granter modification approval email, consent form, compensation (from \$175 to \$135), advertisement material, and surveys for Month 3 and Month 6. There will be no modification on project personnel.

2. Is this study in Data Analysis only (i.e. enrollment, intervention and follow-up are complete)?

No

Total number of subjects enrolled to date:

346

Is this study currently open to the enrollment of new subjects?

Yes

Total number of subjects actively participating (i.e., Total number of subjects involved in the interventional part of this study. If the study is limited to data collection (e.g., surveys, questionnaires, collection of data from existing records), enter '0':

325

3. Do you have plans to re-consent subjects as a result of this modification?

No

4. Is this modification being submitted in response to New Safety Information?

No

5. Have the risks as described in A.6., consent form, or any other study document changed?

This may include new risks not previously listed, changes in frequency of known risks, or removal of previously listed risks.

No

Continuing with Modifications

Click the "save and continue" button to access your existing application.

You may make any changes to the application that you are requesting at this time.

General Information

1. General Information

1. Project Title

Evaluation of HRV Biofeedback as a Resilience Building Intervention

2. **Brief Summary.** Provide a **brief non-technical description** of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: Conduct a field study on the impact of heart rate variability biofeedback on psychological resilience and physiological measures of stress regulation.

Participants: 500 volunteers from the Reserve Component, First Responders, and Military Veterans will be recruited from three mechanisms, direct communication with Units during drilling activities, referrals from behavioral health providers to Reserve Component patients, direct communication with First Responders units, and various forms of advertisement.

Procedures (methods):

Data collection will be through a custom designed application (BART App) that will be installed on the subject's personal phone. The study will track each subject through self-report measures entered directly into the App and physiological signals (heart rate, reported by a Polar H7 chest-strap sensor). Details of the wireless heart rate sensor and its attachment are available in the Polar H7 User Manual (attached). Heart rate data transmitted to the phone will be used in one wing of the study to provide real-time feedback of the level of heart rate variability achieved during a guided breathing exercise within the App. For a second wing of the study, heart rate data will be collected by the App but no bio-feedback will be provided. In all cases, the heart rate data will be stored on the subject's phone and uploaded to the RTI servers through secure transmission. Only de-identified data from the RTI servers will be shared with the UNC team for analysis.

Based on the pilot testing of Blue Tooth connected, wireless heart rate sensors, we selected the more affordable Polar H7 model which has reliably provided data to the App. The Polar sensor will be worn for less than one hour per day during study activities, with the subjects asked to practice three times per week for the first 6-weeks to receive their incentives. Subjects will be encouraged but not required to practice as often as once per day, when possible.

Data collection will proceed in three phases: Baseline (Days 1-3), Regular practice (Weeks 1-6), Follow-up (Month 3,6)

In addition to the slow breathing practice sessions, physiological data will be collected at Day 1, Week 3, and Week 6 during a cognitive stressor task, as well as a brief resting period before and after the stressor. Multiple self-report measures will be collected during Days 1-3, and at each follow-up. A limited number of items will also be asked during the weekly practice sessions.

The data collected will be used to answer the following research questions:

1. What are the associations at baseline between resilience, coping, (post-traumatic growth)PTG, hardiness, PTSD, depression, anxiety, alcohol misuse, physical health measures, stress and HRV (where higher

- HRV indicates lower arousal)?
2. Does the association between HRV, resilience, PTG, and perceived stress depend on demographic characteristics, levels of hardiness, PTSD, depression, anxiety, stress, substance abuse, combat experiences, coping strategies, or social support?
 3. Are there specific parameters of the training (length of breaths [5 breaths per minute versus 6 breaths per minute], presence of biofeedback, length of training, frequency of practice) that have differential effects on HRV or other variables of interest?
 4. What are the trajectories of HRV, PTG, resilience, and other variables of interest (hardiness, PTSD, depression, anxiety, stress, and alcohol misuse) over the course of training and the following six months?
 5. Under what conditions and for whom is the training most effective?

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

If a change to the Principal Investigator is requested during the course of the study, a [PI Change Form](#) must be submitted.

Liaison	Last Name	First Name	Department Name	Role	Detail
University of North Carolina at Chapel Hill (UNC-CH)					
★	Davila-Hernandez	Maria	Psychiatry	Principal Investigator	view

External Institutions

Liaison	Last Name	First Name	Department Name	Role	Detail
Indiana University at Bloomington					
★	Lewis	Gregory	Intelligent Systems Engineering	Co-investigator	view
Research Triangle Institute (RTI International)					
★	Hourani	Laurel	RTI International	Co-investigator	view
	Eckhoff	Randy	RTI International	Research Assistant	view
	Holland	Ashley	RTI International	Research Assistant	view
	Kizakevich	Paul	RTI International	Research Assistant	view
	Krzyzanowski	Michelle	RTI International	Research Assistant	view
	Lane	Marian	RTI International	Research Assistant	view
	Lewis-Evans	Amanda	RTI International	Research Assistant	view
	Litavec	Stephen	RTI International	Research Assistant	view
	Meleth	Sreelatha	RTI International	Research Assistant	view
	Morgan	Jess	RTI International	Research Assistant	view
	Morgan	Tim	RTI International	Research Assistant	view
	Sheff	Carol	RTI International	Research Assistant	view
	Strange	Laura	RTI International	Research Assistant	view
	Watkins	Rebecca	RTI International	Research Assistant	view

Weimer

BeLinda

RTI International

Research Assistant [view](#)

NOTE: The IRB database will link automatically to [UNC Human Research Ethics Training database](#) and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department

Psychiatry

3. Funding Sources

1. Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?

Yes

Is UNC-CH the **direct** recipient of any Federal funding for this study? You should answer 'yes' *only* if you are the grantee. You should answer 'no' if you are the recipient of a sub-award or contractor under the grant.

Yes

Funding Source(s) and/or Sponsor(s)

Sponsor Name	UNC Ramses Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Department of Defense (DOD)	16-1495	Federal				view

2. Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

No

3. Is this research classified (e.g. requires governmental security clearance)?

No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ☒ Grant Application
- ☐ Industry/Federal Sponsor Master Protocol
- ☐ Student Dissertation or Thesis Proposal
- ☐ Investigator Initiated Master Protocol
- ☐ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

[The first question is whether this is RESEARCH \(click for details\)](#)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

[The next questions will determine if there are HUMAN SUBJECTS \(click for details\)](#)

2. Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

Yes

3. Will you be obtaining identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

OR

Will you be using human specimens that are not individually identifiable for [FDA-regulated in vitro diagnostic \(IVD\) device investigations](#)?

No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.)

No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients or does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) or does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. [See guidance.](#)

Yes

5. Multi-site Study Information

1. Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States?

No

2. Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project?

Yes

[Lead Site/Coordinating Center addendum](#)

The Lead Site/Coordinating Center addendum is not required if you are relying on an external IRB. In the attachments section, click Lead Site/Coordinating Center addendum and select the Not Yet Available / Not Applicable checkbox.

3. Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH?

Yes

When a collaborator(s) outside of UNC-CH is (a) exercising authority or responsibility on behalf of a group or organization, (b) performing activities designated by a group or organization, or (c) using the collaboration for scholarly advancement (e.g., promotion, tenure) at a group or organization, complete the following information:

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms	Local Context Worksheet	Agreement
✓ Indiana University at Bloomington	Yes ⓘ	✗	✗	
Personnel	Role	Ethics	CV	MD License
Gregory Lewis	Co-investigator	✗	✗	✗
View sIRB Attachments				

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms	Local Context Worksheet	Agreement
----------------------	--	---------------------	-------------------------	-----------

✔ Research Triangle Institute (RTI International)		Yes ⓘ	✗	✗	✗
Personnel	Role	Ethics	CV	MD License	
Randy Eckhoff	Research Assistant	✗	✗	✗	
Ashley Holland	Research Assistant	✗	✗	✗	
Laurel Hourani	Co-investigator	✗	✗	✗	
Paul Kizakevich	Research Assistant	✗	✗	✗	
Michelle Krzyzanowski	Research Assistant	✗	✗	✗	
Marian Lane	Research Assistant	✗	✗	✗	
Amanda Lewis-Evans	Research Assistant	✗	✗	✗	
Stephen Litavec	Research Assistant	✗	✗	✗	
Sreelatha Meleth	Research Assistant	✗	✗	✗	
Jess Morgan	Research Assistant	✗	✗	✗	
Tim Morgan	Research Assistant	✗	✗	✗	
Carol Sheff	Research Assistant	✗	✗	✗	
Laura Strange	Research Assistant	✗	✗	✗	
Rebecca Watkins	Research Assistant	✗	✗	✗	
BeLinda Weimer	Research Assistant	✗	✗	✗	
View sIRB Attachments					

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.

Exemptions

Request Exemption

Some research involving human subjects may be [eligible for an exemption](#) which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

Additional guidance is available at the [OHRE website](#). Exemptions can be confusing; if you have not completed this page before, please [review this table with definitions and examples](#) before you begin.

1. Would you like your application evaluated for a possible exemption?

No

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

A thorough background is provided in the attached grant application. The modification is being submitted to cover the Main Study activities, following the completion of the pilot testing. From the pilot testing we determined to use Polar H7 heart rate sensor for all physiological data collection activities.

Beat to beat changes in heart rate, such as the slowing and speeding of beating in rhythm with our breathing, convey specific information on how the brain is regulating body functions. These patterns in heart rate changes can be measured, which is broadly referred to as heart rate variability analysis. These same patterns can also be modulated by, for example, changing your breathing pattern. The Main Study concerns evaluating a training program that will teach members of the Reserve Component, First Responders, and Military Veterans to change their breathing in such a way as to reduce stress and increase psychological resilience. In order to facilitate this training, heart rate variability biofeedback will be used to provide real-time information (to the Experimental Group) on the changes in the heart rate patterns as the subjects alter breathing. The comparison group will be trained in Paced Breathing Alone, which will not include any biofeedback, although it will include the passive collection of heart rate data during the Paced Breathing sessions. The breath training/data collection system will be run on a smartphone platform, at home, with a portable heart rate monitor (Polar H7). Multiple dimensions of physical and mental health will also be measured through self-report surveys, conducted on the subject's phone, within the study application (the App).

A.1.2. State the research question(s) (i.e., specific study aims and/or hypotheses).

The specific aims of this study are to:

1. Develop and pilot test the Personal Health Informatics Toolkit (PHIT) platform for use with the biofeedback-assisted relaxation training (BART) protocol. (App is completed, pilot data collection is completed)
2. Examine the relationship between baseline HRV (including resting state, reactivity to, and recovery from a stressor task) and resilience, mental health, substance use, stress, and physical health measures.
3. Examine the individual differences in response to various BART training parameters (Breathing speed, amount of practice, knowledge of and prior use of biofeedback and/or other complementary methods such as meditation). 3a) Determine optimal amount of BART practice and what subgroups (demographic, mental health, etc.) receive the optimal benefit (increase their HRV and resilience scores) the most over time. 3b) Understand the mechanism through which the training operates by comparing BART and paced breathing with paced breathing only; that is, is the breathing or the feedback more important in increasing HRV?
4. Examine the extent to which resilience and mental health symptoms are linked to HRV at baseline and how that relationship changes over time. Explore the effects in which comorbidities may impact the effect of HRV-BART on resilience, coping and PTG scale scores. Specifically, examine the interactions between the following variables: PTSD, depressive symptoms, sleep disturbances, and chronic pain.

A.2. Subjects

A.2.1. Total number of subjects proposed across all sites by all investigators (provide exact number; if unlimited, enter 9999):

520

A.2.2. Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number; if unlimited, enter 9999):

520

A.2.3. If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

20 subjects are from the pilot testing sample, which is recruited from the UNC student population. 500 is the target for recruitment into the main study, which will be restricted to members of the Reserve Component, First Responders, and Military Veterans.

A.2.4. Do you plan to enroll subjects from these vulnerable or select populations:

If you will include children, prisoners or nonviable neonates or neonates of uncertain viability, please check the appropriate category below and complete the additional sections.

You should check "Pregnant women" if you specifically intend to recruit women who are pregnant or are not excluding pregnant women in biomedical research that is greater than minimal risk. Do not check if you are conducting a survey of the general public or conducting secondary data analysis or chart review not aimed at pregnant women.

Only check UNC-CH Student athletes, athletic teams, or coaches if you have specific plans to enroll these subjects. This is not applicable for intramural or club sports. For definitions and guidance see SOP 1201: Vulnerable subjects in research.

☒ Children (under the age of majority for their location)

Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.

☒ Pregnant women

☒ Nonviable neonates or neonates of uncertain viability

☒ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)

If an enrolled participant becomes incarcerated during the course of the research, they must be removed from the research project until such time as the IRB (and OHRP for NIH funded projects) approves the study to include prisoners, unless there is an immediate risk to the participant from ending treatments under the protocol.

☒ UNC-CH Student athletes, athletic teams, or coaches

A.2.5. Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply. This is not applicable to secondary data analysis or chart review.

Based on your responses, the consent form builder will insert the required text into your consent form template.

☒ Decisionally impaired individuals

(e.g., Mini mental state examination (MMSE), Montreal cognitive assessment (MOCA))

☒ Children who are wards of the State (Foster children)

☒ Non-English-speaking individuals

☒ UNC-CH Students

Some research involving students may be eligible for waiver of parental permission (e.g., using departmental participant pools). [See SOP 32.9.1](#)

☒ UNC-CH Employees

☒ People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim.

This would include studies that might uncover or expose child, elder or domestic abuse/neglect. ([See SOP Appendix H](#))

A.2.6. If any of the above populations are checked (excluding 'Decisionally impaired individuals' and 'Children who are wards of the State (Foster children)'), please describe your plans to provide additional protections for these subjects.

UNC-CH Students were recruited for the pilot testing phase, but will not be recruited for the Main Study.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	18
	years
Maximum age of subject enrolled	99
» If no maximum age limit, indicate 99	

years

A.3. Inclusion/exclusion criteria

A.3.1. List required characteristics of potential subjects (i.e., inclusion and exclusion criteria). If not covered, list also characteristics that would preclude their involvement.

Inclusion criteria: All service members with specified smartphones in all Reserve Centers and National Guard armories, First Responders (police officers, firefighters, or Emergency Medical Technicians (EMT)), and Military Veterans with specified smartphones, will be eligible to participate. Subjects must provide their own Device (smartphone or tablet) that is capable of running the App. The technical specifications of the Polar H7 sensor limit this to newer devices capable of communicating over the Bluetooth Low Energy (a.k.a., Bluetooth 4.0 or Bluetooth SMART) protocol. The advertising materials will explicitly point out this restriction and highlight which common devices meet this requirement (e.g., iPhones of model 4s or newer).

Subjects who self-report that they have been hospitalized in the last year for psychosis, suicidal/homicidal ideation, or behavioral health problems will be excluded from the study.

Behavioral health providers will be asked to make information about the study available to all individuals who enter their practice (i.e., in a public space). Screening for inclusion/exclusion will be handled by: 1) making clear statements of these criteria on advertising material, 2) highlighting these criteria in the verbal script used on Day 1, and 3) highlighting these criteria on the consent form.

There are no other exclusion criteria for this sample.

A.3.2. Justify any exclusion based on race, gender or ethnicity

Non-English speaking individuals will be excluded from the study because researchers cannot ensure the presence of a reliable translator of any other language who is familiar with the research.

A.3.3. Will pregnant women or women who become pregnant be excluded?

No

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

A.4.1. Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

Yes

A.4.2. Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

Overview: Following IRB approvals, baseline data collection and training will take place at a facility at or near the drilling site, or first responder's station, or at Providers offices, or at RTI or UNC. Based on the constraints of the selected facility, the activities of the personnel, and guidance from the Reserve Component command or First Responder's command, training will be conducted in one of two settings: 1) All subjects will be trained in group settings with a maximum of 25 subjects per session, or 2) Subjects will be trained in one-on-one sessions with research personnel walking them through the process individually as they arrive onsite. Follow up data collection will include 6 weeks of practice and 2 follow-up survey periods over the six months following baseline.

Baseline data collection: We will work with the drilling site POCs, providers, and First Responders' sites to schedule participants into a forty five minutes (45 min.) introductory training session. Each participant will be randomized to receive either the HRV-BART or paced breathing only (PB). Subjects will not see the training environment of other persons. Following a brief description of the study, participants will complete informed consent. As each subject turns in their signed consent form, they will receive an ID card (with their unique subjectID, an unlock password for the App, and the code for the room's settings), a Polar H7 with a label that identifies the unique Polar device (to distinguish from all other Polar devices in the room), and a printed guide to placing the Polar device. The subject will then be directed to an offline computer that will collect the

linkage file information. On this PC, the subject will: 1) confirm their ID, 2) enter their email address (to receive the incentives), and 3) enter their preferred phone number (for reminders). The registration program will only display information from one subject at a time to prevent any loss of privacy of this information.

Subjects will then be directed to an available private area to attach the Polar device (e.g., a restroom in the facility).

All participants will then be provided with instructions on how to download and install the App. The subject will be configured for either the BART or PB with the breath pacer set at 5 or 6 breaths per minute by entering their unique ID number.

The App will be downloadable through a WiFi hotspot from either the Apple App Store, the Google Play store, or the BART website, to minimize burden on participant's personal cellular plans. Subjects will also be provided with a Polar H7 heart rate monitoring strap for HRV assessment during Baseline tasks, including training on BART or PB.

Self-report items: Subjects will then complete the surveys within the App on their personal devices:

Demographics

Connor-Davidson Resilience Scale (CD-RISC) scores

Coping measures (brief coping scale [COPE])

Perceived Stress Scale

Posttraumatic Growth Inventory (PTGI)

Sleep Disturbance Scale

PCL-C

GAD-7

Center for Epidemiologic Studies Depression Scale [CES-D]

Physical health (Short Form (12-item) Health Survey [SF-12]

TBI

Alcohol use problems (AUDIT)

Given the time constraints for the session, these items have been split into three modules (see Appendix for all items). Subjects will be asked to complete all modules prior to beginning their at-home training (i.e., by Day 3). Detail on the incentive structure is provided in Section-A5 (Benefits to subject). The goal is to provide flexibility in completing the Baseline assessments, while maximizing data representation for the items included in Module 1. Subjects who wish to complete all surveys on Day 1 will be permitted to do so and will receive the same incentive payment as those who spread out the surveys over 3 days.

Subjects will be asked to proceed to the HRV assessment first. The App will first confirm that they are connected correctly to the Polar device.

HRV assessment (Baseline Day): The HRV assessment will include periods of rest, cognitive stress (Eriksen-Flanker), recovery, and Training. For the HRV-BART group, we will utilize PHIT-adapted HRV biofeedback and a paced respiration indicator that will guide the subject towards a target respiration rate of either 5 or 6 breaths per minute. The subject will see a real-time indicator of LF-HRV (i.e., the component of HRV that will be enhanced by slow, paced breathing). Each individual's target range for LF-HRV will be calculated based on their HRV levels during the initial resting period.

At the conclusion of the Training period, subjects will be instructed on how to upload their results (both self-report measures and HRV data) to the RTI servers. Subjects will complete the upload through use of the App. Data will be encrypted prior to transmission to ensure security of all personal information. Data uploaded from the App will not contain the subject's name or email (only the subject's unique StudyID). The

linkage file, matching IDs to contact information will be maintained by the RTI PI (Hourani) and kept offline at RTI in a secure location. For the baseline data, subjects will be allowed to use the WiFi hotspot to handle the upload, further reducing burden on their personal data plans. We will explain to subjects that future data uploads can also be handled through publicly accessible WiFi spots (data will be encrypted on the device before upload) or through their cellular data service. However the amount of data being uploaded from their phones will be kept below 1 MB, which should have minimal impact for subjects who choose to upload data over their personal cellular plans. We will provide an estimate of the data upload sizes for Self-Report Modules 2 & 3, Weekly data for Weeks 1-6, and Quarterly follow-up data for Months 3, and 6.

Weekly at-home practice: Subjects will be prompted to complete their weekly requirements with in-app reminder text and no more than 3 phone system reminders per week. Subjects will be able to opt-out of the phone system reminders at any time with no consequence. In order to receive the weekly incentives, subjects must complete three sessions of BART or PB practice on separate days, fill out a brief six-item survey (see Appendix), and upload the data to the RTI server. Once this is completed, the in-App text reminder will change from Red Bold font to Green Underlined font to make it clear that the requirements for that week's incentives have been met.

Participants in both groups will be asked to practice as much and as often as possible over the next year, and to record and submit their data (e.g., HRV level and resilience scores) whenever possible. The PHIT app will record the date, time, and practice duration as a qualitative measure of practice dose for use in data analyses. Subjects will be informed that this information is being tracked and uploaded along with any other data that is sent from the App.

Post-Training (End of Week 6, at-home practice): the final data practice session for week 6 will include slightly expanded questionnaire items similar to those at baseline to provide a comprehensive pre- and post-training evaluation. The training week (Week 0) and final follow-up sessions will also include the Eriksen-Flanker stressor to enable measurement of physiological reactivity and recovery. The Flanker task measures both attention and inhibitory control, which both require parasympathetic inhibition to optimize performance. We will record performance measures to explore potential impacts of improved autonomic regulation on the task.

Supplementary Survey (participants identified as First Responders): Subjects identified as First Responders will be contacted by email to respond to a survey on military veteran status. This data was not collected at enrollment (baseline questionnaire) because military veterans were included afterwards. The email would contain a hyperlink to a Voxco survey, which complies with all FIPS Low, FIPS Moderate, HIPAA, and 508 Compliance guidelines.

All HRV and questionnaire data will be uploaded via the user's cellular data plan, or a Wi-Fi hotspot, to a secure RTI SQL server using an encrypted data transfer methodology. Study personnel will use a secure website portal dashboard to access uploaded data, screen individual data sets, monitor overall data collection progress, and prepare data sets for analyses. Data will be exported from the SQL server to Excel files, cleaned for gross outliers, and made available for statistical analysis.

All participants will receive a tube of the Spectra 12-02 Parker Laboratories 360 Electrode Gel tube to supplement the heart rate monitor to facilitate conduction between the skin and sensor.

A.4.3. If subjects are assigned or randomized to study "arms" or groups, describe how they are assigned.

- Describe the methods of computing the randomization schedule (if any) and maintaining blinding (if any).
- Who will perform these computations?
- How will you verify each subject's eligibility prior to randomization?

Dr. Meleth (RTI) will create a block randomized list of settings for each training session (e.g., Training Session 1 = {PB, 5 breaths per minute}, Training session 2 = {BART, 6 breaths per minute}...). These settings will be linked to the 'code' on the subject card.

A.4.4. Describe any follow up procedures.

Quarterly follow-ups: Subjects will be reminded by a phone system reminder and an email to complete follow-up survey items at 3, and 6-months post Day 1. They will also repeat the HRV assessment tasks at this point (rest-EriksenFlanker-recovery-Training). Subjects will receive further incentives for completing these measures. Missing one follow-up survey will not impact eligibility for the incentive for completing the other

surveys. Subjects will be given a 1-week window within which to log in and complete the Quarterly follow-up survey. All items for these surveys are outlined in the Appendices/Attachments.

A.4.5. Once this study has been approved by the IRB, for how many months or years will this study be active (you are collecting data or have access to identifiers)?

Start: May 1, 2017

Stop: December 31, 2020

A.4.6. Will this study use any of the following methods?

- ☐ Audio Recording
- ☐ Video Recording
- ☐ Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
- ☐ Pencil and paper questionnaires or surveys
- ☒ Electronic questionnaires or surveys
- ☐ Telephone questionnaires or surveys
- ☐ Interview questionnaires or surveys
- ☐ Other questionnaires or surveys
- ☐ Focus groups
- ☐ Diaries or journals
- ☐ Photovoice
- ☐ Still photography

A.4.7. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

Drs. Lewis, Hourani, and Meleth have completed the HRV Biofeedback online training course from Stens Corporation (Heart Rate Variability Online Seminar). Dr. Lewis has 10 years of experience working in psychophysiology laboratories and collecting and evaluating heart rate data from human subject experiments. Dr. Lewis will evaluate all HRV results. The RTI team includes epidemiologists and statisticians with experience creating and analyzing the self-report items collected during the study.

A.4.8. Are there cultural issues, concerns or implications for the methods to be used with this study population?

No

A.4.A. Biomedical methods and procedures

A.4.A.1. Is this an interventional study?

No

Distinguish what is being done specifically for this research from procedures that would be done anyway for clinical care:

This study is not an evaluation of the intervention, but rather an observational study to refine a theoretical model that links stress reactivity, HRV, resilience and the other psychological parameters.

A.4.A.2. Is this a Clinical Study?

Check YES if this study involves research using human volunteers that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. Do NOT check yes merely because you are conducting research in a clinical setting or using clinical data.

[Click here for additional definition of "Clinical Study"](#) 

No

A.4.A.3. If the study involves the use of placebo control, provide justification

All subjects will receive training on a self-care technique that should increase psychological resilience, reduce stress reactivity, and improve mental health. There is not a placebo control and this is not a clinical trial.

A.4.A.4. Will this study involve drugs, biologics or other substances (such as a botanical or dietary supplement)?
For guidance on dietary supplements, see Section VI, C [FDA guidance document UCM229175.pdf](#)

No

A.4.A.5. Is there an Investigational New Drug application (IND) for this study?

No

Please check below:

- ☒ This study does not involve drugs, biologics or other substances.
- ☒ I am using a U.S. commercially available agent, consistent with labeling.
- ☒ I am studying a botanical substance or dietary supplement intended to affect the structure and/or function of the body; it is **not** intended to cure, treat, mitigate, prevent or diagnose disease, including its associated symptoms.

A.4.A.6. When the intent of a clinical investigation is to collect information about the safety or effectiveness of a device, the need for an Investigational Device Exemption (IDE) must be evaluated. Please review the [Investigational Device Guidance](#) document prior to completing this section. Your response to the following questions will determine if an IDE is needed.

A. Select the response that best describes your investigation:

5. None of the above.

A.4.A.7. Does your study involve any of the following? (check all that apply)

☒ Embryonic stem cells

☒ Fetal tissue

☒ Genetic testing (see [GINA](#) and [GWAS](#))

☒ Clinical laboratory tests

If McLendon Labs will do the testing, you must complete the appropriate form found at [UNC Health Care](#) and submit to them for review.

☒ Testing for communicable diseases that have mandated reporting requirements ([link to state guidance](#))

☒ Point of Care Testing (POCT), which is CLIA-approved testing done at the "bedside" or site of care by hospital or clinic personnel (not by subject). Examples include urine pregnancy testing, glucose monitoring, etc.

If McLendon Labs will do the testing, you must complete the POCT form found at [UNC Health Care](#) and submit to them for review.

☒ If your study utilizes **radiopharmaceuticals** to address basic science questions, an IND is not necessary.

Instead, your study will be reviewed/approved by the [Radioactive Drug Research Committee](#) (RDRC); approval by the Radiation Safety Subcommittee (RSS) is not required.

If you have questions about the RDRC approval process, please contact [Dede Corvinus](#).

☒ Diagnostic or therapeutic ionizing radiation, or radioactive isotopes (not covered under [21 CFR 361.1](#)), which subjects would not receive otherwise if not participating in this research study. Do not check if all radiation is administered as standard of care. Do check if your study includes [views/scans that represent no greater than minimal risk as determined by the Radiation Safety Sub-committee. Application for Human Use of Radiation in Research.](#)

☒ Gadolinium administered as a contrast agent

☒ Recombinant DNA or gene transfer to human subjects

✗ Any research activities conducted in the UNCHC Perioperative areas. This includes Pre-care, Pre-op, Operating room and PACU.

You must complete the [Checklist for Perioperative Services](#) and return it to Susan.Phillips2@unchealth.unc.edu and to richard_feins@med.unc.edu.

✗ Any form of medical imaging (ultrasound, MRI, CT, X-ray, PET-CT, PET-MRI)

A.4.A.8. Will your study involve storage of specimens for future unspecified research?

No

A.5. Benefits to subjects and/or society

A.5.1. Describe how this study will contribute to generalizable knowledge that will benefit society.

The project will provide new information on the effectiveness of HRV biofeedback for promoting psychological resilience. We believe that increasing psychological resilience with low-cost, simple interventions such as HRV biofeedback will mitigate the mental health risks associated with military service and deployments.

National Guard, Reserve Service members (collectively referred to as Reserve Component service members [RCSM]), First Responders, and Military Veterans have a different set of stressors than their active duty counterparts and general population, including balancing civilian employment with military service and public service, varied access to medical and other services, and greater isolation from RC peers and military support systems, making a portable resilience-building option using HRV and biofeedback that can be learned in a single session and practiced at home particularly valuable to this population. Indeed, population-based surveys of RCSM have found higher rates for family stress and suicidal ideation/attempts among RCSM than among active duty service members, particularly among those with high combat exposure.

The findings of this pre-clinical study of BART will have utility in the general population as well. The study will provide new information on the suitability (i.e., "Who benefits the most?"), dosage ("How much practice is required to change resilience?") and optimal settings ("Is biofeedback necessary? Does it change the magnitude of impact or only the time course for impact on mental health?) for paced breathing practice as a self-care technique.

A.5.2. Does this study have the potential for direct benefit to individual subjects in this study?

Yes

Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form, if there is a consent form. Do not cite monetary payment or other compensation as a benefit.

Explain

The subjects will be exposed to a simple set of 'self-care' steps that may promote calm and increase psychological resilience to trauma and other adverse events. This is a direct benefit. There is a modest body of literature on HRV biofeedback and its positive impact on anxiety, stress, sleep disturbances, and depression.

In our past experiences, the exposure to HRV biofeedback is itself very rewarding. All subjects should gain some of this benefit through their weekly practice of slow paced breathing. The study will help determine whether the biofeedback enhances the benefits of slow, paced breath practice, through either direct physiological impact (i.e., greater HRV changes) or indirect impact on frequency/duration of practice.

A.5.3. Are there plans to communicate the results of the research back to the subjects?

No

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Psychological

- ✓ Emotional distress
- ✗ Embarrassment
- ✓ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.2. Describe any potential psychological risks checked above and what will be done to minimize these risks

Distress: Some of the health-related questions are possibly sensitive, and the subject may feel uncomfortable answering them. We will remind them in the instructions that they may choose not to answer specific questions. We will also remind them that if they desire, they may withdraw from the study at any time.

Confidentiality: There is also the unlikely risk of a loss in confidentiality. To reduce this risk, any identifying information we collect will be kept separate from all other collected information. Thus, any questions and health information (like heart rate) will be kept separate from identifying information. We will not enter the subject names into the App at any time (only the unique SubjectID).

All electronic data files, database, and linkage file will be stored on password protected computers with only individuals associated with the study having access. Only a de-identified database of subject physiological signals will be shared outside of RTI and only with IRB listed research personnel at RTI or UNC.

Other information collected during participation, such as heart rate, health-related responses, sleep information, and use statistics (i.e., duration and frequency of training sessions) will be stored on the mobile device/tablet in an encrypted database. This information will be transferred at the subject's discretion to a central study database at RTI using an encrypted process over the internet. None of the questions or measurements will contain personal identifying information. That is, no information that could identify you will be kept on the mobile device/tablet.

Every effort will be made to protect the subject's identity in this study. All information will be encrypted and held in safe computer storage with access limited to persons directly associated with this study. Any written data will be entered into a computer file and the original paper copy will be destroyed. All study data will be combined from all persons for analysis and only combined results will be reported. Names and other identifiers will never be linked with the results of the study.

There is a potential that research information will be shared with other parties in order to meet legal and regulatory requirements. Examples of persons who may access this information include representatives of the U.S. Army Medical Research and Materiel Command (USAMRMC), the Army Clinical Investigation Office (CIRO), or the Army Human Research Protection Office (AHRPO), the Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP), and the DHHS Office for Civil Rights.

The research team at RTI will keep the research information for up to three years after the end of the study. At that time, all information including identifiers will be destroyed, including the linkage file. During the study, the linkage file will be kept on a separate, secured computer, with access limited to the IRB approved research staff. This file will be used to contact participants for reminders, but it will never be stored on the same server as the research data.

All consent forms will be stored separately from data, and no Subject IDs will be on the consent forms.

A.6.3. Social

- ✗ Loss of reputation or standing within the community
- ✗ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.4. Describe any potential social risks checked above and what will be done to minimize these risks

No Answer Provided

A.6.5. Economic

- ☒ Loss of income
- ☒ Loss of employment or insurability
- ☒ Loss of professional standing or reputation
- ☒ Loss of standing within the community
- ☒ Consequences of breach of confidentiality (Check and describe only once on this page)
- ☒ Other

A.6.6. Describe any potential economic risks checked above and what will be done to minimize these risks.

No Answer Provided

A.6.7. Legal

- ☒ Disclosure of illegal activity
- ☒ Disclosure of negligence
- ☒ Consequences of breach of confidentiality (Check and describe only once on this page)
- ☒ Other

A.6.8. Describe any potential legal risks checked above and what will be done to minimize these risks

No Answer Provided

A.6.9. Physical

- ☒ Medication side effects
- ☒ Pain
- ☒ Discomfort
- ☒ Injury
- ☒ To a nursing child or a fetus (either through mother or father)

A.6.10. Describe any potential physical risks checked above, including the category of likelihood and severity, and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25 - 50%)
- Likely (approximate incidence of > 10 - 25%)
- Infrequent (approximate incidence of > 1 - 10%)
- Rare (approximate incidence < 1%)

Describe severity of risks using the following grading scale:

- Mild- No disruption to the subject's ability to perform daily activities; may include non-prescription intervention only
- Moderate- Temporary interference with daily activities; may include prescription intervention
- Severe- Interference with daily activities; medically significant but not life threatening
- Life threatening

Examples:

Rare (Rare (

If you are using these terms differently than described above, please provide your study-specific definitions.

Phase 1 trials: Due to limited experience, incidence may be better described as the number of events that have occurred in the total number of animals/humans studied.

We anticipate a rare likelihood that a subject may find the chest strap heart monitor uncomfortable. We will

provide the subjects with information on the care of the Polar H7 device, including the option to machine wash the straps, to help them maintain clean equipment during the study. These devices are routinely worn for longer duration under greater physical exertion by the athletes they are marketed towards (e.g., those training for a triathlon). With proper care, the likelihood of discomfort will be very small. However, if a subject finds it uncomfortable to continue to wear the device, we will remind them that participation is voluntary and they may withdraw.

There is also a risk of discomfort due to the slow paced breathing during training. Although the incidence is infrequent, some people may begin to feel lightheaded if they are breathing too deeply (and thus not completely exhaling with each breath). We will mitigate this risk by:

1. Reminding the subjects to only practice in a safe, seated posture (to prevent falling as a result of dizziness).
2. Reminding the subject prior to each training session to exhale completely, and to not try too hard to keep up with the breath pacer. We will emphasize that the experience should be relaxing, not stressing. We will repeat the reminder that they should stop if they feel uncomfortable at any time.
3. Based on the anecdotal reports of the pilot test subjects, we are maintaining a slightly longer exhalation duration, relative to inhalation, to minimize the risk of not completely exhaling on each breath.

A.6.11. Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

As mentioned above, some of the items in the survey may be sensitive in nature to participants. To address the possibility that subjects need follow-up psychological counseling, business-type cards with mental health referral information are given to all participants. They will be told during the introductory session that if they should experience any psychological distress during the survey they should tell a study staff member who will provide referral information on getting help. Individuals who exhibit signs of distress will be encouraged to contact the organization on the referral card. In the unlikely event that a participant requests immediate assistance, a distress protocol will be utilized in which one member of the data collection team (always more than 2 research staff will be in the team) leaves the training room to request assistance in referring the member to a health professional. Any such referral will be logged and reported to the IRB. Further, messages in the App in a section clearly marked, will include referral information for each branch of the RC that is represented in the study (e.g., North Carolina Air National Guard).

A.6.12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study?

No

A.7. Data and safety monitoring

A.7.1. When appropriate, describe the plan for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based data and safety monitoring board or committee (DSMB, DSMC, DMC), depending on the study. For studies that do not raise obvious safety concerns, you may still describe your plans for monitoring the study as it progresses.

Participants will not be at an increased risk at any point during these procedures. There is no more than minimal physical safety risk from any of the equipment. The heart rate sensors are commercially available and have long track records of use in fitness and performance monitoring. Heart rate data will not be sufficient to diagnose any cardiac risk, since the data is reduced to the timing between heart beats (as opposed to the full electrocardiogram necessary to diagnose arrhythmia) by the Polar device automatically.

Self-report measures of psychological health will not be tracked by the research team or screened for diagnostic criteria. However, the App will provide the referral information and instructions for who to contact if the subject feels any distress (see the Appendix/Attachment for the information from the card we provide at Day 1. This information will be the same.)

A.7.2. If not already addressed above, describe the plans for aggregate review of unanticipated problems (including but not limited to adverse events) across all sites, in order to monitor subject safety.

Any problems will be reviewed by both PIs (Hourani-RTI and Davila-UNC) during monthly lab meetings. Adverse events will be reported to either PI, and Dr. Davila will alert the UNC IRB immediately. Any changes in study procedures or guidance from the IRB based on an adverse events will be discussed with all study

personnel.

A.7.3. What are the criteria that will be used to withdraw an INDIVIDUAL SUBJECT from this study or halt the research intervention (e.g., abnormal lab tests, allergic reactions, failure or inability to comply with study procedures, etc.)?

Due to the rare chance of irritation by the chest strap heart monitors, subjects who report itching or any pain at the point of contact with these devices will be immediately withdrawn from the study. We do not anticipate that this will occur, but we will not encourage any subject to continue if the devices are uncomfortable.

Subjects who report feeling lightheaded during the initial training will be reminded of the instructions: to not over exert in an attempt to 'keep up' with the breath pacer, to stop if they feel uncomfortable, and to make sure to exhale completely. If the problem persists, and the subject is unable to complete the initial training period, the subject will be withdrawn.

In either case, the subject will be permitted to keep the Polar H7 device and to receive the incentive payments for Day 1.

A.7.4. Are there criteria that will be used to stop the ENTIRE STUDY prematurely (e.g., safety, efficacy, unexpected adverse events, inability to recruit sufficient number of subjects, etc.)?

No

A.7.5. Will this study involve a data and safety monitoring board or committee?

No

A.8. Data analysis

A.8.1. Describe the analytical methods to be used (qualitative or quantitative)

Aim 1 was related to the pilot study data.

Aim 2: To examine the relationship between baseline HRV and our independent variables (see Exhibit 1), we will run bivariate correlations at baseline to assess the associations between all variables of interest: HRV, PTG, resilience, hardiness, PTSD, depression, anxiety, stress, and substance abuse (see RQ1/H1). Simple moderation models will be run using the SAS PROCESS macro (Hayes, 2013;66 Model 1). Significant results will be modeled using simple slopes when appropriate (RQ2/H2). These tests will validate the conceptual model linking physiological regulation to aspects of PTSD.

Aim 3: We will run analyses of variance (ANOVA) to determine if groups assigned to different BART training parameters (see Exhibit 2) show significant differences in results at follow-up. We expect that the inclusion of biofeedback will increase the speed and magnitude of shifts in HRV parameters. (RQ3/H3).

Aim 4: Conditional effect models will be run using the SAS PROCESS macro (Model 1 of Hayes, 2013) as well as moderated mediation models (Model 7 of Hayes, 2013); RQ5/H5. This will enable us to determine the psychological and physiological profile associated with optimal response to the BART intervention. For example, we will be able to determine if PTSD symptoms interact with depressive symptoms in predicting the magnitude of HRV change in response to BART.

Latent growth curve modeling (LGM) will be used to assess the trajectories of each variable over time. The LGM is a mixed effects model that posits a random intercept and random slope for each individual for each outcome (e.g., HRV, resilience, coping, sleep problems, PTSD, etc.). Higher order random effects (e.g., quadratic) can be included to model nonlinear trajectories of change such as the inflection point at which the slowing of improvement starts. This can be used to assess for the optimal number of practice sessions needed for the maximum benefit (i.e., the optimal length of training; see Hypothesis 3).

When feasible, each of the analytic strategies for Aims 2–4 will also be assessed longitudinally through LGM generalizations of the aforementioned regression and ANOVA models. To address missing data, the latent growth curve models will be estimated using maximum likelihood and will retain all participants in the model even if they only complete baseline data collection. This approach assumes data are missing at random (MAR) conditional on other variables in the model. We will examine the relationship of potential model covariates and the propensity to drop out and include variables related to missingness to better meet the MAR assumption. In addition, all models will correct for clustering using either multilevel regression/LGM or by using complex survey standard error corrections for clustering.

A.8.2. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies)

The original power calculations for the proposal were conservative in that they used a single two sample test at 12 months to calculate power and assumed a dropout rate of 60%.

Given the slower than expected recruitment and a higher dropout rate of approximately 68%, we recalculated the power using a repeated measures model since that is what we will be used to analyze data from this study.

When the sample size is 40 in group 1 and 40 in group 2, a two-sided test for the time averaged difference between two means in a repeated measures design with a 0.05 significance level will have 81.3% power to detect a difference in means of 6 in resilience scores in a design with 5 repeated measurements when the standard deviation for resilience is 20 and the between level correlation is 0.03. The ICC observed in the PRESINT study was 0.03 and the SD for the Resilience score was based on the SD of the Resilience score estimated in a sample of PTSD patients (*Wagnild, G. M., & Young, H. M. (1993). Development and psychometric evaluation of the Resilience Scale. Journal of Nursing Measurement, 1 (2), 165-178*). Since we currently have 50% of recruits uploading data and doing the training as recommended, we believe that we can change the minimum N we need for the study to 160 recruits with complete set of data at month 12 and still have sufficient power. We will also be increasing our efforts to reduce the dropout rates with increased outreach to the recruits. The N of 500 for recruitment will not be modified, since a N of 160 is needed at month 12 (32% of 500)

We examined expected effect sizes in prior research and found the smallest expected effect size was for the PTSD outcome where $d = .46$, although Tan et al. found larger effect sizes for baseline differences in HRV between those with and without PTSD ($d = 1.89$) and when evaluating changes in PTSD following HRV biofeedback ($d = 0.8$ for the Clinician-Administered PTSD Scale and $d = 1.08$ on the PCL-S). Note that we expect actual power to be greater than .8 because we will have longitudinal data, which typically increase power over time.

A.9. Identifiers

A.9.1. Check which of the following identifiers you already have or will be receiving, or select "None of the above."

- ☒ Names (this would include names/signatures on consent forms)
- ☒ Telephone numbers
- ☒ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ☐ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ☐ Fax numbers
- ☒ Electronic mail addresses
- ☐ Social Security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- ☐ Device identifiers and serial numbers (e.g., implanted medical device)
- ☐ Web universal resource locators (URLs)
- ☐ Internet protocol (IP) address numbers

- ☒ Biometric identifiers, including finger and voice prints
- ☒ Full face photographic images and any comparable images
- ☒ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
- ☒ None of the above

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ☒ with the research data (i.e., in the same data set and/or physical location)
- ☒ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:

The identifiers will be collected on an off-line (not internet connected) computer during the initial training session. The App will only collect the unique SubjectID (i.e., de-identified). The matching of the linkage file (email/phone) with the SubjectID will occur at RTI for the purpose of distributing incentives. The App data will be collated in a database, and subjects that have qualified for an incentive will have their SubjectIDs output in a single file.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

A.10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

Linkage file will be stored on a separate computer from the App data server.

A.10.2. Describe how data will be transmitted among research team (i.e., personnel listed on this application).

De-identified physiological data will be saved on a password secured PC hard drive that is not on the network. For statistical analysis by research personnel outside of UNC (at RTI), only de-identified databases of physiological parameters will be shared. Raw physiological data will be backed up on an encrypted, password protected hard drive. These raw signals will not contain any identifiable markers.

A.10.3. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?

Yes

If yes, describe the sensitive data being collected

The self-report items include questions about illegal drug use.

A.10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study? Please note that all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable information is [automatically issued a Certificate of Confidentiality](#) (CoC). You should also select "Yes" if your study is NIH funded and has been issued a CoC under this updated NIH policy.

No

A.10.5. If this study is limited to data collection by survey or interview, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

The risk for deductive disclosure is low. We will only disseminate aggregate information. We will not report statistical outputs for cell sizes less than 5.

A.10.6. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

A.11. Data sharing and transmission

A.11.1. Check all of the following who will receive **identifiable data** (contains any of the 18 identifiers listed above) outside the immediate research team (i.e., not listed as personnel on this application)? *

- ☒ No one
- ☐ Coordinating Center
- ☐ Statisticians
- ☐ Consultants
- ☐ Other researchers
- ☐ Registries
- ☐ Sponsor and/or its designee(s)
- ☐ External labs for additional testing
- ☐ Journals
- ☐ Publicly available dataset
- ☐ Other

A.11.2. For any recipients checked above, explain the confidentiality measures to be taken

No Answer Provided

A.12. Post-study disposition of identifiable data or human biological materials

A.12.1. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

Backed up data will be destroyed 5 years following completion of the project or final publication of the processed data, whichever comes later. This will include destruction of the linkage file. De-identified data will be archived for analysis.

Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

- ☒ In person
- ☐ Join the Conquest
- ☐ Participant pools
- ☒ Presentation to classes or other groups
- ☒ Letters
- ☒ Flyers
- ☒ Radio, TV recruitment ads
- ☐ Newspaper recruitment ads
- ☒ Website recruitment ads
- ☒ Telephone script
- ☒ Email or listserv announcements
- ☐ Follow up to initial contact (e.g., email, script, letter)

 OtherIf other, please specify

Facebook advertisement We will post approved material on a study Facebook page and ads including only approved materials via Facebook advertising.

B.1.2. Describe how subjects will be identified

To obtain the broadest representation of those with and without behavioral health problems, participants will be recruited from multiple sources: (1) behavioral health providers and (2) participants in Inactive Duty Training (IDT)/drilling status, (3) employment locations believed to have multiple RC members (e.g., police and fire stations), (4) First Responders' stations. Behavioral health providers will be contacted via mail and email and asked to provide information about the study to anyone who enters their practice (i.e., display in the lobby area), providers will be compensated \$50 for agreeing to make recruitment brochures available to their clients. Employment areas will be asked to display the approved flyer and/or permit a presentation of the approved briefing script. All service members with smartphones in all Reserve Centers, National Guard armories, First Responders, and Military Veterans will be eligible to participate.

For the IDT/drilling status recruitment, we will work with POCs to arrange a brief introduction of the study (either display of IRB approved materials or verbal description of the study to last 2-5 minutes during the morning briefing).

B.1.3. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

RTI International has successfully recruited thousands of RC personnel in previous studies. Pilot study recruitment is completed. For the main study, a four-prong recruitment methodology will be used. The first prong will involve utilizing community partners' outreach to a random sample of North Carolina behavioral health providers. Providers will be identified via the Citizen Soldier Support Program mapping system (see CSSP description in the partnership section). Initially, we will contact a small number (50-100) of providers to elicit their support and explain the study, including the study's goals, eligibility criteria, and participation requirements. Providers who choose to contact us will be asked to display trifold brochures that indicate that the study is limited to smartphone users and to provide contact information for the study staff from whom they can obtain additional information and schedule an introductory session. Our initial interactions with providers reflect that their core clientele are veterans; in consequence, we anticipate to mainly recruiting Military Veterans under this strategy. During the introductory session, detailed study information will be provided, informed consent will be obtained, and randomization and group-specific training will be conducted. These sessions will consist of a maximum of 25 individuals.

The second prong of the recruitment effort will involve our Office of Reserve Affairs and National Guard consultants who will socialize the study with the RC leadership and ultimately obtain approvals from The Adjutant General (TAG) of North Carolina and the Chief, Army Reserve Command (CARC) to offer the study to their personnel. This process has already begun (see attached consultant letters). The TAGs and CARC will be asked to provide access to their personnel for group or individual training sessions during an IDT period. In addition, they will be asked to provide a list of point of contact (POC) names at each major command to assist in identifying and scheduling units and to allow their organization's behavioral health staff to receive information about the study so they can make study brochures available to personnel they support. We will further socialize the study through local employers near RTI/UNC, and telephone contacts with the drilling site POCs to explain the study, answer any questions they may have, and request their participation and assistance in scheduling the training sessions, which will be at their convenience.

The third effort for recruitment will be focus on first responders. The Raleigh-Durham-Chapel Hill area counts with an estimate of 2400 first responders (according to Google Search); mainly police officers and firefighters; we plan to recruit 5% of them for a projection of 120 participants. We will select the headquarters for the police and the fire station from each of those in Raleigh, Durham and Chapel Hill and invite all responders in them to participate. We will contact the different stations by phone, email or their standard procedure to socialize the project with the station leadership and get approval to promote the study to their personnel via posters, emails and/or presentations. Contact information for the first responders' leadership is public and available on the Internet. This process was successful when we first approached the Chapel Hill Fire Department and offer the study to their reservist component; other firefighters showed interest on participating. The recruitment and training will be scheduled at either UNC or RTI facilities at a time of their convenience.

Participants will be trained in groups of minimum 5 to maximum 20.

The fourth prong for recruitment focus on advertisement. Three forms of advertisement are proposed: Web media (Facebook and Study web page), written ads (posters and pamphlets), and radio. Reservists, national guardsmen, first responders, and military veterans will be the target on the different channels of advertisement. Using the study contact information the potential participants will communicate with the research team to evaluate their eligibility for the study; eligible participants will be schedule for recruitment. The recruitment and training will take place at either UNC or RTI facilities at a time of their convenience. Participants will be trained in groups of maximum 20.

B.1.4. Describe how you will protect the privacy of potential subjects during recruitment

There will be no way for the research staff to distinguish patient referrals from the general population due to the broad dissemination of recruitment materials.

B.1.5. Describe how subjects will be contacted, if not addressed above

After the initial training, contact will be limited to reminders to practice presented on the subject's phone, a single e-mail reminder before each quarterly follow-up survey, and e-mail reminders if the subject has missed a data upload requirement to encourage continued participation (one e-mail per missed upload only, subject can withdraw and we will not continue communication in any way).

B.1.6. Describe who (by role) will do the recruiting

PI, Co-Investigators, and research assistants

B.1.7. Describe efforts to ensure equal access to participation among women and minorities

There will be no exclusion in the methods of recruiting, besides age (18 or older) and English language proficiency. We expect the recruited sample to reflect the overall distribution of female and minority members of the RC.

B.2. Protected Health Information (PHI)

Protected Health Information (PHI) is any identifiable information about the subject's health that relates to their participation in this research and is obtained from sources other than the subject, such as medical records, health care providers, insurance plans, etc. [more](#)

B.2.1. Are you requesting a limited waiver of HIPAA authorization?

If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a [limited waiver of HIPAA authorization \(see SOP 29.3\)](#). This does not apply to situations where you will never contact subjects directly (e.g., retrospective chart review), in which case you should request a full waiver under section D.

No

B.2.2. Will you need ongoing access to PHI (e.g., medical records) to conduct the study, beyond the identification of potential subjects as addressed above? In this case you will need to obtain a signed HIPAA Authorization from each subject.

No

B.3. Subject Contact, Duration and Privacy

B.3.1. Number of contacts per subject (contacts includes in-person, telephone, email, mailings, etc.)

13 for participants enrolled for a year follow-up and 11 for participants enrolled for a six months follow-up

B.3.2. Duration of each contact. If multiple contacts, provide the range or average time for each contact.

45 minutes for the initial training. Less than 5 minutes each for reminder contacts (email first, then phone) for reminders at each incentive period: 1) One year follow-up: (Day 1-3, Weeks 1-6, Month 3, 6, 9 and 12), 2) Six months follow-up: (Day 1-3, Weeks 1-6, Month 3 and 6).

B.3.3. Total duration of individual subject's participation, including follow up evaluation, if applicable

Max of hours over the length of the study: 1) One year follow-up: 10, 2) Six months follow-up: 9.

B.3.4. Where are you studying subjects or obtaining their data?

Non-healthcare setting

B.3.5. Provide more information about the location(s) where research will be conducted (e.g., if UNC Medical Center is checked in #4 above and study visits will be conducted in the CTRC, enter "CTRC" here.)

We will reserve large rooms near the drilling sites. We expect to use conference rooms in local hotels or classrooms at the armory or stations. We expect to use conference rooms or classrooms at either RTI or UNC.

B.3.6. Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope)

All sensitive subject data will be collected on the users personal device, encrypted when saved, and transmitted to the RTI server through secure transmission. Furthermore, the App will have a default setting where the screen is locked after 3-minutes of non-use, and must be unlocked with a 4-digit PIN number that the subject selects during setup.

Consent will be on a written form provided in the conference room.

B.4. Incentives for participation**B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate or are you reimbursing subjects for study-related costs (e.g., travel, parking, hotel accommodations or childcare)?**

Yes

A. Please describe any incentives and/or reimbursements for study-related costs separately below.

All subjects will receive the Polar H7 Heart Monitor for use in the study (current Amazon.com list price is \$53.84). There is an incentive schedule listed below and in an attachment. These incentives will be provided as amazon.com gift card codes, sent by email to the subject in the week following completion of the requirements. Participants will complete the study on their free time (off duty, off work hours).

" Military personnel are not being compensated for research conducted while on duty"

B. Specify the schedule for incentives and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.

Time period	Incentive \$ value	Required Subject Activities
Baseline Assessments	25	HRV assessment + Baseline Survey Module 1 = \$15 Baseline Survey Module 2 = \$5 Baseline Survey Module 3 = \$5
Week 1	10	Practice at home (x3) Complete Brief Weekly Follow-up Survey
Week 2	10	Practice at home (x3) Complete Brief Weekly Follow-up Survey
Week 3	10	Practice at home (x3) Complete Brief Weekly Follow-up Survey
Week 4	10	Practice at home (x3) Complete Brief Weekly Follow-up Survey
Week 5	10	Practice at home (x3) Complete Brief Weekly Follow-up Survey

Week 6	10	Practice at home (x3) HRV assessment Complete Brief Weekly Follow-up Survey
Month 3	20	HRV assessment Quarterly Follow-up Survey
Month 12	20	HRV assessment Quarterly Follow-up Survey*
Supplementary Survey	10	Supplementary Survey for First Responders
Total	135	

If a subject withdraws from the study, they will simply keep any incentive codes e-mailed to them already. If they have earned an incentive, but withdraw before the gift code is emailed, they will not be penalized (i.e., the code will still be sent).

C. For compensation in foreign currency, provide a US dollar equivalent.

No monetary compensation offer.

D. Discuss the potential for coercion, given factors like the amount of the incentive, the age of the subjects, the purchasing power in foreign countries, the time involved and complexity of procedures, etc.

The incentive amounts are not sufficient to coerce subject participation.

E. If the subjects are children who will receive the compensation, i.e., the child, the parents or both?

Subjects under 18 years old will not be recruited.

B.4.2. Are you collecting Social Security numbers for payment and/or tax-related purposes?

No

B.5. Costs to be borne by subjects

B.5.1. Will there be any costs that subjects will incur related to participation in the study? Do not include costs for standard care for which patients would be billed if they were not in this study. Also do not include the time spent participating in the study.

Yes

If yes, please check all that apply:

- ☒ Child care
- ☒ Travel
- ☒ Parking
- ☒ Clinic fees
- ☒ Diagnostic tests
- ☒ Laboratory tests
- ☒ Drugs
- ☒ Devices
- ☒ Increased operating room or anesthesia time
- ☒ Other

Please explain any items checked above

It is unlikely, but possible, that the small amount of data transmitted from the subject's phone to the RTI server could incur a cost on their cellular plan. The study team has endeavored to minimize the data transmission requirements where possible. Further, we have allowed the subject to control the timing of data upload, so that they may make use of WiFi access (available for free at many public locations and likely also at the subject's home) to avoid this potential cost. Finally, we have sought to clearly inform the subjects about the amount of data being used to transmit study information at each stage (e.g., the App size will be less than 60 MB and we will have WiFi available in the training room; the follow-up uploads will be less than 1MB each).

Part C. Existing Data, Records, Specimens

C.1. Data Sources

C.1.1. What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'):

☒ Medical records in any format.

ALERT: You must check both boxes: 1) Medical records in any format and 2) Electronic medical record using Epic, or you/your study team will not be granted access to Epic for research purposes.

☒ Electronic medical records using Epic, WebCIS or other electronic system

☒ Carolina Data Warehouse for Health (CDW-H) (for UNC and its affiliates only)

☒ Carolinas Collaborative Data Request and Review Committee (DRRC)

☒ Paper medical records

If you access the medical records of fewer than 50 patients under a full or limited waiver of HIPAA, submit a copy of your IRB approval letter and a completed [Research Disclosure Form](#) to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at : 919-595-5591 or 919-966-1225 or 919-595-5580.

☒ Data already collected from another research study

Were the investigators for the current application involved in the original collection? --

☒ Patient specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess? --

☒ Data already collected for administrative purposes

☒ Student records ([You will need to satisfy FERPA requirements: see SOP 2301, section 1.1 for guidance](#))

☒ UNC Dental Records

☒ Data coming directly from a [health plan, health care clearinghouse, or health care provider?](#)

☒ Publicly available data

☒ Other

☒ None of the above

For EACH data source checked above, provide a description of the data, proposed use, how data were collected (including consent procedures), and where data currently reside.

--

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., pathology dept, tissue bank, original researcher):

No Answer Provided

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

No

C.2. Coding and Data Use Agreements

C.2.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."

No

Part D. The Consent Process

D.1. Obtaining informed consent from subjects

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances. If you will be requesting a waiver answer "not applicable" for any of the following questions that will not pertain to this study. You will be asked to provide relevant information in the section below on waivers.

D.1.1. Will children under the age of majority in their locale (18 years in NC) be enrolled?

(Note: Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.)

No

D.1.2. Will adult subjects be enrolled in your study?

Yes

Explain the process for obtaining consent from the subject.

Consent documents will be printed and available for each subject to review and sign prior to the initial training session. Subjects will be permitted to read at their own pace, and not pressured to sign before they are comfortable with the study requirements. Once the signed consent form is returned to the session coordinator, the subject will receive their study materials and then be asked to register their email address and phone with their unique subjectID on a computer in the training room.

D.1.3. Will decisionally-impaired subjects be enrolled in your study? (includes unconscious patients, some psychiatric disorders, others who lack the capacity to give consent)

No

D.1.4. Are you planning to obtain consent from any Non-English speaking subjects?

No

D.1.5. Describe who (by role) will be obtaining consent or parental permission.

PI, Co-Investigators, and research assistants

D.1.6. Discuss the potential for influencing the subject's decision to participate. Describe steps that will be taken to minimize undue influence during the consent process. These might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician).

There is no potential for influencing the subject's decision to participate. Before and during consent, participants will be informed that they can terminate the session at any time if they wish. The study personnel will not have any position of authority (e.g., no member of the RC command is part of the study team) over the subjects.

D.1.7. Has the sponsor of this study provided a model consent form?

No

D.2. Waiver of written documentation of informed consent

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

D.2.1. Are you requesting a waiver of any aspect of written (signed) documentation?

No

D.3. Full or partial waiver of consent

The default is for subjects to give informed consent. A waiver might be requested for research involving only existing data or human biological specimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

D.3.1. Are you requesting any of the following:

- ☒ a waiver of informed consent in its entirety
- ☒ a waiver or alteration of some of the elements of informed consent
- ☒ a waiver of HIPAA authorization (If you are accessing patient records for this research, you must also request a waiver of HIPAA authorization)

D.3.2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

No Answer Provided

D.3.3. Does this request for waiver support a study design that involves deception or withholding of information?

No Answer Provided

Consent Forms

This submission requires the following consent forms

Template Type
Adult Consent Form

This submission includes the following consent forms

File Name	Document Type
BART_Consent_Form_08-03-18.docx	Adult Consent Form

[view consent forms](#)

Attachments

This submission requires the following attachments

Document Type
Grant Application
Lead Site/Coordinating Center addendum
This attachment not provided because: Not Yet Available / Not Applicable
Electronic Questionnaire Survey
Script for Class Recruitment
Letter for Recruitment
Flyer for Recruitment
Radio or TV Ad for Recruitment
Website for Recruitment
Telephone Script for Recruitment
Email or Listserv Recruitment
Other Materials for Recruitment

This submission includes the following attachments

File Name	Document Type
Budget Justification_RTI_BART.pdf	Grant Application
BudgetJustification_UNC_BART.pdf	Grant Application
ProjectNarrative.pdf	Grant Application
Polar_H7_Heart_Rate_Sensor_accessory_manual_English.pdf	Device Description
RecruitmentAdPsych.docx	Recruitment Ad for Participant Pool
RC_Briefing_Script_08-03-18.docx	Script for Class Recruitment
CSSP Email to Providers Mar16.docx	Email or Listserv Recruitment
Introscrip_t_for_1on1_08-03-18.doc	Script for In-person Recruitment
BART-poster-08-03-18.pdf	Flyer for Recruitment
BART_Participant_recruitment_letter_08-03-18.docx	Letter for Recruitment
BART_Provider_recruitment_letter_psgLH_BL[279]01-29-18.docx	Letter for Recruitment
BART_Email_to_Providers-01292018.pdf	Other Materials for Recruitment
BART_radio_advertisement_02-02-18.docx	Radio or TV Ad for Recruitment
Call_Center_Script_January18.docx	Telephone Script for Recruitment
BART_rti_org.pdf	Website for Recruitment
App_Questionnaire_Example_AUDIT.doc	Electronic Questionnaire Survey
BART FollowUp_3_6_Months_Extension_IRB_07-18-18.docx	Electronic Questionnaire Survey
BART VETERAN survey measures CLEAN-IRB-BASELINE-DAY-1_1-23-18.docx	Electronic Questionnaire Survey
BART VETERAN survey measures CLEAN-IRB-BASELINE-DAY-2_1-23-18.docx	Electronic Questionnaire Survey
BART VETERAN survey measures CLEAN_IRB-BASELINE-DAY-3_1-23-18.docx	Electronic Questionnaire Survey
BART survey Weeks 1-6.docx	Electronic Questionnaire Survey
Veteran Supplementary Questions.docx	Electronic Questionnaire Survey
Demographic_HRV_BART.doc	Pencil and Paper Questionnaire Survey
BART_IRB_Amendment_email.pdf	Email Correspondence (convert to PDF or TXT)
Ashley_Holland_CV.pdf	Other
BARTPrivacyPolicy.docx	Other
BART_Contact_Card_08-03-18.pdf	Other
BART_modification_DOD_approval_07-11-18.pdf	Other
Biosketch_Eckhoff.pdf	Other
Biosketch_Kizakevich.pdf	Other
Biosketch_Lane.pdf	Other
Biosketch_Melesh.pdf	Other
Biosketch_Strange.pdf	Other
Carol_Sheff_CITI.pdf	Other
Carol_Sheff_CV.pdf	Other
Carol_Sheff_Independent_Investigator_Confirmation.pdf	Other
Gregory_Lewis_CV.pdf	Other
HOURANI_LAUREL_CV.docx	Other
IRB Reliance Request - Indiana University (1709200326).docx	Other
Introscrip_t_BaselineDay_08-03-18.doc	Other
Kizakevich_CITI.pdf	Other

Lane_CITI_2012_2017.pdf	Other
Laura_Strange_BART_Independent_Investigation_Confirmation.pdf	Other
Laura_Strange_CITI_training.pdf	Other
Laura_Strange_CV.pdf	Other
Lewis-Evans_CITI.pdf	Other
MORGAN_JESSICA-CV.pdf	Other
MORGAN_JESSICA_CITI_RTI.pdf	Other
MORGAN_TIM-CV.pdf	Other
Meleth_CITI_2.pdf	Other
Michelle_Krzyzanowski_CV.pdf	Other
Morgan_Tim_CITI.PDF	Other
PI-change-form-ver.-2-2-2017 signed.doc	Other
Proposal for Add-on - revised.docx	Other
RandomizationCards.pdf	Other
Script for phone call to drop off follow questions.docx	Other
Stephen_Litavec_CV.pdf	Other
USAMRMC-OPR-HRPO-approvals for BART study 01-10-2018.pdf	Other
Voxco Online survey description.docx	Other
WATKINS_REBECCA-CV.pdf	Other
WEIMER_BELINDA-CV.pdf	Other
Weimer BeLinda_CITI_RTI.pdf	Other
houraniethicsCertificate2016.pdf	Other
human-subjects-training_watkins-rebecca.pdf	Other
reckhoff_CITI_CompletionReport.pdf	Other
Ashley_Holland_CITI.pdf	Research Ethics Training
Gregory_Lewis_CITI.pdf	Research Ethics Training
Michelle_Krzyzanowski_CITI.pdf	Research Ethics Training
Rebecca_Watkins_CITI.pdf	Research Ethics Training
Stephen_Litavec_CITI.pdf	Research Ethics Training

[view attachments](#)

Addenda

 Data Security Requirements

[view addenda](#)

If Principal Investigator of this study is a Student or Trainee Investigator, the Faculty Advisor certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed [here](#).

Certifying Signatures:**Signature:** Electronic Signature Received

Maria Davila-Hernandez

Date: 7/18/2018 03:36:37 PM

BART



Biofeedback Assisted
Resilience Training



Dear Military Veteran, Reservist, National Guard Member, or First Responder,

You are invited to participate in a research study that will be evaluating heart rate variability biofeedback versus relaxation breathing interventions for building resilience among Reserve Component service members. Participants in this study will learn to reduce stress by controlling their breathing.

The Department of Defense has funded RTI International, a non-profit research organization, and the University of North Carolina (UNC) working with UNC's Citizen Soldier Support Program (<http://warwithin.org/>) to conduct this study.

Participation in this study is voluntary and participants will be offered up to \$135 for participation and a free heart rate monitor. Your participation will include a 45 minute onsite training and at home practice periods.

You may participate in this study if you:

- Are a Military Veteran, a current Reservist, member of the National Guard, or a First Responder
- Have a smart phone
- Have not had suicidal ideation, psychosis or hospitalization for a behavioral health problem in the past 12 months.

To participate, please visit our website: <https://bart.rti.org/>

Thank you very much for your support. Please contact the website or email:
BARTStudy@rti.org if you have any questions.

Sincerely,

Laurel Hourani, Ph.D., M.P.H., Senior Research Epidemiologist, RTI international.

Maria Davila, Ph.D., Department of Psychiatry, University of North Carolina.

BART



Biofeedback-Assisted Resilience Training among Reserve Component Personnel (BART)

The BART program is being conducted to teach Reservists, National Guardsmen, First Responders, and Military Veterans how to control their heart rate and deal with stress.

Participants will received up to \$135 in Amazon gift cards and a free heart monitor for completing questionnaires and practicing breathing techniques on their smart phones or tablets.



THE UNIVERSITY
OF NORTH CAROLINA
AT CHAPEL HILL



Produced by RTI International and the University of North Carolina, Chapel Hill with funding from the Department of Defense.

TO LEARN MORE LOG ON AT: **BART.RTI.ORG**

Questions?
Email: BARTstudy@rti.org
Or Call: Study Coordinator at 1-800-647-9655



Learn how to control your heart rate and

manage stress *in your life...*



log on to
bart.rti.org

BART

Biofeedback Assisted
Resilience Training



- **Earn up to \$135** in gift cards and a free heart rate monitor
- **Confidential** - **no one** in the command will see your data
- **Free** - Single training session with at home practice
- **Web-based** - all you need to participate is a smart phone or tablet



Questions? Email: BARTstudy@rti.org
Or Call: Study Coordinator at 1-800-647-9655



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



Conducted by RTI International and the University of North Carolina, Chapel Hill with funding from the Department of Defense.

**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study**

Consent Form Version Date: 07/18/18

IRB Study # 16-2312

Title of Study: Evaluation of HRV Biofeedback as a Resilience Building Intervention

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Co-Investigators: Laurel Hourani

Funding Source and/or Sponsor: Department of Defense (DOD)

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. There are no consequences if you decide not to participate in the study. Refusal to participate will not result in any punishment or loss of benefits to which you are otherwise permitted. Please read the information below, and ask questions about anything you do not understand, before deciding to take part in this research study.

This study, supported by the U.S. Army and funded by the Department of Defense (DoD), is being conducted by researchers at RTI International, a not-for-profit research organization in the Raleigh/ Durham area of North Carolina and the University of North Carolina-Chapel Hill.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of the study is to compare the effectiveness of paced breathing with or without biofeedback in helping to build resilience in reserve component military personnel, first responders and military veterans, and ultimately to prevent psychological health problems.

- You are being asked to be in the study because you are a U.S. reserve component military member, a First Responder, or a Military Veteran who owns a smartphone. Approximately 500 individuals will take part in the study.

Are there any reasons you should not be in this study?

You should not be in this study if you have been hospitalized in the last year for psychosis, suicidal/homicidal ideation, or behavioral health problems.

How many people will take part in this study?

A total of approximately 500 people at more than 20 institutions will take part in this study.

How long will your part in this study last?

Your participation in the study will last up to six months, with a total of about 9 hours of time spread over that period.

What will happen if you take part in the study?

You will be assigned to one of two groups, Group 1, a biofeedback/paced breathing (BART) group, or Group 2, a paced breathing (PB) group.

- During a 45-minute training session, you will learn how to use the BART or PB mobile app and the heart rate sensor that will be worn periodically during the study
- During the training, your heart rate will be recorded while you are resting, while you are performing some challenging tasks, and while you are learning the paced breathing technique or the biofeedback technique.
- Use the BART or PB mobile app and wear the sensor on your own for 15 minutes at least 3 times a week for six weeks while in a non-drill status.
- Using the BART or PB app, during the first few days of the study, to answer a set of questions concerning personal information (e.g., age, weight, height, sex, etc.), your emotions, and your exposure to stressful events.
- Using the BART or PB app and the heart rate sensor, collect heart rate information while practicing biofeedback/paced breathing or paced breathing, at least monthly during the study.
- Using the BART or PB app, answer questionnaires about stress-related topics at 3 and 6 months

The total expected time burden for your participation will be about 15-90 minutes for the 6-weeks and 3-25 minutes to complete the stress-related questionnaires.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study should include learning relaxation techniques that may last a lifetime. Further, you may have a feeling of satisfaction knowing that you are participating in a project that may have long-term benefits for other individuals, particularly military personnel, who may experience combat and operational stress.

What are the possible risks or discomforts involved from being in this study?

We believe that the risks or discomforts to you are small. Some of the health-related questions are possibly sensitive, and you may feel uncomfortable answering them. You may choose not to answer specific questions. If you feel uncomfortable while you are using either app, you may stop, inform the investigators, and, if you desire, withdraw from the study.

Similarly, although there are no known risks to wearing the heart rate sensor, it is a commercially available “off-the-shelf” product. While it should be worn to fit snugly, when used in this study protocol, it should not cause any discomfort or irritation. If you decide to use it as part of your workout, outside of the study requirements, it may cause a skin irritation. If you feel uncomfortable while you are wearing it, you may remove it, inform the investigators, and, if you desire, withdraw from the study.

There is also the unlikely risk of a loss in confidentiality.

If you desire, you can review your own research information once the study ends.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

To reduce this risk, your name will not be stored with your data in any electronic files, and we will not share your information with anyone outside the project staff. You further have the right to refuse to answer any questions that you do not wish to answer. The file linking your unique subject ID to your contact information will be maintained on a separate, password protected computer, not linked to the study data.

The research team at RTI and UNC will keep the research information for up to five years after the end of the study. At that time, all the information will be destroyed. Participants will not be identified in any report or publication about this study. Although every effort will be made to

keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

Since your participation in this study will take place during off-duty hours, over the course of the study you may potentially receive up to \$135. You will receive \$25 when you complete each set of the questionnaires at the start of the study, and \$20 each at 3, 6 and months. You'll receive \$10 /week for the 6 weeks in which you practice the BART or PB exercises at home. You will also gain free use of either app during the period of your participation in the study and may keep the heart rate sensor at the study conclusion. **Military personnel are not being compensated for research conducted while on duty.**

Will it cost you anything to be in this study?

If you enroll in this study, you could potentially incur a cost for the transmission of data to or from your cellular device through your cellular data plan. We have tailored the study App to allow manual upload of data at your discretion so that you may do so when connected to WiFi, which will eliminate this cost. Data is secured prior to transmission, so you can use any available WiFi access to make this data upload. WiFi is also available in the room today to enable you to download the App without incurring a cost to your data plan. The following estimates of data transmission sizes are provided as a guideline, should you choose to transmit data over your cellular plan:

App Download (less than 60MB)
Weekly Uploads (less than 1MB)
Quarterly Uploads (less than 2MB)

Who is sponsoring this study?

When appropriate, the last sentence should be modified/expanded to disclose the nature of any potential conflicts of interest relating to this study, financial or otherwise.

This research is funded by the Department of Defense (DOD) through the Congressionally Directed Medical Research Programs. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form. By agreeing to take part in this research, you are not giving up any of your legal rights.

If you have any questions about the research project, research-related injury, or to end your involvement, please contact the Study Coordinator at 1-866-214-2038 or email:

Bartstudy@rti.org.

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. If you have questions about this, you should discuss this issue thoroughly with the principal investigators, Dr. Laurel Hourani or Dr. Maria Davila, before you enroll in the study.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact Dr. Laurel Hourani, Principal Investigator, at (800) 334-8571 (extension 2-7719) or hourani@rti.org. Dr. Davila can also be reached for these issues using the contact information above. A copy of this consent form will be provided to you upon request and is available from within the App.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent

Introductory Script for One on One

EVALUATION OF HRV (HEART RATE VARIABILITY) BIOFEEDBACK AS A RESILIENCE BUILDING INTERVENTION IN THE RESERVE COMPONENT

1. Thank you for stopping by, please allow me to introduce the BART study which stands for Biofeedback-assisted Resilience Training. I am _____ from RTI/UNC. We have been funded by DoD to help build psychological resilience in reservists, National Guardsmen, First Responders, and Military Veterans; and evaluate 2 different breathing techniques. You will need to have a smartphone with an operating system IOS 10 or above or an Android 6 and install our App on your phone for as long as you participate, which will be up to a year. Do you have your phone with you? Do you have a few minutes to hear more about the study?

2. If Yes and No, or No and No: Thank you for your time.

3. If No and Yes: Please come back with your phone later, if possible, otherwise Thank you for your time.

4. If Yes and Yes: We are going to teach you how to control your heart rate today using well known relaxation breathing techniques. We will be randomly selecting you into one of 2 groups: A biofeedback group or a paced breathing group. Both will help you learn to control stress and improve your mental resilience. We will be using heart rate monitors called polar straps that go around your chest along with a software app to provide information about your heart rate. The app will not take more than 110 MB of space.

- Today you will learn how to use the breathing techniques on the app and the heart rate sensor which will last approximately 20 minutes.
- During the training, your heart rate will be recorded while you are resting, while you are performing some challenging tasks and while you are learning the breathing technique.
- Using the app and the heart rate sensor, you will be sending heart rate information while practicing the breathing techniques, periodically during the study
- We will also be asking you to complete 10 short questionnaires over the six months. Today and for the next 2 days, we will be asking you some personal information (e.g., age, weight, height, sex, etc.) and some questions about your emotions and exposure to stressful events. We will also send you on your app a brief questionnaire once a week for the next 6 weeks and then 2 more to complete at 3 and 6 months from now.
- Since your participation in this study will take place during off-duty hours, you may potentially receive up to \$135. You will receive \$25 when you complete the first 3 questionnaires and training at the start of the study, and \$20 each at 3 and 6 months. You'll also receive \$10 /week for the first 6 weeks in which you practice the Biofeedback or Paced Breathing exercises at home. You will also gain free use of the app during the period of your participation in the study and may keep the heart rate sensor at the study conclusion. If you withdraw from the study prior to its completion, you will receive a prorated amount based on the length of time you participated. There is a table about these amounts in the app but mostly we want you to use the app to practice your breathing technique as much as possible for your benefit.

5. Your participation is completely voluntary. There are no consequences if you decide not

to participate in the study. Refusal to participate will not result in any punishment or loss of benefits. Your name will not be stored with your data in any electronic files, and we will not share your information with anyone outside the project staff. [HAND OUT THE CONSENT FORM.] Please read the consent form, and ask questions about anything you do not understand, before deciding to take part in this research study. We hope you will take part in this study that will not only teach you techniques to handle stress but also help other military personnel who may experience combat and operational stress.

[AFTER CONSENTING START THE PROCESS OF ENROLLMENT AND TRAINING, PROCEDURE]

Time of Introductory Script for One on One 4.5 minutes.

Good morning. My name is _____ and I am a researcher with RTI/UNC. I would like to thank _____ for allowing us a minute here to introduce our study to you. We are conducting a study on Biofeedback Assisted Resilience Training, or BART for short. We are evaluating an at-home exercise regime that should train your mind to help you bounce back from stressful events. We are going to be running a training session tonight at _____ that will last an hour and a half. That will be the only time you will spend with us for this study, after that, all your participation will be at your home (or wherever you want), on your phone.

If you agree to participate, you will receive one of these (hold up Polar H7 monitor) heart monitors, and an App that we have developed. You will need a phone that is compatible with this (wave the Polar device). That means a fairly recent phone, for an iPhone, that is model 4s or later. For Samsung that would be a Galaxy S3 or later. If you want to check to see if your phone might work, you should do a quick search to see if it supports “Bluetooth 4 or Bluetooth Low Energy”.

If you want to look us up online before tonight’s session, our website is bart.rti.org.

Oh, and there are incentives for participating. You can earn up to \$135 in Amazon gift cards for your continued participation over the next year. That’s all we have for now. I hope that I will see some of you at _____ tonight at _____ PM.

Thank you for your attention.

Biofeedback for Resilience

3, 6 – Month Follow-Up Surveys

INTRODUCTION

[3-MONTH] Thank you for your continued participation in the Biofeedback for Resilience Survey. The following questions are part of the 3-month follow-up survey and are part of your incentive package. As you may recall, you answered many of the same questions during the baseline survey. We are collecting this information again to measure any changes over time. You will receive a \$20 incentive for completing the 3-month follow-up survey. If your email or telephone number has changed since the baseline training, please contact the Bart Study Coordinator at BARTstudy@rti.org or at 1-866-214-2038.

[6-MONTH] Thank you for your continued participation in the Biofeedback for Resilience Survey. The following questions are part of the 6-month follow-up survey. This is the last survey you will complete for this study. As you may recall, you answered many of the same questions as part of the baseline and the 3-month follow-up survey. We are collecting this information again to measure any changes over time. You will receive a \$20 incentive for completing the 6-month follow-up survey. If your email or telephone number has changed since the baseline training, please contact the Bart Study Coordinator at BARTstudy@rti.org or at 1-866-214-2038.

For each question, use your finger or a stylus to select the radial button that corresponds to the answer you want to select. At the bottom of the page, click on the “Next” button to go to the next question.

The first set of questions ask about your stress, anxiety, and other problems you may have experienced.

1. **[3-MONTH FOLLOW-UP ONLY]** Please indicate how much you agree with the following statements as they apply to you over the last month. If a particular situation has not occurred recently, answer according to how you think you would have felt.

	Not true at all	Rarely true	Sometimes true	Often true	True nearly all the time
a. I am able to adapt when changes occur.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I can deal with whatever comes my way.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I try to see the humorous side of things when I am faced with problems.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Having to cope with stress can make me stronger	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. I tend to bounce back after illness, injury, or other hardships.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

f. I believe I can achieve my goals, even if there are obstacles.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. Under pressure, I stay focused and think clearly	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. I am not easily discouraged by failure.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. I think of myself as a strong person when dealing with life's challenges and difficulties.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
j. I am able to handle unpleasant or painful feelings like sadness, fear and anger	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

OR

[6-MONTH FOLLOW-UP ONLY] Please indicate how much you agree with the following statements as they apply to you over the last month. If a particular situation has not occurred recently, answer according to how you think you would have felt.

	Not true at all	Rarely true	Sometimes true	Often true	True nearly all the time
a. I am able to adapt when changes occur.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I have at least one close and secure relationship which helps me when I am stressed.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. When there are no clear solutions to my problems, sometimes fate or God can help.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. I can deal with whatever comes my way	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. Past successes give me confidence in dealing with new challenges and difficulties.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. I try to see the humorous side of things when I am faced with problems.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. Having to cope with stress can make me stronger	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. I tend to bounce back after illness, injury, or other hardships.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. Good or bad, I believe that most things happen for a reason.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
j. I give my best effort, no matter what the outcome may be.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
k. I believe I can achieve my goals, even if there are obstacles.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
l. Even when things look hopeless, I don't give up.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
m. During times of stress/crisis, I know where to turn for help.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
n. Under pressure, I stay focused and think clearly.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
o. I prefer to take the lead in solving problems, rather than letting others make all the decisions.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
p. I am not easily discouraged by failure	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
q. I think of myself as a strong person when dealing with life's challenges and difficulties.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
r. I can make unpopular or difficult decisions that affect other people, if it is necessary.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
s. I am able to handle unpleasant or painful feelings like sadness, fear and anger.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
t. In dealing with life's problems, sometimes you have to act on a hunch, without knowing why.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
u. I have a strong sense of purpose in my life.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

v. I feel in control of my life.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
w. I like challenges.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
x. I work to attain my goals, no matter what roadblocks I encounter along the way.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
y. I take pride in my achievements.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Over the last 2 weeks, how often have you been bothered by the following problems.

	Not at all sure	Several days	Over half the days	Nearly every day
Feeling nervous, anxious, or on edge	☐ 1	☐ 2	☐ 3	☐ 4
Not being able to stop or control worrying.....	☐ 1	☐ 2	☐ 3	☐ 4
Worrying too much about different things	☐ 1	☐ 2	☐ 3	☐ 4
Trouble relaxing	☐ 1	☐ 2	☐ 3	☐ 4
Being so restless that it's hard to sit still	☐ 1	☐ 2	☐ 3	☐ 4
Becoming easily annoyed or irritable	☐ 1	☐ 2	☐ 3	☐ 4
Feeling afraid as if something awful might happen	☐ 1	☐ 2	☐ 3	☐ 4

3. Below is a list of ways you might have felt or behaved. Please indicate how often you felt this way during the past week:

	Rarely or None of the Time (Less Than 1 Day)	Some or a Little of the Time (1–2 Days)	Occasionally or a Moderate Amount of the Time (3–4 Days)	Most or All of the Time (5–7 Days)
I was bothered by things that usually do not bother me	☐ 1	☐ 2	☐ 3	☐ 4
I had trouble keeping my mind on what I was doing	☐ 1	☐ 2	☐ 3	☐ 4
I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4
I felt like everything I did was an effort	☐ 1	☐ 2	☐ 3	☐ 4
I felt hopeful about the future	☐ 1	☐ 2	☐ 3	☐ 4
I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4
My sleep was restless.....	☐ 1	☐ 2	☐ 3	☐ 4
I was happy.....	☐ 1	☐ 2	☐ 3	☐ 4
I felt lonely.....	☐ 1	☐ 2	☐ 3	☐ 4
I could not “get going”	☐ 1	☐ 2	☐ 3	☐ 4

4. The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way.

	Never	Almost Never	Some- times	Fairly Often	Very Often
During the past month, how often have you felt that you were unable to control the important things in your life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the past month, how often have you felt confident about your ability to handle your personal problems?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
During the past month, how often have you felt that things were going your way?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
During the past month, how often have you felt difficulties were piling up so high that you could not overcome them? .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. These next questions ask you to indicate what you generally do and feel when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress.

	I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
a. I turn to work or other activities to take my mind off of things.....	☐ 1	☐ 2	☐ 3	☐ 4
b. I concentrate my efforts on doing something about the situation I'm in.....	☐ 1	☐ 2	☐ 3	☐ 4
c. I say to myself "this isn't real."	☐ 1	☐ 2	☐ 3	☐ 4
d. I use alcohol or other drugs to make myself feel better.....	☐ 1	☐ 2	☐ 3	☐ 4
e. I get emotional support from others.....	☐ 1	☐ 2	☐ 3	☐ 4
f. I give up trying to deal with it.....	☐ 1	☐ 2	☐ 3	☐ 4
g. I take action to try to make the situation better.....	☐ 1	☐ 2	☐ 3	☐ 4
h. I refuse to believe that it has happened.....	☐ 1	☐ 2	☐ 3	☐ 4
i. I say things to let my unpleasant feelings escape.....	☐ 1	☐ 2	☐ 3	☐ 4
j. I get help and advice from other people.....	☐ 1	☐ 2	☐ 3	☐ 4
k. I use alcohol or other drugs to help me get through it.....	☐ 1	☐ 2	☐ 3	☐ 4
l. I try to see it in a different light, to make it seem more positive....	☐ 1	☐ 2	☐ 3	☐ 4
m. I criticize myself.....	☐ 1	☐ 2	☐ 3	☐ 4
n. I try to come up with a strategy about what to do.....	☐ 1	☐ 2	☐ 3	☐ 4
o. I get comfort and understanding from someone.....	☐ 1	☐ 2	☐ 3	☐ 4
p. I give up the attempt to cope.....	☐ 1	☐ 2	☐ 3	☐ 4
q. I look for something good in what is happening.....	☐ 1	☐ 2	☐ 3	☐ 4
r. I make jokes about it.....	☐ 1	☐ 2	☐ 3	☐ 4
s. I do something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.....	☐ 1	☐ 2	☐ 3	☐ 4
t. I accept the reality of the fact that it has happened.....	☐ 1	☐ 2	☐ 3	☐ 4
u. I express my negative feelings.....	☐ 1	☐ 2	☐ 3	☐ 4
v. I try to find comfort in my religion or spiritual beliefs.....	☐ 1	☐ 2	☐ 3	☐ 4
w. I try to get advice or help from other people about what to do.....	☐ 1	☐ 2	☐ 3	☐ 4
x. I learn to live with it.....	☐ 1	☐ 2	☐ 3	☐ 4
y. I think hard about what steps to take.....	☐ 1	☐ 2	☐ 3	☐ 4
z. I blame myself for things that happened.....	☐ 1	☐ 2	☐ 3	☐ 4
aa. I pray or meditate.....	☐ 1	☐ 2	☐ 3	☐ 4
ab. I make fun of the situation.....	☐ 1	☐ 2	☐ 3	☐ 4

6. How much stress have you experienced in the past month?

- ☐₁ None at all
☐₂ A little
☐₃ Some
☐₄ A lot

7. In general, how well do you think you handled stress during the past month?

- ☐₁ Poorly
☐₂ Fairly well
☐₃ Well
☐₄ Very well

8. Please indicate how much each statement below describes you.

	Quite a lot	Some	A little	Not at all
a. I often act on the spur of the moment without stopping to think.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
b. I get a real kick out of doing things that are a little dangerous.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
c. You might say I act impulsively.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
d. I like to test myself every now and then by doing something a little chancy or risky.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
e. Many of my actions seem to be hasty.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
f. I'm always up for a new experience.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
g. I like to try new things just for the excitement.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
h. I go for the thrills in life when I get a chance.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
i. I like to experience new and different sensations.	☐ ₁	☐ ₂	☐ ₃	☐ ₄

9. Below are statements that people often feel differently about. Please indicate how much you think each one is true. Give your own honest opinions. There are no right or wrong answers.

	Not at all true	A little true	Quite true	Completely true
a. Most of my life gets spent doing things that are meaningful.	☐ 0	☐ 1	☐ 2	☐ 3
b. By working hard you can nearly always achieve your goals.	☐ 0	☐ 1	☐ 2	☐ 3
c. I don't like to make changes in my regular activities.	☐ 0	☐ 1	☐ 2	☐ 3
d. I feel that my life is somewhat empty of meaning.	☐ 0	☐ 1	☐ 2	☐ 3
e. Changes in routine are interesting to me.	☐ 0	☐ 1	☐ 2	☐ 3
f. How things go in my life depends on my own actions.	☐ 0	☐ 1	☐ 2	☐ 3
g. I really look forward to my daily activities.	☐ 0	☐ 1	☐ 2	☐ 3
h. I don't think there's much I can do to influence my own future.	☐ 0	☐ 1	☐ 2	☐ 3
i. I enjoy the challenge when I have to do more than one thing at a time.	☐ 0	☐ 1	☐ 2	☐ 3
j. Most days, life is really interesting and exciting for me.	☐ 0	☐ 1	☐ 2	☐ 3
k. It bothers me when my daily routine gets interrupted.	☐ 0	☐ 1	☐ 2	☐ 3
l. It is up to me to decide how the rest of my life will be.	☐ 0	☐ 1	☐ 2	☐ 3
m. Life in general is boring for me.	☐ 0	☐ 1	☐ 2	☐ 3
n. I like having a daily schedule that doesn't change very much.	☐ 0	☐ 1	☐ 2	☐ 3
o. My choices make a real difference in how things turn out in the end.	☐ 0	☐ 1	☐ 2	☐ 3

10. Below is a list of problems and complaints that people sometimes have in response to a stressful life experiences. Please indicate how much you have been bothered by each problem during the last month.

	Not at all	A little bit	Moderately	Quite a bit	Extremely
a. Repeated, disturbing memories, thoughts, or images of a stressful experience from the past..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Repeated, disturbing dreams of a stressful experience from the past	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Suddenly acting or feeling as if a stressful experience were happening again (as if you were reliving it).....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Feeling very upset when something reminded you of a stressful experience from the past	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. Having physical reactions (e.g., heart pounding, trouble breathing, sweating) when something reminded you of a stressful experience from the past.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. Avoid activities or situations because they remind you of a stressful experience from the past.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. Trouble remembering important parts of a stressful experience from the past	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. Loss of interest in activities you used to enjoy ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
j. Feeling distant or cut off from other people.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
k. Feeling emotionally numb or being unable to have loving feelings for those close to you	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
l. Feeling as if your future will be cut short somehow	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
m. Trouble falling or staying asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
n. Feeling irritable or having angry outbursts	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
o. Having difficulty concentrating	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
p. Being "super alert" or watchful on guard	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
q. Feeling jumpy or easily startled	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. Please think of the most adverse or traumatic event that you have experienced. Which of the following most accurately describes this event? (Select only one.)

- ☐1 Combat
- ☐2 Loss of a loved one
- ☐3 Chronic or acute illness
- ☐4 Violent or abusive crime
- ☐5 Accident or injury
- ☐6 Disaster
- ☐7 Job loss
- ☐8 Financial hardship
- ☐9 Career or location change/move
- ☐10 Change in family responsibility
- ☐10 Divorce
- ☐12 Retirement
- ☐13 Other (please specify): _____

12. Think back to the most adverse or traumatic event you have ever experienced. Indicate for each of the statements below, the degree to which this change happened to you as a result of your most adverse or traumatic experience.

	I experienced this change to a <u>very great</u> degree	I experienced this change to a <u>great</u> degree	I experienced this change to a <u>moderate</u> degree	I experienced this change to a <u>small</u> degree	I experienced this change to a <u>very small</u> degree	I <u>did not</u> experience this change
a. I changed my priorities about what is important in life.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b. I have a greater appreciation for the value of my own life.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c. I am able to do better things with my life.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
d. I have a better understanding of spiritual matters.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
e. I have a greater sense of closeness with others	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
f. I established a new path for my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
g. I know better that I can handle difficulties.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
h. I have a stronger religious faith.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
i. I discovered that I am stronger than I thought I was.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
j. I learned a great deal about how wonderful people are	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

The next set of questions ask about you're your health, health care, and health-related behaviors.

13. **[6-MONTH FOLLOW-UP ONLY]** In the last year, have you ever drunk alcohol or used drugs more than you meant to?

- ☐1 Yes
☐2 No

14. **[6-MONTH FOLLOW-UP ONLY]** In the last year, have you felt you wanted or needed to cut down on your drinking or drug use?

- ☐1 Yes
☐2 No

15. **[6-MONTH FOLLOW-UP ONLY]** **[IF MILITARY (Q1 DAY 1=YES) OR IF VETERAN (Q5 DAY 1=YES)]** During the past year, did you receive counseling or therapy for mental health or substance abuse from the following?

	Yes	No
a. Mental health professional at a military or VA facility (e.g., psychologist, psychiatrist, clinical social worker, or other mental health counselor)	☐ 1	☐ 2
b. General medical doctor at a military or VA facility	☐ 1	☐ 2
c. Military chaplain	☐ 1	☐ 2
d. Civilian mental health professional (e.g., psychologist, psychiatrist, clinical social worker, or other mental health counselor)	☐ 1	☐ 2
e. General medical doctor at a civilian facility	☐ 1	☐ 2
f. Civilian pastor, rabbi, or other pastoral counselor	☐ 1	☐ 2
g. Self-help group (e.g., AA, NA)	☐ 1	☐ 2

OR

- [6-MONTH FOLLOW-UP ONLY]** **[IF NOT MILITARY (Q1 DAY 1=NO) OR NOT VETERAN (Q5 DAY 1=NO)]** During the past year, did you receive counseling or therapy for mental health or substance abuse from the following?

	Yes	No
d. mental health professional (e.g., psychologist, psychiatrist, clinical social worker, or other mental health counselor)	☐ 1	☐ 2
e. General medical doctor	☐ 1	☐ 2
f. pastor, rabbi, or other pastoral counselor	☐ 1	☐ 2
g. Self-help group (e.g., AA, NA)	☐ 1	☐ 2

16. **[6-MONTH FOLLOW-UP ONLY]** For what concerns did you seek counseling or therapy during the past year? (MARK ALL THAT APPLY.)

- ☐1 I did not seek help from a mental health professional in the past year
☐2 Depression
☐3 Anxiety
☐4 Family problems
☐5 Substance use problems (alcohol or drug)
☐6 Anger management

- ☐7 Stress management
- ☐8 Combat/operational stress
- ☐9 Other (specify): _____

17. In general, would you say your health is:

- ☐1 Excellent
- ☐2 Very good
- ☐3 Good
- ☐4 Fair
- ☐5 Poor

18. Does your health now limit you in these activities?

	YES, limited a lot	YES, limited a little	NO, not limited at all
a. <u>Moderate activities</u> such as moving a table, pushing a vacuum cleaner, bowling or playing golf.....	☐ 1	☐ 2	☐ 3
b. Climbing <u>several</u> flights of stairs.....	☐ 1	☐ 2	☐ 3

19. During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?

- ☐1 Not at all
- ☐2 A little bit
- ☐3 Moderately
- ☐4 Quite a bit
- ☐5 Extremely

20. The following questions are about how you have been feeling during the past 4 weeks. For each questions, please give the one answer that comes closest to the way you have been feeling.

How much during the past 4 weeks...	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c. Have you felt down-hearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

21. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ☐1 All of the time
- ☐2 Most of the time
- ☐3 Some of the time
- ☐4 A little of the time
- ☐5 None of the time

22. In the past 7 days. . . .

	Not at all	A little bit	Some- what	Quite a bit	Very much
My sleep was restless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I was satisfied with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My sleep was refreshing.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I had trouble staying asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I had trouble sleeping	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I got enough sleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

23. In the past 7 days, my sleep was. . .

- ☐1 Very poor
- ☐2 Poor
- ☐3 Fair
- ☐4 Good
- ☐5 Very good

24. Please select how many minutes of each type of exercised you participated in today.

Exercise Intensity	0 minutes	15 minutes	30 minutes	45 minutes	60 or more minutes
Vigorous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Moderate.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Mild.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Vigorous Activity- A person should find it hard to carry on a conversation during the activity. Examples included jogging, high impact aerobics, chopping wood, swimming continuous laps, bicycling uphill.

Moderate Activity – A person should feel some exertion but should be able to carry on a conversation comfortably during the activity. Examples include walking briskly, dancing, swimming, bicycling on a level terrain.

Mild Activity – A person should not feel any exertion and should have no problem carrying on a conversation comfortably during the activity. Examples include walking slowly or at normal pace, stretching, walking up a stairs. Many mild activities are conducted during common daily routines.

25. Are you currently taking medication for depression, anxiety, or sleeping problems prescribed by a doctor or other health professional?

- ☐1 Yes
- ☐2 No

26. How many caffeinated beverages (e.g., coffee, tea, soda) or energy drinks (e.g., Red Bull) have you had today?

- ☐1 None
- ☐2 1–2 drinks
- ☐3 3–4 drinks
- ☐4 5 or more drinks

27. Have you used any tobacco or vapor products today? Examples of tobacco products include cigarettes, cigars, chewing tobacco, and snuff. Examples of vapor products include vaporizers and electronic cigarettes, cigars, and pipes.

☐1 Yes

☐2 No

28. **[IF EXPERIMENTAL GROUP]** How would you rate your overall experience using the biofeedback to date?

☐1 Very dissatisfied

☐2 Dissatisfied

☐3 Neither satisfied or dissatisfied

☐4 Satisfied

☐5 Very satisfied

OR

[IF CONTROL GROUP] How would you rate your overall experience using the paced breathing technique to date?

☐1 Very dissatisfied

☐2 Dissatisfied

☐3 Neither satisfied or dissatisfied

☐4 Satisfied

☐5 Very satisfied

29. During the past 3 months, how often did you practice slow, deep breathing without an app?

☐1 None

☐2 1 time

☐3 2 times

☐4 3 or more times

Please feel free to share any comments you may have about biofeedback or your participation in this study: _____

Thank you very much for your participation in this study!

**If you have any questions, please contact the BART Study Coordinator at
BARTstudy@rti.org.**

Appendix C. Quad Chart

Evaluation of HRV Biofeedback as Resilience Building Intervention in the Reserve Component
PR151616

Award Number: W81XWH-16-1-0346



PI: Laurel Hourani, Ph.D., M.P.H.

Org: RTI International

Award Amount: \$1,833,144

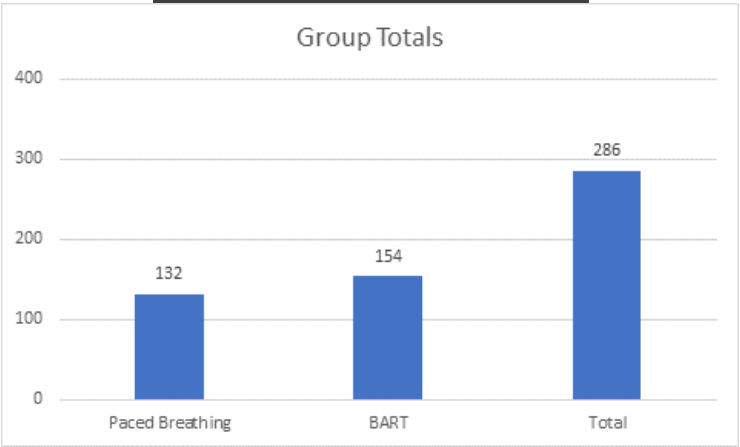
Study/Product Aim(s)

- 1. Develop and test the PHIT platform for use with the BART protocol.
- 2. Examine the relationship between baseline HRV and resilience, mental health, substance use, stress, and physical health measures.
- 3. Examine the individual differences in response to various BART training parameters (Breathing speed, amount of practice, knowledge of and prior use of biofeedback and/or other complementary methods).
- 4. Examine the extent to which resilience and mental health symptoms are linked to HRV at baseline and how that relationship changes over time. Explore the effects in which comorbidities may impact the effect of HRV-BART on resilience, coping and PTG scale scores.

Approach

Participants will be trained in one of two protocols: HRV-BART with paced breathing (PB) or PB alone. They will provide weekly status updates on their resilience scores by smartphone app. Data will be analyzed at weekly intervals through the 6 week at-home practice period and later at 3-, 6-, 9- and 12-month follow-up intervals.

Distribution of study participants by group as of July. 31, 2018



Accomplishments: Baseline data collection continued. Preliminary analysis of collected data indicates that the vast majority of participants have useable data and HRV changes as expected.

Timeline and Cost

Activities	CY	16	17	18	19
Completed pilot report Physio data collection platform					
All IRB & HRPO approvals received Finalized data collection platforms					
All data collection material ready Sample size requirement met					
Baseline technical report/paper Final analyses and manuscript					
Estimated Budget (\$K)		\$458,286	\$458,286	\$458,286	\$458,286

Goals/Milestones

- CY16 Goal – Obtained IRB approvals and begin software development
- CY17 Goal – Determined the utility of HRV as biomarker for resilience building
- CY18 Goal – Determine most efficient HRV biofeedback protocol for increased resilience and decreased stress-related conditions
- CY19 Goal – Determine efficacy of HRV BART over PB only

Comments/Challenges/Issues/Concerns

RTI Budget Expenditure through July, 2018

Projected Expenditure: \$1,222,003

Actual Expenditure: \$1,377,846

Updated: August, 2018