Lifestyle Medicine

WILEY

Lifestyle Medicine Open Access

REGISTERED REPORT STAGE 1 OPEN ACCESS

A Lifestyle Medicine Intervention to Reduce GERD Symptoms and Medication Use

Emily Senay[1] | Maya Korin[2] | Elizabeth Garland[2] | Michael S. Smith[3] | John D. Meyer[2]

[1]Department of Occupational Medicine, Epidemiology, and Prevention, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health, Hempstead, New York, USA | [2]Department of Environmental Medicine, Icahn School of Medicine at Mount Sinai, New York, New York, USA | [3]Department of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, New York, USA

Correspondence: Emily Senay (esenay@northwell.edu)

Received: 11 April 2024 | **Revised:** 7 November 2024 | **Accepted:** 28 February 2025

Funding: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health R21OH012247.

ABSTRACT

Lifestyle modifications (LMs) are recommended as first-line therapy for gastroesophageal reflux disease (GERD). This study aims to evaluate in a population with a high burden of GERD a lifestyle medicine intervention aimed at reducing GERD symptoms and medication use through patient-driven health goal setting, health coaching, and SMART LM prescribing. First responders to the attacks at the World Trade Center on September 11, 2001 have a high GERD burden associated with exposures at Ground Zero and lifestyle. An LM GERD-specific intervention, delivered virtually and integrating health technology for data capture, will be implemented in this cohort with the goal of reducing GERD symptoms and/or medication use. This study aims to investigate the value, feasibility, and satisfaction of full LM six-pillar of health intervention that includes patient-driven health goal setting and health coaching over a 6-month period in the treatment of GERD. A nonrandomized, noncontrolled prospective intervention will be implemented in patients with GERD who expressed interest in LMs. All participants will complete a self-administered (delivered via text) baseline American College of Lifestyle Medicine six-pillars of health survey and monthly GERD-Health Related Quality of Life (HRQL) symptom and medication use questionnaires. Participants will receive seven telemedicine visits over 6 months with LM physicians that will include an initial GERD history evaluation and health coaching on GERD-specific modifications. Additionally, participants will self-rate confidence in achieving three LM modifications of high interest and SMART prescriptions will be written. Monthly coaching sessions to monitor progress with LM modifications will be provided and progress tracked over the 6-month study period. A satisfaction survey will be completed approximately 1 week after study completion. Outcome measures include GERD-HRQL scores and medication use. Patient satisfaction, feasibility, and acceptability will be surveyed at the end of the intervention.

1 | Introduction

1.1 | Overview of Gastroesophageal Reflux Disease

Chronic diseases, the leading cause of death and disability in the United States, are in large part driven by lifestyle habits including poor nutrition, physical inactivity, tobacco use, and excessive alcohol consumption [1]. Fewer than 3% of Americans meet criteria consistent with following a healthy lifestyle [2]. Gastroesophageal reflux disease is a chronic gastrointestinal disorder that is characterized by the regurgitation of gastric contents into the esophagus and is the most common chronic

gastrointestinal-related diagnosis in the United States with an estimated prevalence in North America between 18.1 and 27.8% [3, 4]. The global burden of GERD has increased significantly, with prevalent cases worldwide rising by 77.5% from an estimated 441 million in 1990 to 784 million in 2019 [5]. Risk factors for GERD include older age, excessive body mass index (BMI), smoking, anxiety/depression, and reduced physical activity [6–10]. Food choices and eating habits also contribute to GERD; these include the acidity and spicing of food, alcohol consumption, as well as size and timing of meals, particularly with respect to symptoms during sleep [8, 11]. Recreational physical activity appears to be protective, except when performed postprandially [12].

GERD can increase risk of laryngopharyngeal reflux, obstructive sleep apnea, erosive esophagitis, esophageal stricture, Barrett's esophagus, and esophageal adenocarcinoma (EADC) [4, 13–15]. GERD may also increase risk for esophageal squamous cell carcinoma, and laryngeal squamous cell carcinoma [16]. In the United States, EADC represents about 1% of all cancers with an overall 5-year survival rate of 20%. Globally incidence and mortality of EADC are on the rise [16]. GERD-related medications are among the most prescribed drugs globally. It is estimated that 100 million prescriptions for GERD are written annually in the United States [17, 18].

At the same time, long-term Proton Pump Inhibitor (PPI) use has come under scrutiny due to potential association with a number of side effects including increased risk of fractures [19, 20], pneumonia [21, 22], vitamin B12 deficiency, chronic kidney disease, dementia [22–26], myocardial infarction [27]. While the strength of evidence for harm is variable and PPI use is generally considered safe, awareness of potential risk has increased concern among many patients [23]. Patient awareness of potential adverse effects of PPI use has generated increased interest in alternate approaches to symptom and disease management.

Symptoms related to GERD include heartburn, regurgitation, and noncardiac chest pain, and have been consistently shown to reduce quality of life (QOL) in those affected [24–27]. Symptomatic GERD impacts QOL through sleep disturbance (e.g., nighttime awakening) [28, 29], psychological distress (e.g., fear of worsening disease or cancer initiation) [30–33], social and interpersonal disruption (e.g., impact on social gatherings, dining out, travel, intimacy), work productivity (e.g., fatigue and/or discomfort affecting job attendance and performance) [34–37], fear or difficulty adhering to dietary restrictions (e.g., anticipation of symptoms and limitation of food choices), and the financial burden of costs associated with treating and managing GERD [31, 38–40].

1.2 | Growing Role of Lifestyle Modifications in Patient-Centered and Value-Based Care

Patient-centered and value-based care revolves around the idea of improving healthcare quality for patients through an emphasis on preventive measures to reduce risk before problems begin. Patient-reported health outcomes such as measures of QOL are increasingly important indicators of patient-centered quality of care. Patient-centered quality of care focuses on an individual's particular healthcare needs with the goal of empowering them to become active participants in their care [41, 42]. Patient-reported outcome measures (PROMs) assess patients' perceptions of the status of their health and QOL, measured over time. PROMs are an integral component of a value-based healthcare system and the practice of value-based medicine.[43–45]. Lifestyle modifications by necessity are patient driven requiring active participation to set and acheive goals patients themselves deem important to their QOL.

Treatment guidelines uniformly endorse lifestyle modifications such as weight loss, dietary restrictions, and meal timing as first-line GERD therapy [46–49]. For GERD, the strength of evidence for the efficacy of recommending lifestyle changes such as weight loss is low to moderate [49, 50]. Reasons for low supportive evidence include lack of randomized controlled trials and standardization, focus on single variables such as weight loss despite causal heterogeneity, variation in individual physiologic response, inadequate follow-up time, confounding factors such as ongoing medication use, and the paucity of lifestyle modification and intervention research in general [46–48, 51–54].

Advice such as smoking cessation or weight loss from clinicians to modify risk factors is recommended for a number of chronic conditions, including for patients with known cardiovascular disease risk factors [55]. However, even when physicians are highly confident in the efficacy of behavior change, many fail to initiate, or even discuss it with patients due to limited time, inadequate training, or the belief that patients are not capable of meaningful lifestyle change [56]. The pervasive sentiment that recommending behavior change is essentially futile may tacitly disincentivize clinicians and researchers from more fully exploring the role of lifestyle modifications in the treatment of GERD. Evidence based modalities to improve adherence to lifestyle modifications may improve QOL, patient-centered outcomes, and value based healthcare delivery.

1.3 | Lifestyle Medicine to Optimize Behavior Change

Lifestyle medicine (LM) is a relatively new medical specialty that aims to address the root causes of chronic conditions using evidence-based lifestyle interventions as the primary therapeutic modality—*before prescribing medications*—to prevent, treat, and manage chronic diseases [57]. LM represents a paradigm shift toward proactive, collaborative, wholistic healthcare to help patients optimize the six pillars of health—good nutrition, adequate physical activity, stress management, sleep hygiene, positive social connections, and the avoidance of harmful substances such as tobacco and alcohol. LM helps patients move along a continuum toward maintaining whole food, plant-predominant nutrition, regular physical activity, restorative sleep, stress management, avoidance of risky substances, and positive social connection to treat and reverse chronic disease [56, 58].

In traditional physician–patient interactions, clinicians typically provide general advice that patients should improve lifestyle habits such as diet or exercise but offer little practical guidance on how to achieve change. In contrast, LM uses behavioral psychology techniques to help patients discover their own motivations for change, determine health goals of importance to them, and

undertake concrete steps to achieve change. Rather than passive recipients of expert directives, LM patients are active participants engaged as the experts in their own care. LM providers must be versed in the transtheoretical model for behavior change, motivational interviewing (MI), cognitive behavioral therapy, and positive psychology techniques [59–63]. LM requires that providers adjust their mind frame to facilitate a process of patient self-discovery to uncover their own goals, priorities, values, strengths, and weaknesses and then working with them to build confidence to undertake practical steps toward successful change [56].

A key component of the practice of LM is health coaching to help patients implement personalized action plans through collaboration, empowerment, and accountability [62]. In contrast to traditional approaches, health goals are *patient-derived* and based on readiness and confidence to make a particular health behavior change that the patient feels is of importance. Health coach clinicians negotiate with patients to devise specific, measurable, actionable, relevant, and time-bound (SMART) lifestyle actions they are confident they can undertake [64]. These SMART actions then become LM prescriptions for which patients agree to be held accountable. At subsequent sessions, LM providers congratulate success, reinforce progress, explore solutions for obstacles, problem solve for setbacks, and adjust goals and SMART prescriptions as needed. LM as promulgated by the American College of Lifestyle Medicine (ACLM) formalizes the skills, knowledge, and training to move beyond advising change toward activating change that can improve clinical outcomes [56].

1.4 | Virtual Care Integration

A new era of virtual care, ushered in by the Covid-19 pandemic, has accelerated the adoption of telemedicine and remote healthcare services and transformed the delivery of healthcare, making it more accessible and convenient for patients. Virtual consultations and digital health platforms have become integral components of modern healthcare systems, revolutionizing the patient–provider relationship. Frequent contact with healthcare providers (face-to-face and virtual) who support, or "coach" patients has been shown to increase success of long-term behavioral change [65]. Virtually delivered care has been in common use in the behavioral healthcare setting for years, as it facilitates more frequent opportunities to engage and support patients over time—an essential component of behavior change management [66].

Synchronous, virtual, "face-to-face" encounters help to "meet" patients more often in the places where their lifestyle habits are best understood [67]. Asynchronous encounters via health apps, texts, emails, or electronic medical record (EMR) patient portals expand ways to connect with patients to provide education, tips, support, and reminders. Digital technology is revolutionizing healthcare by enabling bidirectional information flow between patients and healthcare providers and permitting the capture of health-related data outside of clinic walls. Patients can receive HIPAA-compliant information, access apps, and send HIPAA-compliant health data back to providers via the internet, smart medical devices and implants, wearable fitness/health trackers, and cell phones [68–70]. Surveys suggest that patients enrolled in clinical trials prefer using mobile technology over traditional in-person forms of assessment [71, 72]. Virtual care and digital health technology opens new possibilities to support patients as they undertake behavior change.

1.5 | Novel Intervention for GERD Therapy

This paper describes a novel intervention, believed to be the first of its kind, which combines virtual encounters, digital healthcare technology, and an LM intervention (as defined by ACLM) to reduce symptoms and medication use in a population with a high burden of GERD. The intervention will be delivered solely through telemedicine encounters and data will be collected using digital technology. This digital-forward approach facilitates real time capture of PROMs of symptom and medication use to guide a 6-month program of health coaching and nonpharmacologic prescribing for the treatment of GERD. Study outcome measures are patient report of GERD symptoms and/or medication use. The study is referred to as the *Lifestyle Medicine for GERD Program*—the "LMG Program."

1.6 | Hypothesis and Aims

We hypothesize that participants in the WTC LMG Program will experience a reduction in symptoms and/or medication use associated with GERD. Additionally, we aim to (Aim 1) assess the feasibility of incorporating health data tracking technology (online portals, text messages) to quantify and track GERD symptoms and medication use in program participants, and (Aim 2) evaluate participant behavior change and satisfaction with a telemedicine LM intervention for GERD.

2 | Ethics

The Mount Sinai Institutional Review Board in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the protocol (21-00261, approved 8/11/2021 and renewed 7/7/23). All recruitment methods respect patients' privacy and confidentiality and comply with HIPAA standards when using patient data. Communication is unbiased, providing accurate and thorough information about the program. The voluntary nature of participation is emphasized to avoid any perception of coercion.

3 | Methods

3.1 | Participants and Setting

This study will draw participants from the World Trade Center Health Program (WTCHP) Clinical Center of Excellence at the Selikoff Centers for Occupational Health located at Mount Sinai Hospital in New York City. The WTCHP General Responder Cohort (the cohort) consists of workers and volunteers who were part of the rescue and recovery effort that followed the September 11, 2001 attack on the World Trade Center (WTC) towers.

Eligibility criteria for entry into the WTCHP have been described previously [73]. In 2020, the Mount Sinai WTCHP implemented a robust virtual telehealth program, with the WTCHP data center reporting that nearly 68% of all visits were delivered via telehealth between March 2020 to March 2021 [67].

Study participants must have certification for WTC-related disorders to receive treatment at the WTCHP. This requires medical professional attestation that exposures present during the WTC effort (airborne dusts, smoke, fumes, or other toxins), psychological stressors (danger, contact with bodies or body parts), and physical stressors (heavy lifting or repetitive strain) played a significant role in causing, aggravating, or contributing to the responder's physical or mental health condition. Gastrointestinal disorders are connected to WTC dust and fume exposure with irritation of the esophageal lining leading to prolonged inflammation. According to the WTCHP data center, of the 61% of responders who are certified for a WTC-related conditions, 53% are certified for GERD, the second most common WTC-associated condition [74]. GERD impairs health-related QOL in the cohort. WTCHP member patients additionally express concern about safety and potential side effects associated with common GERD medications.

3.2 | Providers/Interventionists

All LMG Program interventions will be delivered by WTCHP providers with experience in GERD management and who have successfully completed the ACLM Board Review Course Education Module (30 CME) and/or are board certified in LM by the American Board of Lifestyle Medicine (ABLM).

3.3 | Technology

The intervention will be offered virtually only and will integrate health assessment and data tracking digital technology accessed via smart phone or online. Participants must have smart phones or home computers to access self-administered survey tools and educational components. All surveys will be delivered and responded to via HIPAA-compliant text messaging to participant smart phones. Participants will receive secure text message prompts via short message service on their mobile device, including links to a secure web form accessed on the device's native web browser, allowing patients to securely submit the requested survey data. We will utilize the quality reviews (Q-Reviews) platform, an established HIPAA-compliant, patient engagement platform, fully approved by Mount Sinai Health System. Quality reviews provides a digital engagement platform that helps providers stay connected with their patients and members across the care continuum [75].

3.4 | Patient Education Materials

Patient education materials will be developed to support the LMG Program and will be shared with patients on-line, email, and text platforms. Materials will be available on the Selikoff Centers website and the app and accessible via all electronic devices. One printed copy of the general informational educational packet including the consent form will also be mailed to participants. Our educational materials will adhere to the best practices of health literacy levels and include:

- General information about GERD.
- General information about LM approach to chronic disease management (e.g. bespoke LMG Program participant educational packet, and ACLM promulgated materials).
- General information about the WTC LMG Program; its overview, concept, and benefits for GERD.
- Personalized tips and information to enhance behavioral change success will be emailed via EMR patient portal as appropriate for each participant.
- Resources with links to educational materials, websites that will include information on diet, nutrition, smoking cessation, exercise and fitness, alcohol influence, heart health, and so on.
- Information for clinic contacts, expectations, processes/procedures, technical assistance, and consent.

3.5 | Surveys

The GERD-HRQL survey is a questionnaire consisting of 15 questions (plus a satisfaction question) used to measure symptomatic change after medical or surgical treatment of GERD [76]. Symptoms are rated for each question along a 0–5 scale according to the degree that participants find them bothersome, or they interfere with daily life. The questionnaire generates three scores, a total score (scale from 0 to 75), and heartburn and regurgitation scores (both from 0 to 30). Scores on these latter two scales that sum to $\leq$12 with each individual question not exceeding a response of "2" indicate heartburn and regurgitation elimination respectively. The GERD Medication Use questionnaire queries the number, frequency, and type of medications taken for GERD across the past week and past month.

Feasibility focuses on the program's acceptability, practicality, implementation, and integration. We will be modifying questions from the acceptability of intervention measure (AIM), the intervention appropriateness measure (IAM), and the feasibility of intervention measure surveys, all valid and reliable measures of implementation outcomes, consisting of four questions and a 5-point Likert scale. Open-ended questions will also be utilized to receive feedback on participants' experience using this new program and use of technology.

Satisfaction will be measured with the client satisfaction questionnaire adapted to Internet-based interventions (CSQ-I) [77] to gauge if the LMG Program was well received and implemented. The CSQ-I has shown to have internal consistency, factorial structure, and construct validity. It utilizes a 4-point Likert scales and covers intervention quality, if participants felt their needs were met, if they would recommend the intervention, and if the intervention was well explained and communicated.

3.6 | Recruitment and Retention

Recruitment strategy includes referrals from other providers, posters and flyers available in clinic waiting areas and exam rooms, and mailed letters and text messages to potential participants. During routine visits providers screen participants and refer to the LMG Program if they meet criteria: (1) WTC-related GERD certification; (2) either (i) desire to reduce GERD symptoms occurring ≥1 days per week and/or (ii) interest in reducing use of GERD-specific medications (PPIs, H2 receptor blockers [H2B], and/or over-the-counter antacids [OTCAA]); (3) an interest in LM approaches to GERD treatment; and (4) proficiency in English.

The LMG Program coordinator will provide potential participants (via text, email, on-line, and/or paper determined by participant preference) program information, patient education packets, assessment questionnaires, surveys, and consent forms. The LMG Program coordinator will also discuss enrollment expectations including inclusion/exclusion evaluation during initial visit, LM virtual visits monthly over 6 months (total of seven visits), pre/post evaluations and monthly surveys, and the provision of verbal consent. We will use the "talk-back" method of assessing understanding related to any risks or concerns that participants express during consent or any phase of the LMG Program.

Retention strategies for participants will include telephone or text reminders and confirmation prior to scheduled appointments, and persistent follow-up for all no-shows with rescheduling, through mechanisms already in place at WTCHP.

4 | Experimental Design

4.1 | Inclusion/Exclusion

During the initial LMG Program visit with the LMG Program provider, potential participants will be screened for inclusion or exclusion. Inclusion criteria include (1) WTCHP certification for GERD; (2) heartburn symptoms defined as burning sensation in (retrosternal) chest, usually after eating, which might be worse at night and is not cardiac in nature, greater than once per week; or (3) previous partial or full response to acid reduction therapy (H2BPPI or OTCAA, or other "natural" therapies [aloe, apple cider vinegar, etc.]). Participants are screened for exclusion criteria that might preclude or make inadvisable enrollment in the program. Expert gastroenterologist advisors review each case for final decision to exclude. (Table 1).

TABLE 1 | Exclusion criteria.

- Primary symptoms are abdominal (i.e., not in the chest, epigastric), early satiety, postprandial fullness (dyspepsia)
- Any history of esophagitis Los Angeles Grade B, C, D on EGD
- Previous maxed acid reduction therapy w/ no response
- Any history of Barrett's esophagus or H. Pylori infection (unless proof of eradication, Test of Cure (TOC) in chart, if no TOC refer to GI)
- Upper GI cancer in 1st degree relative
- Any h/o of chemotherapy or radiation therapy to the chest
- Patient presenting with alarm features in need of endoscopy, such as:
  - New onset upper GI symptoms in patient ≥55 y/o
  - GI bleeding (hematemesis, melena, hematochezia, occult blood in stool)
  - Iron deficiency anemia
  - Anorexia/unexplained weight loss
  - Dysphagia/odynophagia
  - Persistent vomiting

4.2 | Intervention

Participants who meet inclusion criteria will undergo the full LMG Program clinical intervention. To identify habits and behaviors for improvement and to inform goal setting, participants will take pre- and postintervention surveys including the LM 6 Pillars of Health Vital Sign Survey (nutrition, physical activity, sleep, substance use, stress, social connections) [56] and the 4Leaf Survey [74], which estimates percent daily intake of whole foods. The full intervention is described in Table 2. The LMG Program is entirely telemedicine based—all contact with participants will be via real-time video or audio telemedicine encounters. The intervention consists of self-administered baseline standardized questionnaires delivered via text, or hard copy if preferred, just prior to a visit; an initial telemedicine visit of 1-hour duration; and subsequent follow-up visits of 20—40 minutes duration scheduled at 2-weeks after initial visit, then monthly through 6 months of follow up for a total of seven visits.

Prospective participants who are excluded from the full LMG Program will be provided with general information on Lifestyle Modifications for GERD, advised to continue their present care, encouraged to discuss with their primary care physician, and schedule for a 6-month follow up with a LMG Program provider.

4.3 | Data Collection

Data relevant to GERD symptoms and medication use will be collected just prior to each visit at (baseline), 2 weeks later, and at monthly intervals for 6 months. Relevant covariate and confounder data will be collected on the initial visit and if relevant at the last visit and will include age, sex, race/ethnicity, BMI, and current alcohol and tobacco use. Project investigators will have secure access to downloaded data in comma separate value format from the Q-Reviews platform. These data are then transferred into an SPSS database for inspection, cleaning, and analysis.

Data related to feasibility and satisfaction will be collected via a texted survey approximately 1 week after completion of the LMG Program. For measures of satisfaction the number of referred, consented, eligible, and enrolled patients from the WTCHP will be documented. Those who complete at least the baseline visit

TABLE 2 | The intervention utilizes a standardized approach consisting of the following steps.

1. Questionnaire responses reviewed by LM provider at beginning of encounter ("LM 6 Pillar Vital Signs Survey," 4Leaf Survey, GERD-HRQL, GERD-medication use, and five preliminary action step goals)
2. LM provider reviews with participants the six-pillar LM approach, emphasizing nutrition and physical activity, and its application to GERD
3. Discussion of the comparison of participant's "LM Vital Sign" assessment to current guidelines/recommendations
4. Highlight areas of possible action (e.g. eliminate sugary beverages)
5. Health coaching to negotiate and identify action goals
6. Identification of five potential goals (e.g. "I will drink one less sugary beverage/day for next 30-days")
7. Assess each goal on a scale of 1–10 for readiness to change and confidence level for achieving each goal
8. Choice of top three goals (of five) based on change readiness and participant confidence levels rated at 7/10
9. Revision of goals if none meet these criteria, with use of MI techniques
10. Using SMART criteria, creation of an action step plan for each of the three goals, documentation in the chart, and discussion of lapse/relapse prevention strategies
11. Write LM prescription using SMART criteria for which the patient agrees to be held accountable
12. Review and summarization of the visit and virtual "handshake" with participant to get buy-in
13. Scheduling follow-up visit

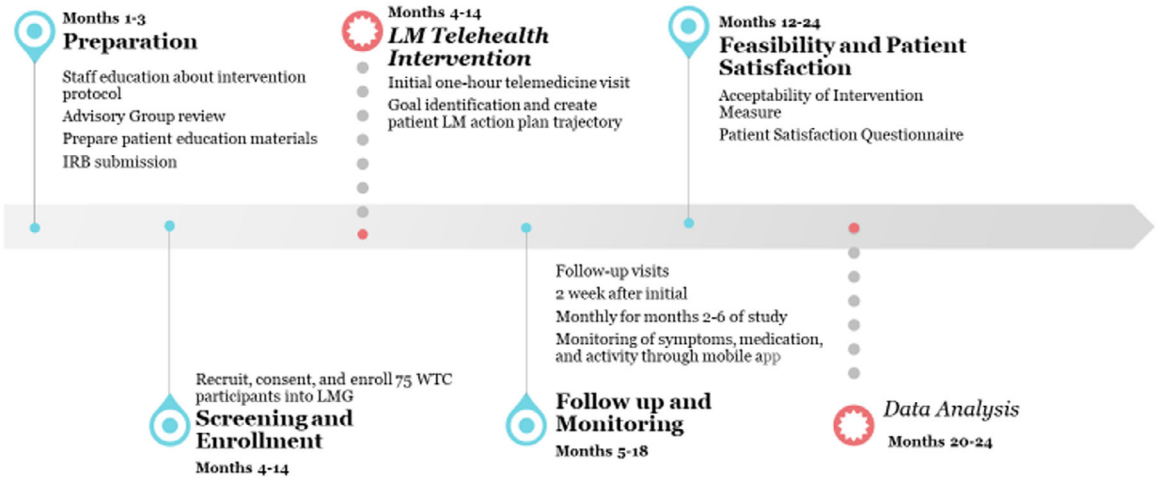

FIGURE 1 | Study timeline.

will be tracked by the LM coordinator to determine the number of encounters and retention rate in the program.

4.4 | Sample Size

We propose to enroll a total of 75 WTCHP cohort members into a pilot LM intervention to reduce medication use and/or symptoms. Sample-size estimates were made based on previous research using the GERD-HRQL questionnaire. Full discontinuation of long-term PPI therapy in GERD patients (without peptic ulcer or esophagitis and using no other substitute treatment) was successful in 27% of patients [78]. Using this figure and the assumption that discontinuation with our intervention substituted as treatment would yield a two-fold increase in full PPI discontinuation, in a pre/post design with the same subjects, a sample size of 50 subjects would be required to have 80% power to demonstrate an effect at an alpha of 0.05. A sample of 75 participants is therefore likely sufficient to demonstrate a positive effect (or a non-negative effect) with respect to reduction or discontinuation of medicines as well as symptom scores, accounting for both overestimation of effect and potential drop-out from the study.

4.5 | Analytic Plan

4.5.1 | Hypothesis 1: Participants in the WTC LMG Program will Experience a Reduction in Symptoms and/or Medication Use Associated with GERD

The analytic plan will take the form of an interrupted time-series design with the initial and 2-week questionnaire results serving as the preintervention assessment (the two early assessments accounting for potential regression to the mean and intrasubject

repeat-test variability) and subsequent data representing post-intervention results. Repeated-measures ANOVA and ANCOVA analyses will assess changes in symptomatology based on GERD-HRQL scores and medication use reported on the questionnaires.

The interrupted time-series analysis is chosen for several reasons; by using the participant as their own control, greater statistical power is obtained to estimate the effect of the intervention; internal evidence indicates that use of PPI and related medication remains stable with little fluctuation in the WTC responders; and a comparable control-treatment mechanism beyond usual care is not available. Responses on the GERD-HRQL will be contrasted with the published literature indicative of responses to treatment and reduction of symptomatology in prior trials of medical treatment for GERD. Most trials use cut-points on the GERD-HRQL of 10 or lower to indicate little or no GERD symptoms, and therefore success in treatment, whereas an increase to a score of 15 is indicative of clear and persistent GERD in most participants. Estimation of the effects of various components of the LM intervention can also be made by including these as covariates; for example, through comparison (pre/post) of both self-reported data on habits (alcohol and tobacco use) and their effect in the overall analyses on the outcome measures.

4.5.2 | Specific Aim 1 will Assess the Feasibility of Incorporating Health Data Tracking Technology to Quantify and Track GERD Symptoms and Medication Use in Program Participants

Descriptive statistics will be used to analyze answers from the modified AIM, the IAM, and the feasibility of intervention measure.

4.5.3 | Specific Aim 2 will Evaluate Participant Behavior Change and Satisfaction with a Telemedicine LM Intervention for GERD

Satisfaction will be measured with the client satisfaction questionnaire adapted to Internet-based interventions (CSQ-I) [77], to gauge if the LMG Program was well received and implemented. Additionally, satisfaction will be assessed via answers to open-ended questions will be entered into a qualitative data analysis program such as Atlas.ti and analyzed for common themes. Study timeline from preparation to data analysis is illustrated in Figure 1.

Acknowledgments

The authors thank Dr Claudine Holt, patient coordinators Sahara Curtis, and Alisha Green, and the Mount Sinai World Trade Center program for their support and assistance with this project.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data sharing is not applicable to this article. No new data were created or analyzed as this paper delineates methods only.

References

1. About Chronic Diseases | CDC. Accessed March 5, 2024. https://www.cdc.gov/chronicdisease/about/index.htm.

2. P. D. Loprinzi, A. Branscum, J. Hanks, and E. Smit, "Healthy Lifestyle Characteristics and Their Joint Association With Cardiovascular Disease Biomarkers in US Adults," *Mayo Clinic Proceedings* 91, no. 4 (2016): 432–442, https://doi.org/10.1016/j.mayocp.2016.01.009.

3. J. Maret-Ouda, S. R. Markar, and J. Lagergren, "Gastroesophageal Reflux Disease a Review," *JAMA—Journal of the American Medical Association* 324, no. 24 (2020): 2536–2547, https://doi.org/10.1001/jama.2020.21360.

4. R. Kellerman and T. Kintanar, "Gastroesophageal Reflux Disease," *Primary Care* 44, no. 4 (2017): 561–573, https://doi.org/10.1016/J.POP.2017.07.001.

5. D. Zhang, S. Liu, Z. Li, and R. Wang, "Global, Regional and National Burden of Gastroesophageal Reflux Disease, 1990–2019: Update From the GBD 2019 Study," *Annals of Medicine* 54, no. 1 (2022): 1372–1384, https://doi.org/10.1080/07853890.2022.2074535.

6. M. Jarosz and A. Taraszewska, "Risk Factors for Gastroesophageal Reflux Disease: The Role of Diet," *Przeglad Gastroenterologiczny* 9, no. 5 (2014): 297, https://doi.org/10.5114/PG.2014.46166.

7. Z. Zheng, H. Nordenstedt, N. L. Pedersen, J. Lagergren, and W. Ye, "Lifestyle Factors and Risk for Symptomatic Gastroesophageal Reflux in Monozygotic Twins," *Gastroenterology* 132, no. 1 (2007): 87–95, https://doi.org/10.1053/j.gastro.2006.11.019.

8. D. Festi, E. Scaioli, F. Baldi, et al., "Body Weight, Lifestyle, Dietary Habits and Gastroesophageal Reflux Disease," *World Journal of Gastroenterology* 15, no. 14 (2009): 1690–1701, https://doi.org/10.3748/wjg.15.1690.

9. S. Emerenziani, X. Zhang, K. Blondeau, et al., "Gastric Fullness, Physical Activity, and Proximal Extent of Gastroesophageal Reflux," *American Journal of Gastroenterology* 100, no. 6 (2005): 1251–1256, https://doi.org/10.1111/j.1572-0241.2005.41695.x.

10. E. Ferriolli, R. B. Oliveira, N. M. Matsuda, F. Braga, and R. O. Dantas, "Aging, Esophageal Motility, and Gastroesophageal Reflux," *Journal of the American Geriatrics Society* 46, no. 12 (1998): 1534–1537, https://doi.org/10.1111/J.1532-5415.1998.TB01538.X.

11. C. Newberry and K. Lynch, "The Role of Diet in the Development and Management of Gastroesophageal Reflux Disease: Why We Feel the Burn," *Journal of thoracic disease* 11 (2019): S1594–S1601, https://doi.org/10.21037/jtd.2019.06.42.

12. M. Zhang, Z. K. Hou, Z. B. Huang, X. L. Chen, and L. Feng-Bin, "Dietary and Lifestyle Factors Related to Gastroesophageal Reflux Disease: A Systematic Review," *Ther Clin Risk Manag* 17 (2021): 305–323, https://doi.org/10.2147/TCRM.S296680.

13. A. Bansal and P. J. Kahrilas, "Treatment of GERD Complications (Barrett's, Peptic Stricture) and Extra-Oesophageal Syndromes," *Best Practice & Research. Clinical Gastroenterology* 24, no. 6 (2010): 961–968, https://doi.org/10.1016/J.BPG.2010.09.007.

14. W. A. Phillips, R. V. Lord, D. J. Nancarrow, D. I. Watson, and D. C. Whiteman, "Barrett's Esophagus," *Journal of Gastroenterology and Hepatology* 26, no. 4 (2011): 639–648, https://doi.org/10.1111/J.1440-1746.2010.06602.X.

15. J. He, C. Wang, and W. Li, "Laryngopharyngeal Reflux in Obstructive Sleep Apnea-Hypopnea Syndrome: An Updated Meta-Analysis," *Nature and Science of Sleep* 14 (2022): 2189, https://doi.org/10.2147/NSS.S390272.

16. S. M. Wang, N. D. Freedman, H. A. Katki, et al., "Gastroesophageal Reflux Disease: A Risk Factor for Laryngeal Squamous Cell Carcinoma and Esophageal Squamous Cell Carcinoma in the NIH-AARP Diet and Health Study cohort," *Cancer* 127, no. 11 (2021): 1871–1879, https://doi.org/10.1002/cncr.33427.

17. L. G. T. Shanika, A. Reynolds, S. Pattison, and R. Braund, "Proton Pump Inhibitor Use: Systematic Review of Global Trends and Practices,"

European Journal of Clinical Pharmacology 79, no. 9 (2023): 1159, https://doi.org/10.1007/S00228-023-03534-Z.

18. V. Rosenberg, R. Tzadok, G. Chodick, and R. Kariv, "Proton Pump Inhibitors Long Term Use-Trends and Patterns Over 15 years of a Large Health Maintenance Organization," *Pharmacoepidemiology and Drug Safety* 30, no. 11 (2021): 1576–1587, https://doi.org/10.1002/PDS.5352.

19. M. R. Fattahi, R. Niknam, M. Shams, et al., "The Association Between Prolonged Proton Pump Inhibitors Use and Bone Mineral Density," *Risk Management and Healthcare Policy* 12 (2019): 349–355, https://doi.org/10.2147/RMHP.S223118.

20. J. Ding, D. A. Heller, F. M. Ahern, and T. V. Brown, "The Relationship Between Proton Pump Inhibitor Adherence and Fracture Risk in the Elderly," *Calcified Tissue International* 94, no. 6 (2014): 597–607, https://doi.org/10.1007/S00223-014-9855-6.

21. A. B. Jena, E. Sun, and D. P. Goldman, "Confounding in the Association of Proton Pump Inhibitor Use With Risk of Community-Acquired Pneumonia," *Journal of General Internal Medicine* 28, no. 2 (2013): 223–230, https://doi.org/10.1007/S11606-012-2211-5.

22. A. K. Nehra, J. A. Alexander, C. G. Loftus, and V. Nehra, "Proton Pump Inhibitors: Review of Emerging Concerns," *Mayo Clinic Proceedings* 93, no. 2 (2018): 240–246, https://doi.org/10.1016/j.mayocp.2017.10.022.

23. A. Rameau, K. Andreadis, A. Bayoumi, M. Kaufman, and P. Belafsky, "Side Effects of Proton Pump Inhibitors: What are Patients' Concerns?," *Journal of Voice* 35, no. 5 (2021): 809, https://doi.org/10.1016/J.JVOICE.2020.01.018. e15-809.e20.

24. E. J. Irvine, "Quality of Life Assessment in Gastro-Oesophageal Reflux Disease," *Gut* 53, no. SUPPL. 4 (2004): iv35–iv39, https://doi.org/10.1136/gut.2003.034314.

25. I. Wiklund, "Review of the Quality of Life and Burden of Illness in Gastroesophageal Reflux Disease," *Digestive Diseases* 22, no. 2 (2004): 108–114, https://doi.org/10.1159/000080308.

26. A. Mari, W. Na'amnih, L. Ghantous, H. S. Ahmad, T. Khoury, and K. Muhsen, "Quality of Life and Severity Of Symptoms Among Patients With Various Degrees of Reflux Esophagitis: A Prospective Study," *Scientific Reports* 13, no. 1 (2023): 1–8, https://doi.org/10.1038/s41598-023-41332-w.

27. J. Tack, A. Becher, C. Mulligan, and D. A. Johnson, "Systematic Review: The burden of Disruptive Gastro-Oesophageal Reflux Disease on Health-Related Quality of Life," *Alimentary pharmacology & therapeutics* 35, no. 11 (2012): 1257–1266, https://doi.org/10.1111/J.1365-2036.2012.05086.X.

28. R. Dickman, C. Green, S. S. Fass, et al., "Relationships Between Sleep Quality and pH Monitoring Findings in Persons With Gastroesophageal Reflux Disease," *Journal of Clinical Sleep Medicine* 3, no. 5 (2007): 505–513, https://doi.org/10.5664/JCSM.26915.

29. P. Gurges, B. J. Murray, and M. I. Boulos, "Relationship Between Gastroesophageal Reflux Disease and Objective Sleep Quality," *Journal of Clinical Sleep Medicine* 18, no. 12 (2022): 2731–2738, https://doi.org/10.5664/JCSM.10198.

30. L. H. Baker, D. Lieberman, and M. Oehlke, "Psychological Distress in Patients With Gastroesophageal Reflux Disease," *American Journal of Gastroenterology* 90, no. 10 (1995), https://doi.org/10.1111/j.1572-0241.1995.tb08074.x.

31. M. Craven, J. Craft, O. Alexeeva, et al., "A Qualitative Analysis of Patient Attitudes and Perceptions Related to Gastroesophageal Reflux Disease," *Gastroenterology* 152, no. 5 Supplement 1 (2017): S750.

32. Y. Kimura, T. Kamiya, K. Senoo, et al., "Persistent Reflux Symptoms Cause Anxiety, Depression, and Mental Health and Sleep Disorders in Gastroesophageal Reflux Disease Patients," *Journal of Clinical Biochemistry and Nutrition* 59, no. 1 (2016): 71–77, https://doi.org/10.3164/jcbn.16-9.

33. M. H. Núñez-Rodríguez and A. Miranda Sivelo, "Psychological Factors in Gastroesophageal Reflux Disease Measured by SCL-90-R Questionnaire," *Digestive Diseases and Sciences* 53, no. 12 (2008): 3071–3075, https://doi.org/10.1007/s10620-008-0276-0.

34. S. Bruley des Varannes, P. Ducrotté, T. Vallot, et al., "Gastroesophageal Reflux Disease: Impact on Work Productivity and Daily-Life Activities of Daytime Workers. A French Cross-Sectional Study," *Digestive and Liver Disease* 45, no. 3 (2013): 200–206, https://doi.org/10.1016/j.dld.2012.11.005.

35. P. Wahlqvist, M. Reilly, and A. Barkun, "PGI13 the Impact of Gastroesophageal Reflux Disease on Work Productivity: A Systematic Review," *Value in Health* 8, no. 6 (2005), https://doi.org/10.1016/s1098-3015(10)67520-1.

36. W. G. Shin, H. U. Kim, S. G. Kim, et al., "Work Productivity and Activity Impairment in Gastroesophageal Reflux Disease in Korean Full-Time Employees: A Multicentre Study," *Digestive and Liver Disease* 44, no. 4 (2012), https://doi.org/10.1016/j.dld.2011.10.027.

37. J. P. Gisbert, A. Cooper, D. Karagiannis, et al., "Impact of Gastroesophageal Reflux Disease on Work Absenteeism, Presenteeism and Productivity in Daily Life: A European Observational Study," *Health and Quality of Life Outcomes [Electronic Resource]* 7 (2009): 90, https://doi.org/10.1186/1477-7525-7-90.

38. J. Fashner, "Gastroesophageal Reflux Disease: A General Overview," *HCA Healthcare Journal of Medicine* 1, no. 4 (2020): 191–199, https://doi.org/10.36518/2689-0216.1042.

39. M. Craven, J. Craft, O. Alexeeva, et al., "A Qualitative Analysis of Patient Attitudes and Perceptions Related to Gastroesophageal Reflux Disease," *Gastroenterology* 152, no. 5 (2017): S750, https://doi.org/10.1016/s0016-5085(17)32602-1.

40. P. Sharma, G. W. Falk, M. Bhor, et al., "Healthcare Resource Utilization and Costs Among Patients With Gastroesophageal Reflux Disease, Barrett's Esophagus, and Barrett's Esophagus-Related Neoplasia in the United States," *J Health Econ Outcomes Res* 10, no. 1 (2023): 51–58, https://doi.org/10.36469/001C.68191.

41. D. M. Wolf, L. Lehman, R. Quinlin, T. Zullo, and L. Hoffman, "Effect of Patient-Centered Care on Patient Satisfaction and Quality of Care," *Journal of Nursing Care Quality* 23, no. 4 (2008): 316–321, https://doi.org/10.1097/01.NCQ.0000336672.02725.a5.

42. A. Zucca, R. Sanson-Fisher, A. Waller, M. Carey, and D. Boadle, "The First Step in Ensuring Patient-Centred Quality of Care: Ask the Patient," *European Journal of Cancer Care* 26, no. 1 (2017), https://doi.org/10.1111/ecc.12435.

43. Y. H. Tan, J. X. Siew, B. Thomas, and K. C. Ng, "Patient-Reported Outcome Measures and Value-Based Medicine in Paediatrics: A Timely Review," *Singapore Medical Journal* 64, no. 5 (2023): 285–293, https://doi.org/10.11622/smedj.2021102.

44. K. Churruca, C. Pomare, L. A. Ellis, et al., "Patient-Reported Outcome Measures (PROMs): A Review of Generic and Condition-Specific Measures and a Discussion of Trends and Issues," *Health Expectations* 24, no. 4 (2021): 1015–1024, https://doi.org/10.1111/hex.13254.

45. B. Wiering, D. de Boer, and D. Delnoij, "Patient Involvement in the Development of Patient-Reported Outcome Measures: A Scoping Review," *Health Expectations* 20, no. 1 (2017): 11–23, https://doi.org/10.1111/hex.12442.

46. E. Ness-Jensen, K. Hveem, H. El-Serag, and J. Lagergren, "Lifestyle Intervention in Gastroesophageal Reflux Disease," *Clinical Gastroenterology and Hepatology* 14, no. 2 (2016): 175–182, https://doi.org/10.1016/j.cgh.2015.04.176. e3.

47. L. Z. Yuan, P. Yi, G. S. Wang, et al., "Lifestyle Intervention for Gastroesophageal Reflux Disease: A National Multicenter Survey of Lifestyle Factor Effects on Gastroesophageal Reflux Disease in China," *Therap Adv Gastroenterol* 12 (2019): 1756284819877788, https://doi.org/10.1177/1756284819877788.

48. J. Ayoub and N. D. White, "GERD Management: The Case for Lifestyle in an Era of PPIs," *American Journal of Lifestyle Medicine* 11, no. 1 (2017): 24–28, https://doi.org/10.1177/1559827616671505.

49. P. O. Katz, K. B. Dunbar, F. H. Schnoll-Sussman, K. B. Greer, R. Yadlapati, and S. J. Spechler, "ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease," *American Journal of Gastroenterology* 117, no. 1 (2022): 27–56, https://doi.org/10.14309/AJG.0000000000001538.

50. A. P. Hungin, R. Yadlapati, F. Anastasiou, et al., "Management Advice for Patients With reflux-Like Symptoms: An Evidence-Based Consensus," *European Journal of Gastroenterology & Hepatology* 36, no. 1 (2024): 13, https://doi.org/10.1097/MEG.0000000000002682.

51. K. Haruma, Y. Kinoshita, S. Sakamoto, K. Sanada, S. Hiroi, and H. Miwa, "Lifestyle Factors and Efficacy of Lifestyle Interventions in Gastroesophageal Reflux Disease Patients With Functional Dyspepsia: Primary Care Perspectives From the LEGEND Study," *Internal Medicine* 54, no. 7 (2015): 695–701, https://doi.org/10.2169/internalmedicine.54.3056.

52. L. Yuan, D. Tang, J. Peng, N. Qu, C. Yue, and F. Wang, "Study on Lifestyle in Patients With Gastroesophageal Reflux Disease," *Journal of Central South University (Medical Sciences)* 42, no. 5 (2017): 558–564, https://doi.org/10.11817/j.issn.1672-7347.2017.05.013.

53. Ü. Dağlı and İ. H. Kalkan, "The Role of lifestyle Changes in Gastroesophageal Reflux Diseases Treatment," *Turkish Journal of Gastroenterology* 28 (2017): S33–S37, https://doi.org/10.5152/tjg.2017.10.

54. A. Commisso and F. Lim, "Lifestyle Modifications in Adults and Older Adults With Chronic Gastroesophageal Reflux Disease (Gerd)," *Critical Care Nursing Quarterly* 42, no. 1 (2019): 64–74, https://doi.org/10.1097/CNQ.0000000000000239.

55. A. H. Krist, K. W. Davidson, C. M. Mangione, et al., "Behavioral Counseling Interventions to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: US Preventive Services Task Force Recommendation Statement," *Jama* 324, no. 20 (2020): 2069–2075, https://doi.org/10.1001/JAMA.2020.21749.

56. Lifestyle Medicine. Accessed November 19, 2020. https://lifestylemedicine.org/What-is-Lifestyle-Medicine.

57. B. I. Yeh and I. D. Kong, "The Advent of Lifestyle Medicine," *J Lifestyle Med* 3, no. 1 (2013): 1–8, Accessed November 12, 2020. http://www.ncbi.nlm.nih.gov/pubmed/26064831.

58. J. M. Rippe, "Lifestyle Medicine: The Health Promoting Power of Daily Habits and Practices," *American Journal of Lifestyle Medicine* 12, no. 6 (2018): 499–512, https://doi.org/10.1177/1559827618785554.

59. L. Lianov, "The Role of Positive Psychology in Lifestyle Medicine," *American Journal of Lifestyle Medicine* Published online 2023, https://doi.org/10.1177/15598276231184157.

60. J. Ma, L. G. Rosas, and N. Lv, "Precision Lifestyle Medicine: A New Frontier in the Science of Behavior Change and Population Health," *American Journal of Preventive Medicine* 50, no. 3 (2016): 395–397, https://doi.org/10.1016/j.amepre.2015.09.035.

61. S. A. Cole, D. Sannidhi, Y. T. Jadotte, and A. Rozanski, "Using Motivational Interviewing and Brief Action Planning for Adopting and Maintaining Positive Health Behaviors," *Progress in Cardiovascular Diseases* 77 (2023): 86–94, https://doi.org/10.1016/j.pcad.2023.02.003.

62. S. Conn and S. Curtain, "Health Coaching as a Lifestyle Medicine Process in Primary Care," *Australian Journal of General Practice* 48, no. 10 (2019): 677–680, https://doi.org/10.31128/AJGP-07-19-4984.

63. M. Moore, "Ground Zero in Lifestyle Medicine: Changing Mindsets to Change Behavior," *American Journal of Lifestyle Medicine* 17, no. 5 (2023): 632–638, https://doi.org/10.1177/15598276231166320.

64. N. D. White, V. Bautista, T. Lenz, and A. Cosimano, "Using the SMART-EST Goals in Lifestyle Medicine Prescription," *American Journal of Lifestyle Medicine* 14, no. 3 (2020): 271–273, https://doi.org/10.1177/1559827620905775.

65. K. R. Middleton, S. D. Anton, and M. G. Perri, "Long-Term Adherence to Health Behavior Change," *American Journal of Lifestyle Medicine* 7, no. 6 (2013): 395–404, https://doi.org/10.1177/1559827613488867.

66. S. Mace, A. Boccanelli, and M. Dormond. *The Use of Telehealth Within Behavioral Health Settings: Utilization, Opportunities, and Challenges KEY FINDINGS*.; 2018. Accessed November 24, 2020. http://www.behavioralhealthworkforce.org-2.

67. E. Senay, D. Byrne, C. Mattson, G. Shukla, and L. Crowley, "Telehealth for COVID-19 in World Trade Center Responders: Meeting the Needs of This Unique Population," *Journal of Occupational and Environmental Medicine* 63, no. 11 (2021): e834–e837, https://doi.org/10.1097/JOM.0000000000002385.

68. C. Ernsting, S. U. Dombrowski, M. Oedekoven, et al., "Using Smartphones and Health Apps to Change and Manage Health Behaviors: A Population-Based Survey," *Journal of Medical Internet Research [Electronic Resource]* 19, no. 4 (2017): e101, https://doi.org/10.2196/jmir.6838.

69. D. Szinay, A. Jones, T. Chadborn, J. Brown, and F. Naughton, "Influences on the Uptake of and Engagement With Health and Well-Being Smartphone Apps: Systematic Review," *Journal of Medical Internet Research [Electronic Resource]* 22, no. 5 (2020): e17572, https://doi.org/10.2196/17572.

70. O. T. Nguyen, C. P. Renfro, J. Hughes, et al., "Patients' Use of Smartphone Apps for Health Record Access in 2019: A Cross-Sectional Study," *International Journal of Medical Informatics* 166 (2022): 104858, https://doi.org/10.1016/J.IJMEDINF.2022.104858.

71. B. Perry, C. Geoghegan, L. Lin, et al., "Patient Preferences for Using Mobile Technologies in Clinical Trials," *Contemporary Clinical Trials Communications* 15 (2019): 100399, https://doi.org/10.1016/J.CONCTC.2019.100399.

72. S. Duane, M. Tandan, A. W. Murphy, and A. Vellinga, "Using Mobile Phones to Collect Patient Data: Lessons Learned From the SIMPle Study," *JMIR Research Protocols* 6, no. 4 (2017): e61, https://doi.org/10.2196/RESPROT.6389.

73. C. R. Dasaro, W. L. Holden, K. D. Berman, et al., "Cohort Profile: World Trade Center Health Program General Responder Cohort," *International Journal of Epidemiology* 46, no. 2 (2017): e9, https://doi.org/10.1093/ije/dyv099.

74. Take Survey | 4Leaf Global, LLC. Accessed September 13, 2024. https://4leafprogram.com/4leaf-survey/.

75. Q-Reviews: Real Time Patient Feedback & Engagement Platform. Accessed April 10, 2024. https://q-reviews.com/.

76. V. Velanovich, "The Development of the GERD-HRQL Symptom Severity Instrument," *Diseases of the Esophagus* 20, no. 2 (2007): 130–134, https://doi.org/10.1111/j.1442-2050.2007.00658.x.

77. L. Bo, D. Lehr, D. Reis, et al., "Reliability and Validity of Assessing User Satisfaction With Web-Based Health Interventions," *Journal of Medical Internet Research [Electronic Resource]* 18, no. 8 (2016): e234, https://doi.org/10.2196/jmir.5952.

78. E. Björnsson, H. Abrahamsson, M. Simrén, et al., "Discontinuation of Proton Pump Inhibitors in Patients on Long-Term Therapy: A Double-Blind, Placebo-Controlled Trial," *Alimentary pharmacology & therapeutics* 24, no. 6 (2006): 945–954, https://doi.org/10.1111/j.1365-2036.2006.03084.x.