

Award Number: W81XWH-10-1-0593

TITLE: Probiotic (VSL#3) for Gulf War Illness

PRINCIPAL INVESTIGATOR: Ashok Tuteja, M.D. M.P.H.

CONTRACTING ORGANIZATION: Western Institute for Biomedical Research
Salt Lake City, UT 84148

REPORT DATE NOVEMBER 2022

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE NOVEMBER 2022			2. REPORT TYPE Annual		3. DATES COVERED 8SEPT2021 - 7SEPT2022	
4. TITLE AND SUBTITLE Probiotic (Visbiome) for Gulf War Illness					5a. CONTRACT NUMBER W81 XWH-10-1-0593	
					5b. GRANT NUMBER	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Ashok Tuteja, M.D. E-Mail: ashok.tuteja@va.gov					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Western Institute for Biomedical Research Salt Lake City, UT 84148					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT: The overall objective of the study is to determine the effect of probiotic Visbiome™ on: 1) Intestinal symptoms of Irritable Bowel Syndrome (IBS) and 2) Non-intestinal symptoms (fatigue, joint pain, insomnia, general stiffness and headache) associated with IBS, the symptoms of Gulf War (GW) illness, 3) Serum pro- and anti-inflammatory cytokines, 4) fecal microbiota. The manuscript on The Effect of probiotics on IBS and GW illness was published in Oct, 2022. The effect of probiotics on serum cytokines was presented on Oct 25, 2022 in the Am Gastroenterology Conference. The stool samples analysis is ongoing.						
15. SUBJECT TERMS Irritable bowel syndrome, probiotic, Gulf War Illness, diarrhea						
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRDC	
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)	

Table of Contents

	<u>Page</u>
Introduction.....	5
Body.....	5
Key Research Accomplishments.....	6
Reportable Outcomes.....	7
Conclusion.....	8
References.....	9
Appendices.....	10

Introduction:

Gastroenteritis plays a major role in changing intestinal microflora. More than one third of Gulf War (GW) veterans report gastroenteritis during deployment and it is a risk factor for development of irritable bowel syndrome (IBS) after deployment. We also demonstrated that there is a strong association between IBS and extra-intestinal disorders (e.g. fatigue, joint pains, insomnia, generalized stiffness, and headache). This would suggest that IBS as well as extra-intestinal disorders in GW veterans have a unifying etiology. There is scientific evidence that probiotics by restoring normal gut flora improve symptoms of IBS. Probiotics have also been shown to improve arthritis and fatigue by changing fecal flora. This is the basis for our present protocol to study the effect of probiotics on GW illness.

Body:

During this year the following goals were accomplished:

The manuscript, The Effect of Probiotics on IBS with GW illness was published in the peer reviewed journal. *Fed Pract.* 2022 October;39(10):410-417 | 10.12788/fp.0322

The effect of Probiotics on serum cytokines was completed and was presented as a poster in the American College of Gastroenterology annual meeting.

The stool samples have been transported to V.A. Medical Center in Charleston, SC for microbiota analysis. The previous collaborator at Laurence Berkeley Laboratory, CA retired last year and is no longer available to complete the stool microbiota analysis. We have found another collaborator in South Carolina who has kindly agreed to complete the analysis. This investigator has further moved to Long Beach VAMC in Sacramento, CA. We hope to complete the stool microbiota analysis by the end of this year (December 2022).

The methods used by the previous collaborator in Laurence Berkeley Laboratory to do partial work were different; now newer methods are available; all the samples will be re-analyzed.

Key Research Accomplishments.....

- The manuscript on the “Effect of Probiotics on Irritable Bowel Syndrome with Gulf War illness” was published this month.
Fed Pract. 2022 October;39(10):410-417 | 10.12788/fp.0322
- The poster on the Effect of Probiotics on Serum Cytokines in Irritable Bowel Syndrome with Gulf War illness was presented in the Am College of Gastroenterology meeting in October 2022. The manuscript is under publication.
- Stool microbiota analysis should complete later this year.

Reportable Outcomes.....

Nil.

Conclusion:

Study has stopped enrolling; abstract was published and the manuscript is under review for publication.

Stool samples microbiota data are being analyzed.

References.....

Nil.

Appendices.....

Nil.