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Award Number: W81XWH-17-1-0691

TITLE: Factors Associated With Outcomes in Patients with Vestibular Symptoms Related to Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: Dr. Faith Akin

CONTRACTING ORGANIZATION: Mountain Home Research and Education Corporation
Mountain Home, TN 37684

REPORT DATE: October 2019

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE			<i>Form Approved</i> <i>OMB No. 0704-0188</i>		
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1. REPORT DATE (DD-MM-YYYY) Oct 2019		2. REPORT TYPE Annual Report		3. DATES COVERED (From - To) 9/29/2018-9/28/2019	
4. TITLE AND SUBTITLE Factors associated with outcomes in patients with vestibular symptoms related to traumatic brain injury			5a. CONTRACT NUMBER W81XWH-17-1-0691		
			5b. GRANT NUMBER		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S) Faith Akin, Ph.D. & Mary Jo Pugh, Ph.D.			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Mountain Home Research & Education Corporation Sidney & Lamont St Mountain Home, TN 37684			8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S) USAMRMC		
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution is unlimited.					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT <i>Objective:</i> Dizziness and imbalance are common symptoms following head injury that can continue for months or years in some individuals. Chronic dizziness is a serious health concern that can lead to increased fall risk, emotional and psychological distress, as well as work disability. Multiple causes of post-concussive dizziness can present a challenge to diagnosis, and obstacle to treatment. The Departments of Veterans Affairs and Defense (VA/DoD) developed clinical practice guidelines that outline recommendations for managing individuals with post-concussive dizziness, but it is unclear how these recommendations impact treatment for post-concussion dizziness/imbalance. In addition, some Veterans may seek care outside the VA or use alternative approaches to manage their post-concussive dizziness. The purpose of this study is to determine factors that contribute to successful outcomes of patients with concussion/blast-related dizziness. <i>Methodology:</i> We will use VA and DoD health databases to identify and examine characteristics of Veterans with specific (for example, inner ear balance dysfunction) and non-specific diagnoses of post-concussion dizziness. Then, we will survey Veterans using questionnaires and access the VA electronic medical records to determine factors that impact long-term recovery of post-concussion dizziness. Specifically, we will examine the impact of factors such as type of treatment, the presence or absence of health conditions such as headache and anxiety, the severity of head injury, as well as age and gender. <i>Findings:</i> An initial mailing of 225 surveys was completed in July. Chart abstraction has just begun following receipt of 50 returned surveys. <i>Impact/Significance:</i> This study is the first step towards developing novel therapeutic approaches to reduce the negative impact of dizziness and imbalance on individuals with dizziness related to mTBI. This project will contribute to improved quality of life for active duty service members and Veterans suffering from TBI, and blast-related mTBI.					
15. SUBJECT TERMS Vertigo, Dizziness, Vestibular, Otoliths, Traumatic Brain Injury, Patient Outcome					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 26	19a. NAME OF RESPONSIBLE PERSON Faith Akin, Ph.D.
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code) 423.926.1171 x.7376

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Chronic dizziness or imbalance is a common symptom following head injury that can negatively impact quality of life. Injured Veterans of the recent wars typically enter the Veterans Health Administration through the Polytrauma clinics and undergo the Comprehensive TBI Evaluation (CTBIE) which includes the Neurobehavioral Symptom Inventory. Although there are several clinical practice guidelines for post-concussive symptoms, there are no data on the effectiveness of clinical management pathways for reducing symptoms of dizziness. We are examining long-term outcomes of post-concussive dizziness in Veterans with TBI to determine factors and clinical management strategies associated with successful outcomes. We will use a chart review and Veteran survey to examine clinical referral patterns, diagnostic testing, and types of VA and non-VA care used to treat Veterans with post-concussive dizziness. This research effort is part of a long-term goal to establish a unique treatment platform to diagnose, localize, and treat dizziness and imbalance related to mTBI.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Vertigo, Dizziness, Vestibular, Otoliths, Traumatic Brain Injury, Patient Outcomes

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

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Complete Regulatory Requirements for Study	Timeline (Months)	Percentage Completed
Prepare Regulatory Documents and Research Protocol		
Finalize consent, human subjects protocol chart abstraction tool / Survey	1	100%
Coordinate with Sites for MOU/ DTA completion, nondisclosure agreements	1-5	100%
Secondary site IRB protocol submission (expedited)	1-4	100%
Submit amendments, adverse events and protocol deviations as needed	1-36	N/A
Coordinate with Sites for annual IRB report for continuing review	Annually	N/A
<i>Milestone Achieved: Local IRB and HRPO approval at Mountain Home Research and Education Corporation (MHREC) and Western Institute for Biomedical Research, Salt Lake City (WIBR)</i>	3-6	100%

Major Task 2: Identify cohort who meet criteria for high NSI vestibular symptomology	Timeline (Months)	Percentage Completed
Subtask 1: Obtain VA data for Post-9/11 Veterans		
Complete data request documentation for VA and DoD data sources	4-6	100%
Obtain VA and DOD data, calculate NSI severity, identify comorbidities, including TBI and TBI characteristics, and other clinical characteristics	6-7	100%
<i>Milestone Achieved: Raw Data obtained</i>	7	100%
Subtask 2: Identify vestibular and non-specific dizziness diagnoses in FY02-FY15 cohort		
Compile data from VA and DoD data sources and identify vestibular and non-specific dizziness diagnoses	7	100%
<i>Milestone Achieved: Cohort of Veterans with Dizziness identified</i>	7-8	100%
Conduct/interpretation of logistic regression analyses on Post-9/11 VA cohort and complete manuscripts	8-12	100%
<i>Milestone Achieved: Aim 1 completed</i>	12	100%
Major Task 3: Conduct survey of Veteran with high vestibular symptomology	Timeline (Months)	Percentage Completed
Obtain survey supplies, develop REDCap and paper survey administration forms, and develop logistics for survey process. (WIBR)	1-7	100%
Identify sample with high vestibular symptomology (NSI vestibular scale score of ≥ 3) AND who received care in a vestibular relevant clinic AND who received a diagnosis vestibular-specific or non-specific dizziness. (WIBR)	7-8	100%
Verify contact information and prepare survey mailings for administration. (WIBR)	7-26	50%
Conduct survey administration via online, mail (and telephone if preferred by respondents) modalities. (WIBR)	7-26	5%
Treatment responders will be identified: improvement in an individual's vestibular symptom score of ≥ 2 points or 20% improvement in the NSI vestibular subscale score. (WIBR)	7-27	0%
<i>Milestone Achieved: Study sample frame for Aim 2 identified and characterized; Survey data for Aim 2 collected</i>	27	20%
Major Task 4: Identify Sample for Aim 2 and conduct chart abstraction	Timeline (Months)	Percentage Completed
Develop and finalize chart abstraction data elements. (MHREC)	1-6	100%

Develop chart abstraction form in REDCap. (MHREC)	7-8	100%
Conduct preliminary training for chart abstraction on test cases identified from administrative data with high vestibular symptomology (NSI vestibular scale score of ≥ 3) AND who received care in a vestibular relevant clinic AND who received a diagnosis vestibular-specific or non-specific dizziness. (MHREC)	8-10	50%
Perform chart abstraction from electronic medical record via VISTA web system to describe type of care received and sample characteristics, including TBI, comorbidities, demographics. (MHREC)	11-30	0%
<i>Milestone Achieved: Study sample frame for Aim 2 identified and characterized</i>	30	10%
Major Task 5: Conduct analyses comparing Veterans with and without vestibular specific diagnoses who Responded vs. Non-responders	Timeline (Months)	Percentage Completed
Conduct interim and final analyses/ interpretation for Aim 2. (WIBR + MHREC)	30-34	0%
Complete manuscripts for publication. (WIBR + MHREC)	30-36	0%
<i>Milestone Achieved: Report findings comparing Veterans who Responded vs. Non-responders (Aim 2)</i>	36	0%

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) Major Activities:

- a. Obtained HRPO approval.
- b. Identified cohort who meet criteria for high NSI vestibular symptomology.
- c. Completed logistic regression analyses on Post-9/11 VA cohort.
- d. WIBR staff obtained all survey supplies, developed REDCap and paper surveys, and developed the logistics for the survey administration.
- e. WIBR verified contact information for all potential survey participants N=4200.
- f. WIBR administered a survey pilot (n=225) to finalize all of the survey logistics. Pilot surveys were mailed on July 3, 2019. We designed a within-study randomized control trial to test the effectiveness of the survey recruitment process. The response rate for the survey pilot is 22% to date. Survey responses from the pilot are still being collected. We have used the survey pilot to refine our recruitment strategy. We have submitted an amendment for the IRB in SLC to allow survey administration staff to allow potential survey participants to call and have the survey completed by phone, and to contact non-respondents by phone. We have prepared for the next major survey mail-out of 2000 surveys to begin in October 2019.

- g. MHREC staff finalized REDCap database developed for chart abstractions.
- h. Preliminary training for chart abstraction using test cases has begun for MHREC staff. MHREC will continue to train until 90% agreement between all reviewers has been achieved.
- i. Continued biweekly conference calls with key personnel at all study sites.

2) Specific Objectives:

- a. Identified the cohort who meet criteria for high NSI vestibular symptomology (Major Task 2).
- b. The publication by Alicia Swan et al. suggests measures to facilitate the identification of individuals with heightened vestibular symptomology, potentially through the already mandatory comprehensive traumatic brain injury evaluation (CTBIE) (Major Task 2).

3) Significant Results:

- a. Publication by Alicia Swan et al. (2019). This study of post-9/11 veterans is among the largest to date to estimate the prevalence and impact of vestibular dysfunction and dizziness and evaluate their association with traumatic brain injury. Dizziness, balance, and coordination problems are common symptom complaints seldom distinguished from more specific vestibular pathology. We suggest measures to facilitate the identification of individuals with heightened vestibular symptomology, potentially through the already mandatory comprehensive traumatic brain injury evaluation (CTBIE) at the VA. Such identification could accelerate referrals to vestibular specialists, enabling more efficient identification, management and treatment of these profoundly debilitating conditions.
- b. We found that approximately 60% of our sample had a score of three or higher on the vestibular subscale. This distribution differs from the publication by Soble et al. (2014) that found that 95% of soldiers without mTBI scored <3. To match the desired distribution, we changed criteria to a score of ≥ 6 on the vestibular subscale.
- c. After creating the final cohort, we found that the majority of the sample did not fall into the vestibular dysfunction or dizziness subgroups. Approximately 85% of the sample fell into a third group that had no vestibular or dizziness diagnosis but reported high vestibular symptomology (≥ 6) on the NSI. We have conducted analyses to determine how this group differs from the dizziness and vestibular groups and found that they are somewhat younger, entered VA care in 2009 vs. 2008 (dizziness) and 2007 (vestibular); the time from VA entry to CTBIE was also somewhat faster. Scores on each of the subscales were not significantly different among groups. The no diagnosis group was less likely to receive care at a site with a polytrauma rehabilitation center (level 1 polytrauma system of care), and more likely to receive care in a level 3 or 4 polytrauma system of care facility. This suggests that where care is received may play a role. We are currently exploring how different types of care and geographic location may also be associated with lack of diagnosis despite high symptomology. We believe this will have significant application to understanding quality of care for Veterans with dizziness/vestibular dysfunction.

4) Other Achievements:

Nothing to report at this time

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project.

“Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Mentoring junior research assistant to conduct national survey processes and research staff participating in VA cyberseminars related to TBI, mental health and sensory dysfunction.

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

As described above, our team completed a peer review publication examining the association of TBI with vestibular dysfunction. We are working on development of lay content for distribution through the TBI Warrior Foundation and other TBI stakeholder groups.

Dr. Pugh also presented findings from this paper as a guest lecturer for Clinical Epidemiology to doctoral students in Population Health Sciences program at the University of Utah.

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

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- 1) Complete survey administration.
- 2) Complete chart abstraction.
- 3) Identify treatment responders: improvement in an individual’s vestibular symptom score of ≥ 2 points or 20% improvement in the NSI vestibular subscale score.
- 4) Drs. Pugh and Swan will present a VA cyberseminar on multisensory dysfunction associated with TBI.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

- 5. CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Over the past year we have made substantial progress in study design since full hiring and training of staff at both VA Salt Lake City/WIBR and the MHREC sites. No problems to report during this reporting period.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated. development

Our expenditures continue to be below expected due to delays in hiring. We are making up ground on that issue since hiring has been successful.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report during this reporting period, however we are in process of getting approval to contact potential participants by telephone as described above.

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**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Swan AA, Nelson JT, Pogoda TK, Akin FW, Riska KM, Hall CD, Amuan ME, Yaffe K, Pugh MJ & the Chronic Effects of Neurotrauma Consortium. Association of Traumatic Brain Injury with Vestibular Dysfunction and Dizziness in Post-9/11 Veterans. J Head Trauma Rehabil. 2019 DOI: 10.1097/HTR.0000000000000513. Acknowledgement of Federal support (yes)

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

Website(s) or other Internet site(s)

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report; we are developing a dissemination platform through the University of Utah and stakeholders such as the TBI Warrior Foundation.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name:

Mary Smith

Project Role:

Graduate Student

Researcher Identifier (e.g. ORCID ID): 1234567

Nearest person month worked: 5

Contribution to Project:

Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support:

The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name:	<i>Faith Akin</i>
Project Role:	<i>Co-Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0001-9739-738X</i>
Nearest person month worked:	<i>3</i>
Contribution to Project:	<i>Dr. Akin has overseen project startup planning and chart abstraction development at MHREC.</i>
Funding Support:	

Name:	<i>Mary Jo Pugh</i>
Project Role:	<i>Co-Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0003-4196-7763</i>
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Dr. Pugh has overseen project startup planning, survey development, and survey administration at WIBR.</i>
Funding Support:	

Name:	<i>Courtney Hall</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0001-9403-1980</i>
Nearest person month worked:	<i>3</i>
Contribution to Project:	<i>Dr. Hall has assisted with survey and chart abstraction development, as well as startup planning and training at MHREC.</i>
Funding Support:	

Name:	<i>Alicia Swan</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0003-2412-0499</i>
Nearest person month worked:	<i>2.0</i>
Contribution to Project:	<i>Dr. Swan has assisted with regulatory requirements, survey and chart abstraction development.</i>
Funding Support:	

Name:	<i>Kristal Riska</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1.2</i>
Contribution to Project:	<i>Dr. Riska has assisted with survey and chart abstraction development.</i>
Funding Support:	

Name:	<i>Kara McGregor</i>
Project Role:	<i>Study Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>12</i>
Contribution to Project:	<i>Dr. McGregor has assisted with regulatory requirements, project startup planning, and chart abstraction development at MHREC.</i>
Funding Support:	

Name:	<i>Silvia Padilla</i>
Project Role:	<i>Research Specialist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>4</i>
Contribution to Project:	<i>Ms. Padilla is responsible for survey administration at WIBR.</i>
Funding Support:	

Name:	<i>Andrea Kalvesmaki</i>
Project Role:	<i>Senior Research Scientist</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0002-4282-0619</i>
Nearest person month worked:	<i>6.0</i>
Contribution to Project:	<i>Ms. Kalvesmaki is responsible for overall project management, staff training, and survey administration at WIBR.</i>
Funding Support:	

Name:	<i>Megan Amun</i>
Project Role:	<i>Data Scientist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2.0</i>
Contribution to Project:	<i>Ms. Amun prepares and analyzes data.</i>
Funding Support:	

Name:	<i>Sarah Leonhart</i>
Project Role:	<i>Research Analyst</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1.5</i>
Contribution to Project:	<i>Ms. Leonhart assists with survey administration and data processing at WIBR.</i>
Funding Support:	

Name:	<i>Kelly Cronkhite</i>
Project Role:	<i>Research Analyst</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1.0</i>
Contribution to Project:	<i>Ms. Cronkhite assists with survey administration at WIBR.</i>
Funding Support:	

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

Nothing to Report

What other organizations were involved as partners?

Organization Name:	Location of Organization:	Organization Contributions:
Duke University	Durham, North Carolina	Collaboration
University of Texas San Antonio	San Antonio, Texas	Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: WIBR will submit this annual review as well.

QUAD CHARTS: Please see Appendix A for Quad Chart.

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: FY19 Quad Chart	pg. 17
Appendix B: FITBIR Information Sheet	pg. 18
Appendix C: Surveys	pg. 19-26

**APPENDIX A
FY2019 Quad Chart**

Factors associated with outcomes in patients with vestibular symptoms related to traumatic brain injury

W81XWH-16-PHTBIRP-CTTRA

PI: Akin F./ Pugh M.J.

Org: Mountain Home Research & Education Corporation

Award Amount: \$1,499,715



Study/Product Aim(s)

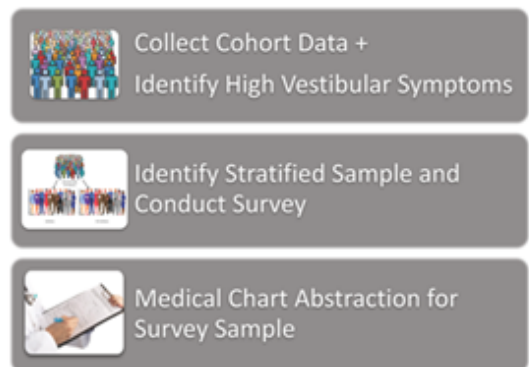
Aim 1: Identify the proportion of Veterans evaluated in the CTBIE who report high NSI vestibular symptomology, the extent to which individuals with high NSI vestibular scores have a vestibular specific diagnosis based on ICD-9 codes, and the relationship between vestibular symptomology, vestibular specific diagnosis codes and TBI characteristics.

Aim 2: Among Veterans with vestibular specific and non-specific dizziness diagnoses, identify those who experienced a clinically significant reduction of symptoms ("responders" and "non-responders") and factors associated with amelioration of symptoms.

Approach

This observational cohort study will use VA and DoD data, medical chart abstraction, and survey data to address the aims described above using a multiphase process summarized in the figure.

Three Study Phases



Accomplishments: obtained HRPO approval, identified cohort who meet criteria for high NSI vestibular symptomology, obtained all survey supplies, launched online survey, began pilot survey dissemination to 225 potential participants, completed development of REDCap database and began training for chart abstraction.

Timeline and Cost

Activities	CY	2017	2018	2019	2020
Phase 1: Administrative Data Compilation (Aims 1 & 2)					
Phase 2: ID Stratified Random Sample & Conduct Survey (Aim 2)					
Phase 3: Medical Chart Abstraction (Aim 2)					
Projected Budget Expenditure:		-	\$479k	\$504k	\$517k
Actual Budget Expenditure:		-	\$81.2k	-	-

Goals/Milestones

- CY17 –**
- Hired & trained study staff
 - Initiated the regulatory process at study sites
 - Initiated biweekly conference calls with all study sites
 - Added an additional study site
- CY18/19 –**
- Complete regulatory process at study sites
 - Identify cohort for survey dissemination
 - Conduct survey dissemination
 - Conduct chart abstraction for survey participants
- CY20 –**
- Conclude survey dissemination & chart abstraction
 - Conduct final analyses
 - Complete manuscripts for publication
- Comments/Challenges/Issues/Concerns**
- None

Updated: 10/28/2019

APPENDIX B
FITBIR Information Sheet

The information requested below is OPTIONAL.

The Federal Interagency Traumatic Brain Injury Research (FITBIR) information system (<https://fitbir.nih.gov/>) was developed to share data across the entire brain injury research field and to help with cooperation between laboratories. This approach requires common data definitions and standards and enables data to be used in powerful analyses to better examine brain injury outcomes. In order to facilitate this, they request several pieces of personal information in order to link information for that individual across all studies.

Again, the information requested below is OPTIONAL. You do not need to share this information for your responses to benefit research helping Veterans.

Please list the country in which you were born.

Please enter the city or municipality in which you were born.

Please enter your legal first name at birth.

Please enter your legal middle name at birth.

Please enter your legal last name at birth.

Please enter the day, month and year of your birth.

Day _____ Month _____ Year _____

Analyzing Dizziness Associated with Post-9/11 Veterans with TBI
The ADAPT Survey

Thank you for joining us in this important research project. The information you provide will assist in developing programs that will help improve healthcare that is provided to Veterans like you. This survey is voluntary and your answers will be kept confidential. We value your honesty and greatly appreciate your participation.

Do you agree to participate in this study?

- Yes, I am willing to participate in this study. → **Go to Q1** or take this survey online: <https://is.gd/ADAPTSurvey2019>
- No, I do not want to participate in this study. *(Please return the survey to us by mail in the envelope provided.)*

Please answer the following questions to the best of your ability. Leave blank if the question does not apply to you.

Q1. Do you experience balance issues or dizziness?

- Yes → Rarely (less than 25%) Sometimes (26 – 50%) Often (51 – 75%) Most of the time (>75%)
- No

Q2. The purpose of these questions is to identify difficulties that you may be experiencing because of your dizziness or unsteadiness.	Yes	Sometimes	No
Does looking up increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you feel frustrated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you restrict travel for business or recreation?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does walking down the aisle of a supermarket increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you have difficulty getting into or out of bed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your problem significantly restrict your participation in social activities such as going out to dinner, going to movies, dancing, or to parties?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you have difficulty reading?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does performing more ambitious activities like sports, dancing, household chores such as sweeping or putting dishes away increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, are you afraid to leave home without having someone with you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, have you been embarrassed in front of others?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do quick movements of your head increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you avoid heights?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does turning over in bed increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, is it difficult for you to do strenuous housework or yard work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, are you afraid people may think you are intoxicated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, is it difficult for you to go for a walk by yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does walking down a sidewalk increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, is it difficult for you to concentrate?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, is it difficult for you to go for a walk around your house in the dark?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, are you afraid to stay home alone?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, do you feel handicapped?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has your problem placed stress on your relationship with members of your family or friends?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of your problem, are you depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your problem interfere with your job or household responsibilities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does bending over increase your problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q11. If you marked “surgeries” in the table, please list any surgeries you have had related to your dizziness or imbalance:

Q12. If you marked “other” in the table, please describe the treatment you received:

Please answer the rest of the questions to the best of your ability, even if you do not have dizziness.

Q13. Rate the following symptoms for how much they have disturbed you IN THE LAST 2 WEEKS:

Symptoms	None	Mild	Moderate	Severe	Very Severe
Feeling Dizzy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of balance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor coordination, clumsy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Headaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nausea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vision problems, blurring, trouble seeing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sensitivity to light	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hearing difficulty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sensitivity to noise	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Numbness or tingling on parts of my body	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Change in taste and/or smell	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of appetite or increased appetite	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor concentration, can't pay attention, easily distracted	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Forgetfulness, can't remember things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty making decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Slowed thinking, difficulty getting organized, can't finish things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fatigue, loss of energy, getting tired easily	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty falling or staying asleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling anxious or tense	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling depressed or sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Irritability, easily annoyed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor frustration tolerance, feeling easily overwhelmed by things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

NONE: Rarely if ever present. Not a problem at all.

MILD: Occasionally present, but doesn't disrupt activities. I can usually continue what I'm doing. Doesn't really concern me.

MODERATE: Often present; occasionally disrupts activities. I can usually continue what I'm doing with some effort. I feel somewhat concerned.

SEVERE: Frequently present and disrupts activities. I can do things that are fairly simple or take little effort. I feel like I need help.

VERY SEVERE: Almost always present and I have been unable to perform at work, school or home due to this problem. I probably cannot function without help.

Q14. Do you experience headaches?

- Yes →
 Rarely (less than 25%)
 Sometimes (26 – 50%)
 Often (51 – 75%)
 Most of the time (>75%)
 No (please skip to **Q16**)

Q15. Please answer the following questions about ALL of the headaches you have had OVER THE LAST 3 MONTHS.

Write your answer in the box next to each question. Write "0" if the question does not apply to you.

How many days in the last 3 months did you miss work or school because of your headaches?	
How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headache? (Do not include days you counted above where you missed work or school.)	
How many days in the last 3 months did you not do household work (such as housework, home repairs and maintenance, shopping, caring for children and relatives) because of your headaches?	
How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted above where you did not do household work.)	
On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?	

Q16. Below is a list of some of the ways you may have felt or behaved during the PAST WEEK. Please indicate how often you have felt this way by checking the appropriate box for each question.

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)	All of the time (5-7 days)
I was bothered by things that usually don't bother me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had trouble keeping my mind on what I was doing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt depressed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt that everything I did was an effort.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt hopeful about the future.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt fearful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My sleep was restless.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was happy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt lonely.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I could not "get going."	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q17. Were you exposed to **at least one** blast during your military service? (Examples: RPGs, Mortars, and IEDs.)

- Yes
 No (please skip to **Q21**)

Q18. How many blasts were **UP TO 10 FEET** away from you? (Examples: Length of a car or height of a basketball hoop.)

- 0 – None
 1-2 blasts
 3-4 blasts
 5 or more blasts

Q19. How many blasts were **BETWEEN 11 AND 30 FEET** from you? (Examples: Length of a pick-up truck or height of a 2-story home.)

- 0 – None
 1-2 blasts
 3-4 blasts
 5 or more blasts

Q20. How many blasts were **MORE THAN 30 FEET** from you? (Examples: Length of a semi-truck or height of a telephone pole.)

- 0 – None
 1-2 blasts
 3-4 blasts
 5 or more blasts

Q21. Over the PAST 2 WEEKS, how often have you been bothered by the following problems?

	Not at all	Several days	Over half the days	Nearly every day
I felt nervous, anxious, or on edge.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was not able to stop or control worrying.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was worrying too much about different things.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had trouble relaxing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was so restless it was hard to sit still.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I became easily annoyed or irritable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt afraid as if something awful might happen.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q22. If you checked off any problems above, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
 Somewhat difficult
 Very difficult
 Extremely difficult

Q23. Sometimes people experience traumatic events such as wars, natural disasters, physical or sexual assault, seeing someone seriously injured or kill, or other serious events. Have you ever experienced this kind of event?

- Yes
 No (please skip to **Q24**)

In the PAST MONTH ,	YES	NO
Have you had nightmares about the event(s) or thought about the event(s) when you did not want to?	<input type="radio"/>	<input type="radio"/>
Have you tried hard not to think about the event(s) or gone out of your way to avoid situations that reminded you of the event(s)?	<input type="radio"/>	<input type="radio"/>
Have you been constantly on guard, watchful, or easily startled?	<input type="radio"/>	<input type="radio"/>
Have you felt numb or detached from people, activities, or your surroundings?	<input type="radio"/>	<input type="radio"/>
Have you felt guilty or unable to stop blaming yourself or others for the event(s) or any problems the event(s) may have caused?	<input type="radio"/>	<input type="radio"/>

Q24. Did you ever go on combat patrols or have other dangerous duty?

- No
 Yes, 1-3x
 Yes, 4-12x
 Yes, 13-50x
 Yes, 51+ times

Q25. Were you ever under enemy fire?

- No
 Yes, < 1 month
 Yes, 1-3 months
 Yes, 4-6 months
 Yes, 7 or more months

Q26. Were you ever surrounded by the enemy?

- No
 Yes, 1-2x
 Yes, 3-12x
 Yes, 13-25x
 Yes, 26+ times

Q27. What percentage of the soldiers in your unit were killed (KIA), wounded, or missing (MIA) in action?

- None
 1-25%
 26-50%
 51-75%
 76% or more

Q28. How often did you fire rounds at the enemy?					
<input type="radio"/> Never	<input type="radio"/> 1-2x	<input type="radio"/> 3-12x	<input type="radio"/> 13-50x	<input type="radio"/> 51 or more	
Q29. How often did you see someone hit by incoming or outgoing rounds?					
<input type="radio"/> Never	<input type="radio"/> 1-2x	<input type="radio"/> 3-12x	<input type="radio"/> 13-50x	<input type="radio"/> 51 or more	
Q30. How often were you in danger of being injured or killed (i.e., being pinned down, overrun, ambushed, near miss, etc.)?					
<input type="radio"/> Never	<input type="radio"/> 1-2x	<input type="radio"/> 3-12x	<input type="radio"/> 13-50x	<input type="radio"/> 51 or more	

These next questions ask about injuries that may have occurred anytime in your lifetime.

Q31. Have you ever been hospitalized or treated in an emergency room following an injury to your head or neck? (<i>Think about any childhood injuries you remember.</i>)	<input type="radio"/> Yes	<input type="radio"/> No
Q32. Have you ever injured your head or neck in a car accident or from a crash with another moving vehicle like a bicycle, motorcycle, or all-terrain vehicle (ATV)?	<input type="radio"/> Yes	<input type="radio"/> No
Q33. Have you ever injured your head or neck in a fall or from being hit by something? (<i>For example, falling from a bike or horse, rollerblading, falling on ice, being hit by a rock, playing sports or on the playground.</i>)	<input type="radio"/> Yes	<input type="radio"/> No
Q34. Have you ever injured your head or neck in a fight, from being hit by someone, from being shaken violently, or being shot in the neck or head?	<input type="radio"/> Yes	<input type="radio"/> No
Q35. Have you ever been nearby when an explosion or a blast occurred? Think about any military combat- or training-related incidents or prior work-related incidents (for example, construction).	<input type="radio"/> Yes	<input type="radio"/> No

➤ If you responded YES to ANY of the questions above, please answer **Q36** ↓

➤ If you responded NO to ALL of the questions above, please skip to **Q41**

Q36. Were you ever knocked out or did you lose consciousness from any of the injuries you reported above?	<input type="radio"/> Yes	<input type="radio"/> No
If YES, please continue ↓		If NO, please skip to Q40
Q37. What was the longest time you were knocked out or unconscious (choose one)?	<input type="radio"/> < 5 min <input type="radio"/> 5 – 30 min <input type="radio"/> >30 min but less than 24 hours <input type="radio"/> 24 hours or longer	
Q38. How old were you the first time you were knocked out or lost consciousness? _____ years old		
Q39. How old were you the last time you were knocked out or lost consciousness? (<i>If you were only knocked out once, this will be the same age as your answer above.</i>) _____ years old		
Q40. If you were not knocked out by any of the injuries listed above, did any of them cause you to be dazed, confused, or create a gap in your memory?	<input type="radio"/> Yes	<input type="radio"/> No
Q41. Have you ever had a period of time in which you experienced multiple, repeated blows or impacts to your head – for example, a history of playing sports, physical abuse, or during military duty?	<input type="radio"/> Yes	<input type="radio"/> No

Q42. In general, would you say your health is...?

- Excellent
 Very good
 Good
 Fair
 Poor

Q43. Does your health now limit you in the activities listed below?	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing several flights of stairs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q44. <u>During the PAST 4 WEEKS</u> , have you had any of the following problems with your work or other regular daily activities as a result of your physical health ?	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
Accomplished less than you would like.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Were limited in the kind of work or other activities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q45. <u>During the PAST 4 WEEKS</u> , have you had any of the following problems with your work or other regular daily activities as a result of emotional problems ?	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
Accomplished less than you would like.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Didn't do work or other activities as carefully as usual.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q46. During the PAST 4 WEEKS, how much did pain interfere with your normal work (*including both work outside the home and house work*)?

- Not at all
 A little bit
 Moderately
 Quite a bit
 Extremely

Q47. How much of the time <u>during the PAST 4 WEEKS</u> ...	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
Have you felt calm and peaceful ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did you have a lot of energy ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have you felt downhearted and blue ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q48. During the PAST 4 WEEKS, how much of the time **has your physical health or emotional problems interfered** with your social activities (like visiting with friends, relatives, etc.)?

- All of the time
 Most of the time
 A good bit of the time
 Some of the time
 A little bit of the time
 None of the time

Q49. Compared to ONE YEAR AGO, how would you rate your physical health in general now?

- Much better
 Slightly better
 About the same
 Slightly worse
 Much worse

Q50. Compared to ONE YEAR AGO, how would you rate your emotional problems (such as feeling anxious, depressed, or irritable) now?

- Much better
 Slightly better
 About the same
 Slightly worse
 Much worse

