A. COVER PAGE

Project Title: Implementing a Lifestyle Medicine Program via Telehealth to Optimize GERD Management in WTC First Responders	
Grant Number: 5R21OH012247-02	**Project/Grant Period:** 07/01/2021 - 06/30/2023
Reporting Period: 07/01/2022 - 06/30/2023	**Requested Budget Period:** 07/01/2022 - 06/30/2023
Report Term Frequency: Final	**Date Submitted:** 11/14/2024
Program Director/Principal Investigator Information: EMILY SENAY , MD **Phone Number:** 2122416500 **Email:** emily.senay@mssm.edu	**Recipient Organization:** ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI 1 GUSTAVE L. LEVY PL NEW YORK, NY 100296574 **UEI:** C8H9CNG1VBD9 **EIN:** 1136171197A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: JESSICA RUTH MOISE One Gustave L. Levy Place Box 1075 New York, NY 100296574 **Phone number:** 12128248300 **Email:** jessica.moise@mssm.edu	**Signing Official:** JESSICA RUTH MOISE One Gustave L. Levy Place Box 1075 New York, NY 100296574 **Phone number:** 12128248300 **Email:** jessica.moise@mssm.edu
Human Subjects: NA	**Vertebrate Animals:** NA
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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Gastroesophageal reflux disease (GERD) is the most common gastrointestinal (GI) complaint and can significantly affect quality of life (QOL), increase risk of laryngopharyngeal reflux (LPR), obstructive sleep apnea (OSA), erosive esophagitis, esophageal stricture, Barrett's esophagus (BE) and esophageal adenocarcinoma. Longitudinal studies have demonstrated cumulative incidences of GERD of approximately 40% in World Trade Center (WTC) disaster first responders. GERD is #2 on the list of WTC health-program-certified conditions affecting 23,747 WTC first responders. In addition, WTC conditions that have been associated to GERD, include OSA and BE.
Proton pump inhibitors (PPI) are among the most-frequently used medicines in the world with annual expenditures estimated at $14 billion. Use of PPIs is extensive in the World Trade Center Health Program (WTCHP) cohort. GERD has been the focus of dedicated conferences aimed at improving management and reducing medication costs and usage in first responders. Recently, long-term PPI use has been potentially associated with increased risk of fractures, pneumonia, Clostridium difficile diarrhea, vitamin B12 deficiency, chronic kidney disease, dementia, myocardial infarction, and increased risk of secondary infection and death from COVID-19. WTCHP members have grown increasingly concerned about these reports, and many are interested in reducing or discontinuing PPI. Lifestyle modifications are the recommended first line therapy for GERD and include behavioral change related to diet, exercise, weight, substance use, sleep and other habits. Lifestyle Medicine (LM) is a relatively new evidence-based medical intervention that employs proven behavioral change techniques to educate and motivate patients to modify personal habits and behaviors with the goal of reducing the need for medications in chronic conditions such as GERD. Our goal is to pilot a LM clinical intervention via the existing telemedicine platform for WTCHP members with GERD who desire to reduce symptoms and/or decrease medication use. This novel approach could have significant implications for public health serving as a template for care delivery that focuses on the upstream drivers of chronic disease rather than downstream symptoms and that broadens care modalities while maintaining a personalized approach critical to clinical care. Innovations of care that target the root cause of chronic conditions, which are overwhelming lifestyle related, are critically needed to reduce medication use, side effects, and costs; reduce healthcare utilization and associated costs, and improve QOL.
Specific Aims:
In this project we hypothesized that participants in the WTC LMG Program will experience a reduction in symptoms and/or medication use associated with GERD and report satisfaction with the LM intervention: We will test this hypothesis through performance of the following aims:
1. Pilot a LMG Program Intervention to reduce GERD symptoms and/or medication use in eligible and interested WTC patients delivered via telemedicine.
2. Assess feasibility of incorporating health data tracking technology (on-line portals, text messages) to assess and track GERD symptoms and medication use in program participants.
3. Evaluate participant behavior change and satisfaction with a telemedicine LM intervention for GERD.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Abstracts and presentations as of this date have included a NIOSH WTC Health Program Research Webinar Implementing a Lifestyle Medicine Program via Telehealth to Optimize GERD Management in WTC First Responders provided to a national audience, particularly of those responsible for treatment and care of WTC Responders, on 1/11/2024.
Additional presentations and abstracts of results-to-date have been made to the American College of Lifestyle Medicine and American College of Preventive Medicine meetings in the first half of 2024.
A manuscript describing and registering the methods has been revised and awaits final acceptance with the American College of Lifestyle Medicine journal

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Not Applicable

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

1. Pilot a LMG Program Intervention to reduce GERD symptoms and/or medication use in eligible and interested WTC patients delivered via telemedicine.

From July 2022 to January 2023, we took several steps to set up for recruitment of patients. First, we identified and negotiated approval for an alternative HIPAA compliant, texting and data management software, Q Reviews. We obtained IRB approval for the study. New lifestyle medicine providers were identified and trained, as were patient service coordinators to assist in scheduling and recruitment. Weekly meetings were held with Q Reviews platform staff to program and adapt their system for study surveys. We established referral mechanisms through Selikoff clinic providers and communication outreach. The intervention program was launched in January 2023.

At the initial LMG Program visit, participants who met inclusion criteria underwent the full LMG Program clinical intervention. The intervention consists of self-administered baseline standardized questionnaires, initial telemedicine visits of one-hour duration, and subsequent follow-up visits of 20-40 min duration scheduled at 2-weeks after initial visit, then monthly through the 6 months of the intervention period. The intervention utilizes a standardized approach and was previously described in the research protocol. Subsequent visits assessed progress towards goals, engaging participant with motivational interviewing and CBT techniques (e.g., congratulate on any progress and/or reassess goals); addressing lapse/relapse; reinforcing relapse prevention; and linking to resources.

Fifty-three patients were enrolled to date. Mean age overall was 59.6 years (SD 7.8); 26% were women. 38 participants completed at least one treatment visit; 24 completed 6 or more visits. Of those with at least one treatment visit, the median number of visits was 5.5. Mean GERD Health Related Quality of Life questionnaire scores in those completing the program (6+ visits) improved from 25.7 to 13.9; (mean individual difference score 11.8, p= 0.005 by paired t-test). Subscores for heartburn declined by 42% (11.8 to 6.9; p=0.05) and for regurgitation by 44% (10.3 to 5.8; p=0.04). Women had higher baseline GERD scores than men, although differences were not statistically significant, and both sexes exhibit comparable declines in GERD scores across the intervention to date.

Total GERD scores deceased most substantially in those taking medications nearly every day (ie 6-7 days/week), from 39.4 to 11.1 or by 72%. Small improvements were seen in those taking meds less often, and all exhibited reductions in symptoms. GERD medication frequency (meds taken as needed in the previous week) decreased in 61% of patients and increased in only 14%. A median decrease in medication frequency overall of two days (out of seven) per week was noted ($p < 0.02$ by Wilcoxon signed-rank test).

Participant satisfaction with their present health condition improved over the course of the intervention; those reporting they were 'neutral' or satisfied rose from 40.9% to 72.8% (for improvement in satisfaction score across intervention $p = 0.004$ by Wilcoxon signed-rank test). No participant indicated a decrease in satisfaction; of 13 who indicated they were initially 'dissatisfied,' 6 were 'neutral' at the end and one more was 'satisfied.' Self-rated level of health (10-point scale) increased from 6.5 to 7.0; with mean improvement of 0.5 points $p = 0.02$ by paired 2-sided t-test). Changes in time spent sleeping were not seen (median 6 hours in before- and after- questionnaires) although participant assessments of their difficulty staying awake during the day improved across the intervention (median before: 'several days' during the week; median after: 'not at all' with a >10% drop in those who had trouble 'more than half the days' or 'every day')

Additionally, analyses are ongoing and will address additional lifestyle changes, including nutritional profiles and improvements in psychosocial profiles via additional questionnaires.

2. Assess feasibility of incorporating health data tracking technology (on-line portals, text messages) to assess and track GERD symptoms and medication use in program participants.

Our current efforts have been successful in integrating the data tracking technology in monitoring data and incorporating patient survey information into clinical encounters as part of the intervention. We found generally

seamless downloading of data from the Q-reviews software and easy incorporation of these data into analytic software. Additional assessment (eg responses to reminders, continuity of patient care, treatment, and responsiveness) await further analyses and assessment of both platform meta-data and acceptability responses from participants.

3. Evaluate participant behavior change and satisfaction with a telemedicine LM intervention for GERD. Feasibility of the proposed intervention focuses on participants' acceptability, practicality, implementation, and integration. We modified questions from the Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure, both valid and reliable measures of implementation outcomes. Patient behavior change is determined by the attainment of Action Step Plan goals at the 6-month conclusion of the study. The number of referred, consented, eligible and enrolled patients from the WTCHP will be documented.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	Sr/Key	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
EMILYSENAY	Y	Senay, Emily	MD	PD/PI	3.0	0.0	0.0			NA
JMEYER424	Y	MEYER, JOHN D	MPH,MD	PD/PI	0.2	0.0	0.0			NA
EJGARLAND	Y	Garland, Elizabeth J	MD,MS	Co-Investigator	1.7	0.0	0.0			NA
KORINMAYA	Y	Korin, Maya Rom	PHD,MS	Co-Investigator	2.0	0.0	0.0			NA
	N	Curtis, Sahara		Coordinator	1.2	0.0	0.0			NA

Glossary of acronyms:
Sr/Key - Senior/Key
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RS - Reentry Supplement
DS - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Not Applicable

D.2.b New Senior/Key Personnel

Not Applicable

D.2.c Changes in Other Support

Not Applicable

D.2.d New Other Significant Contributors

Not Applicable

D.2.e Multi-PI (MPI) Leadership Plan

Not Applicable

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

NOTHING TO REPORT

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND NOTICE OF FUNDING OPPORTUNITIES REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

Not Applicable

G.4.b Inclusion Enrollment Data

NOTHING TO REPORT

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

I. OUTCOMES

I.1 What were the outcomes of the award?

Overall, we have demonstrated, via this pilot/program developmental R21 award, that a Lifestyle Medicine program targeted at the reduction of GERD symptoms and reduction of medication use, can be effectively developed and used to intervene on lifestyle factors that may reduce GERD in a particularly vulnerable population with a high prevalence of GERD and its related conditions and sequelae. As well, the deliverability of the intervention through a telehealth interface, allowing frequent visits without difficulties in travel and related clinical access problems was demonstrated in this pilot program.
Participants who met inclusion criteria underwent the full LMG Program clinical intervention. The intervention consists of self-administered baseline standardized questionnaires, initial telemedicine visits of one-hour duration, and subsequent follow-up visits of 20-40 min duration scheduled at 2-weeks after initial visit, then monthly through the 6 months of the intervention period. The intervention utilizes a standardized approach incorporating the “six pillars’ of lifestyle medicine management. Subsequent visits assessed progress towards goals, engaging participant with motivational interviewing and CBT techniques (e.g., congratulate on any progress and/or reassess goals); addressing lapse/relapse; reinforcing relapse prevention; and linking to resources.
Fifty-three patients were enrolled. Mean age overall was 59.6 years (SD 7.8); 26% were women. 38 participants completed at least one treatment visit; 24 completed 6 or more visits. Of those with at least one treatment visit, the median number of visits was 5.5. Mean GERD Health Related Quality of Life questionnaire scores in those completing the program (6+ visits) improved from 25.7 to 13.9; (mean individual difference score 11.8, p= 0.005 by paired t-test). Subscores for heartburn declined by 42% (11.8 to 6.9; p=0.05) and for regurgitation by 44% (10.3 to 5.8; p=0.04). Women had higher baseline GERD scores than men, although differences were not statistically significant, and both sexes exhibit comparable declines in GERD scores across the intervention to date.
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Participant satisfaction with their present health condition improved over the course of the intervention; those reporting they were ‘neutral’ or satisfied rose from 40.9% to 72.8% (for improvement in satisfaction score across intervention p = 0.004 by Wilcoxon signed-rank test). No participant indicated a decrease in satisfaction; of 13 who indicated they were initially ‘dissatisfied,’ 6 were ‘neutral’ at the end and one more was ‘satisfied.’ Self-rated level of health (10-point scale) increased from 6.5 to 7.0; with mean improvement of 0.5 points p = 0.02 by paired 2-sided t-test). Changes in time spent sleeping were not seen (median 6 hours in before- and after- questionnaires) although participant assessments of their difficulty staying awake during the day improved across the intervention (median before: ‘several days’ during the week; median after: ‘not at all’ with a >10% drop in those who had trouble ‘more than half the days’ or ‘every day’)
Additionally, analyses are ongoing and will address additional lifestyle changes, including nutritional profiles and improvements in psychosocial profiles via additional questionnaires.
Our efforts were successful in integrating the data tracking technology in monitoring data and incorporating patient survey information into clinical encounters as part of the intervention. We found generally seamless downloading of data from the Q-reviews software and easy incorporation of these data into analytic software. Additional assessment (eg responses to reminders, continuity of patient care, treatment, and responsiveness) await further analyses and assessment of both platform meta-data and acceptability responses from participants.
Feasibility of the proposed intervention focuses on participants’ acceptability, practicality, implementation, and integration. We modified questions from the Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure, both valid and reliable measures of implementation outcomes. Patient behavior change is determined by the attainment of Action Step Plan goals at the 6-month conclusion of the study. In a mid-term program evaluation (9/16 completers) 100% rated the LM program as 5/5 for meeting approval, appealing and would recommend to friends. More recent

analyses show that participants as of Sept 2024 (23/24 completers) rated the LM program highly in terms of acceptability (4.9/5), appropriateness (4.8/5), and feasibility (4.8/5). All participants agreed that they would recommend the LMG intervention to a friend (21/23 completely agree; 2/23 agree), and that the intervention was of high quality (19/23 completely agree; 4/23 agree). Over 90% of participants agreed that the LMG program helped them deal with their GERD more effectively, and 100% of participants were satisfied with the intervention.