Published in final edited form as:

Am J Gastroenterol. 2018 January ; 113(1): 23–30. doi:10.1038/ajg.2017.262.

The Reflux Improvement and Monitoring (TRIM) Program Is Associated with Symptom Improvement and Weight Reduction for Obese Patients with Gastroesophageal Reflux Disease

Rena Yadlapati, MD, MSHS¹, John E Pandolfino, MD, MS¹, Olga Alexeeva, BS¹, Dyanna L. Gregory, BS¹, Meredith R. Craven, MPH¹, David Liebovitz, MD², Abbey Lichten, MPH, CHES¹, Erin Seger, BS, CHES¹, Moira Workman, BS, CHES¹, Nora St. Peter, MS¹, Jenna Craft, MPH¹, Bethany Doerfler, RD¹, and Rajesh N. Keswani, MD, MS¹

¹Northwestern University Feinberg School of Medicine, Chicago, IL, USA

²University of Chicago Pritzker School of Medicine, Chicago, IL, USA

Abstract

Objectives—Current healthcare systems do not effectively promote weight reduction in obese patients with gastroesophageal reflux disease (GERD). The Reflux Improvement Monitoring (TRIM) program provides personalized, multidisciplinary, health education and monitoring over 6 months. In this study we aimed to (1) measure the effectiveness of TRIM on GERD symptoms, quality of life, and weight, and (2) examine patient health beliefs related to TRIM.

Corresponding Author: Rena Yadlapati, MD, Division of Gastroenterology & Hepatology, Northwestern University Feinberg School of Medicine, 676 North St. Clair St. Suite 1400 Chicago, IL 60611, Office: (312) 926-7648; Fax: (312) 695-3999, rena.yadlapati@northwestern.edu.

Potential Conflict of Interest (Financial, Professional or Personal): None

Specific Author Contributions

RY: Study oversight; study concept and design; acquisition of data; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

JEP: Study concept and design; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

OA: Study concept and design; acquisition of data; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

DLG: Study concept and design; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

MRC: Study concept and design; acquisition of data; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

DL: Study concept and design; critical revision of the manuscript for important intellectual content; finalization of manuscript.

AL: Study concept and design; acquisition of data; critical revision of the manuscript for important intellectual content; finalization of manuscript.

ES: Study concept and design; acquisition of data; critical revision of the manuscript for important intellectual content; finalization of manuscript.

MW: Study concept and design; acquisition of data; critical revision of the manuscript for important intellectual content; finalization of manuscript.

NSP: Study concept and design; acquisition of data; critical revision of the manuscript for important intellectual content; finalization of manuscript.

JC: Study concept and design; acquisition of data; analysis and interpretation of data; critical revision of the manuscript for important intellectual content; finalization of manuscript.

BD: Study concept and design; critical revision of the manuscript for important intellectual content; finalization of manuscript.

RNK: Study concept and design; acquisition of data; analysis and interpretation of data; drafting of manuscript; critical revision of the manuscript for important intellectual content; finalization of manuscript.

Methods—This prospective mixed methods feasibility study was performed at a single center between 9/2015–2/2017, and included adult patients with GERD and a body mass index 30kg/m^2 . Quantitative analysis consisted of a pre- to post-intervention analysis of TRIM participants (+TRIM Cohort) and a multivariable longitudinal mixed model analysis of +TRIM versus patients who declined TRIM (-TRIM Cohort). Primary outcomes were change in patient-reported GERD symptom severity (GerdQ) and quality of life (GerdQ-DI), and change in percent excess body weight (%EBW). Qualitative analysis was based on two focus groups of TRIM participants.

Results—Among the +TRIM cohort ($n=52$), mean baseline GerdQ scores (8.7 ± 2.9) decreased at 3 months (7.5 ± 2.2 ; $p < 0.01$) and 6 months (7.4 ± 1.9 ; $p = 0.02$). Mean GerdQ-DI scores decreased, but did not reach statistical significance. Compared to the -TRIM cohort ($n=89$), reduction in %EBW was significantly greater at 3, 6, and 12-months among the +TRIM cohort ($n=52$). In qualitative analysis, patients unanimously appreciated the multidisciplinary approach and utilized weight loss effectively to improve GERD symptoms.

Conclusions—In this mixed methods feasibility study, participation in TRIM was associated with symptom improvement, weight reduction and patient engagement.

Keywords

Weight management; Reflux; Patient Reported Outcomes; Qualitative

Introduction

Obesity is an important independent risk factor for gastroesophageal reflux disease (GERD)^{1,2}. In observational studies and systematic reviews, weight loss is reported as one of the few effective lifestyle modifications for GERD^{1,3,4}. The prevalence of obesity and GERD is rising, and these conditions contribute significant morbidity, resource utilization and healthcare costs⁵. Consequently, appropriate recognition and management of obesity is a core Centers for Medicare and Medicaid Services quality measure and US Preventive Services Task Force recommendation^{6,7}. In addition, documentation of adequate weight management counseling for overweight patients is a valid quality measure in the initial evaluation of patients with GERD⁸.

Although effective weight management in the care of GERD is a national priority, implementing clinically feasible and effective interventions is challenging⁹. A multitude of factors influence the effectiveness of weight loss interventions. Health system barriers include provider time constraints, insufficient reimbursement, and inadequate provider training^{9,10}. In addition, patient engagement is influenced by choices, attitudes, and beliefs; as such effective interventions need to focus on changeable behaviors and objectives^{9–11}. Recognizing these factors, we designed a weight management program tailored to patients with obesity and GERD, known as the reflux improvement and monitoring (TRIM) program. TRIM integrates multidisciplinary care teams and information systems to provide patient-centered weight management education over six months¹².

In this mixed methods feasibility study, we aimed to (1) measure the effectiveness of TRIM on symptoms, health related quality of life (QOL), and weight, and (2) examine patient health beliefs related to TRIM. We hypothesized that participation in TRIM is associated with reduced symptom severity, improved QOL, and weight loss.

Methods

Study Design & Setting

We performed a prospective mixed methods feasibility study at a single academic medical center over 18 months (9/1/2015–2/30/2017). The sequential explanatory mixed methods approach consisted of a quantitative pre- to post-intervention analysis and cohort comparison, and a qualitative analysis of patient focus groups to assess patient perspectives related to the intervention. The Northwestern University Institutional Review Board (IRB) approved the quantitative study and waived informed consent (STU#:60007543), and deemed the focus group component as IRB exempt.

Participant Recruitment

We enrolled eligible patients from 9/1/2015 to 11/30/2016. Electronic health record (EHR) decision support was used to identify adult patients (≥ 18 years old) with a diagnosis of GERD (ICD9 530.81, ICD10 K21.9) and a body mass index (BMI) ≥ 30kg/m². During general internal medicine or gastroenterology clinic visits the EHR prompted providers to accept an auto-generated referral to TRIM. Referred patients received standardized instructions to initiate a consultation with a certified health educator. If a referred patient did not contact the educators within one week, the educators attempted to contact the referred patient by phone on three separate occasions. Eligible patients were separated into two cohorts: Intervention cohort (+TRIM) – those who agreed to participate at the initial educator consultation, and Comparator cohort (-TRIM) – those who declined enrollment. We followed all patients for a minimum of three months and up to 12 months from the time of referral.

Intervention

The goal of TRIM is to provide personalized health education and goal setting to obese patients with GERD. The structure and educational content of TRIM was designed by a multidisciplinary team of gastroenterologists, a nutritionist, certified health educators, and health informatics analysts. TRIM is a six month program consisting of an initial consultation, followed by three weekly follow-up sessions and then five monthly sessions with an educator. Initial and follow-up sessions are conducted in person or over the phone according to patient preference. Initial consultation involves baseline weigh-in, standardized education, personalized goal-setting, weekly meal planning, and instructions on use of electronic and/or written nutrition tracking tools. The educator emphasizes the causal relationship between obesity and GERD symptoms. During follow-up sessions, the educators review change in weight, dietary and exercise goals, reinforce education, and provide resources as needed. At each session the educators conduct the GerdQ questionnaire and record patient-reported weights and GerdQ responses in templates embedded in the EHR. (Figure 1)

GerdQ

GERD symptom severity was measured by the GerdQ, a validated six-item patient-reported GERD instrument which calculates symptom severity over the preceding week based on response to four positive predictors (heartburn, regurgitation, sleep disturbance, and antacid use) and two negative predictors (epigastric pain and nausea). Scores range from 0–18; a higher GerdQ indicates greater symptom severity and 8 is the proposed cut-off. The GerdQ-DI, a sub-score of the GerdQ based on response to sleep disturbance and antacid medication, additionally measures QOL impairment (Supplemental Table 1) ¹³.

Quantitative Analysis

Our *a priori* goal was to analyze all data available 18 months after the beginning of the study; we did not pre-specify a sample size or impute missing values.

Outcomes—The primary outcomes were change in GerdQ score, GerdQ-DI sub-score and percent excess body weight (%EBW).

Data Collection—Baseline clinical data and longitudinal weight data for both +TRIM and -TRIM cohorts, and GerdQ data for +TRIM cohort were extracted from the institutional enterprise data warehouse. Weight data was derived from either patient-reported weights through the TRIM program or vital sign charted data.

Primary Analysis: Pre- to Post-Intervention Comparison Within Intervention (+TRIM) Cohort—The primary analysis used two-tailed paired t-test to examine differences in total GerdQ, GerdQ-DI, and %EBW among the TRIM group at baseline versus 3 and 6 month intervals following enrollment.

Secondary Analysis: Comparison of Intervention (+TRIM) & No Intervention (-TRIM) Cohorts—As this study was not designed as a controlled trial, we conducted a secondary analysis using a longitudinal multivariable mixed model to compare change in %EBW between the +TRIM and -TRIM cohorts up to 12 months from time of referral. First, bivariate analysis of baseline clinical data between the two cohorts were compared via two-tailed t-test and chi square analysis as appropriate. We *a priori* determined covariates of age, sex, race, baseline %EBW, and referring clinician type. Variables significant at the $P < 0.05$ level were included in the multivariable longitudinal mixed model. Longitudinal data were clustered by participant (1-X observations/participant), measured in units of patient-month, and analyzed at 3, 6, and 12 month intervals.

We post-hoc performed a second multivariable longitudinal mixed model adjusting for all covariates regardless of significance in bivariate analysis. Longitudinal data was clustered by participant (1-X observations/participant), measured in units of patient-month, and analyzed at 3 and 6 months. Outcomes were only measured up to 6 months due to missing covariate data and loss of observations past 6 months.

Sensitivity Analysis—Given the variability in data collection of weights for the +TRIM cohort, we *a priori* planned a sensitivity analysis using Spearman's correlation to examine

the correlation between patient-reported weights and vital sign documented weights for weights reported within a 24 hour range. This analysis was limited to the setting where patient-reported weights were collected prior to vital sign documented weights to reduce reporting bias.

The p-values<0.05 were considered statistically significant. Statistical analysis for the quantitative analysis was conducted using STATA 14.2 (College Station, TX) and SAS 9.4 (Cary, NC).

Qualitative Analysis

Focus Group Design & Participants—The qualitative analysis explored the health beliefs surrounding symptoms of GERD and weight loss among TRIM participants. The study team formulated key informant interview guides based on the Health Belief Model to explore perceptions, knowledge, self-efficacy and attitudes related to TRIM, with a particular focus on understanding if multidisciplinary care, education, and monitoring engages and promotes weight loss for patients with GERD¹⁴. Two focus groups were held in September 2016 in Chicago, IL. Each focus group was conducted on a weeknight and lasted for two hours. The same group of participants were present at each focus group. One moderator with a background in gastrointestinal behavior and psychology led the focus groups and two observers took field notes during the focus groups. Despite IRB exemption, we obtained written consent to audio record the focus groups.

We recruited focus group participants by calling a panel of TRIM participants. The sampling strategy aimed to include an equal division of sex, age and race. We then scheduled focus groups with six to ten participants.

Data Analysis—Verbatim transcriptions of the audio recordings were coded using MAXQDA software program (Verbi GmbH, Marburg, Germany). Analysis was conducted using Thematic Analysis and Grounded Theory. First, two researchers reviewed the transcripts, writing reflexive and analytic memos to identify themes and concepts. Subsequently, the researchers developed a codebook based on the research questions, theory constructs, and reoccurring themes and concepts. Both researchers independently coded the transcripts, after which they discussed any discrepancies until they reached a consensus. Finally, the researchers systematically reviewed each code and provided a detailed description of its meaning, context and range of agreement and disagreement.

Results

Primary Quantitative Analysis: Pre- to Post-Intervention Comparison

Subjects & Baseline Characteristics—Of the 123 patients enrolled in TRIM, 52 (42%) patients had at least three months of follow-up data available at the time of study analysis and were included in the +TRIM cohort. The mean age was 54.4 ± 12.8 years and 40/52 (77%) were female. Baseline weight measurements were: mean weight 101.8 ± 19.1 kg, median BMI 34.3 kg/m^2 (IQR 32.5–40.5), and mean %EBW 41.8 ± 10.1 . At enrollment, all patients were taking single- or double-dose proton pump inhibitor (PPI).

Primary Outcome—Baseline mean GerdQ (8.7 ± 2.9) significantly decreased at 3 months (7.5 ± 2.2 , $p < 0.01$), and 6 months (7.4 ± 1.9 , $p = 0.02$). Baseline mean GerdQ-DI (1.5 ± 1.7) significantly decreased at 3 months (0.9 ± 1.5 ; $p = 0.02$) and was lower at 6 months (0.8 ± 1.3 ; $p = 0.38$) (Figure 2).

Compared to mean %EBW at baseline (41.8 ± 10.1), mean %EBW decreased at 3 months (39.4 ± 10.6 , $p = 0.25$) and 6 months (36.3 ± 10.6 , $p = 0.04$).

Secondary Quantitative Analysis: Cohort Comparison

The cohort comparison included 52 +TRIM participants and 89 -TRIM patients. Baseline variables were balanced between the two groups (Table 1).

In the primary longitudinal mixed model, all covariates fell out of the model. Compared to the -TRIM cohort, the +TRIM cohort had a significantly greater reduction in %EBW at 3 months (-1.1 vs -2.0 points; $\beta -0.95$, 95% CI -1.9 to -0.1 , $p = 0.04$), 6 months (-1.0 vs -3.3 points; $\beta -2.4$, 95% CI -3.5 to -1.2 , $p < 0.001$) and 12 months ($+0.1$ vs -3.7 points, $\beta -3.8$, 95% CI -6.5 to -1.2 , $p < 0.01$) (Figure 3). With regard to BMI, among +TRIM participants, mean BMI decreased from $39.6 \text{ kg/m}^2 \pm 10.6 \text{ kg/m}^2$ at 6 months and to $38.6 \text{ kg/m}^2 \pm 10.3 \text{ kg/m}^2$ at 12 months. Among -TRIM participants BMI was $37.5 \text{ kg/m}^2 \pm 6.4 \text{ kg/m}^2$ at 3 months, $35.8 \pm 6.3 \text{ kg/m}^2$ at 6 months and $38.5 \pm 6.2 \text{ kg/m}^2$ at 12 months. The prevalence of obesity ($\text{BMI} > 30 \text{ kg/m}^2$) among +TRIM participants 97% at baseline, 95% at 3 months, 89% at 6 months, and 86% at 12 months, whereas among No TRIM participants was 99% at baseline, 98% at 3 months, 94% at 6 months and 100% at 12 months. The remainder of the groups were overweight ($\text{BMI} 25\text{--}29.9 \text{ kg/m}^2$). Being in the +TRIM cohort, as opposed to -TRIM, was associated with an additional weight reduction of 4.0 kg at 6 months ($p < 0.001$) and 5.7 kg at 12 months ($p = 0.02$).

After adjusting for all pre-specified covariates in the post-hoc multivariable longitudinal mixed model, the +TRIM cohort had a greater reduction in %EBW compared to the -TRIM cohort at 3 months ($p = 0.05$), and 6 months ($p < 0.01$) (Table 2).

Sensitivity Analysis

A total of 68 weights met inclusion criteria for the sensitivity analysis. The median difference between the weights was 0.19 kg (IQR $-0.09\text{--}0.63$). There was significantly high correlation between patient reported weights and vital sign charted weights (Spearman rho 0.99, $p < 0.0001$). In addition, the correlation between change in excess body weight and GERQ score at 6 months was 0.41 ($P = 0.07$).

Qualitative Focus Group Analysis

Nine patients from the TRIM program attended each of the two focus groups (22% men, median age 60 years). Themes and sample quotes from the qualitative analysis are depicted in supplemental Table 2.

In summary, GERD was perceived as a serious, frightening and painful disease that negatively impacted QOL at home and work. Many felt that due to a lack of empathy, clinicians often failed to treat their GERD seriously or provide helpful recommendations.

Although all participants wished to reduce PPI use, barriers included the fear of pain returning and the difficulty in committing to exercise and diet as an alternative approach.

With regards to the TRIM program, the group unanimously expressed positive feelings for their multidisciplinary TRIM team, as the team provided cues to healthy behavioral actions. All participants identified TRIM as a beneficial combined approach to manage GERD symptoms and lose weight.

Discussion

This mixed methods feasibility study consisted of a pre- to post-intervention analysis, a comparison of intervention versus no intervention cohorts, and a qualitative analysis of two patient focus groups to understand the effect of TRIM, a multidisciplinary patient-centered weight management program for obese patients with GERD. Overall, patients participating in TRIM had continuous improvements in symptom severity and QOL, as well as reduction in weight. Reductions in %EBW were significantly greater among TRIM participants compared to patients who declined TRIM participation. Finally, qualitative patient focus groups reinforced the benefits of multidisciplinary care and education as mechanisms to promote healthy behaviors. Thus, our feasibility study supports that TRIM is an acceptable and practical program associated with positive outcomes.

The epidemic of obesity continues to rise, and contributes a significant health care burden. Recently, several major societies developed joint practice guidelines and episode-of-care bundles on obesity and weight management, education, and resources (POWER)^{11,15}. These papers identify obesity as a major modifiable cause of gastrointestinal diseases such as GERD, and exert that gastroenterologists are integral to the multidisciplinary care of obesity¹¹. According to POWER, obesity therapy must integrate multidisciplinary care and behavioral programs providing individualized dietary and physical activity plans.

Although developed prior to POWER, TRIM provides these precise cornerstones of obesity therapy. Moreover, TRIM by design overcomes common implementation challenges such as difficulty in patient identification, provider unwillingness to refer patients, and patient disengagement^{9–11}. TRIM uniquely leverages the EHR to identify patients via automated triggers, generate semi-automated referrals, and store longitudinal patient-reported outcomes via embedded questionnaire templates. The EHR functionality minimizes workflow disruption and human error, provides ease of access to participants, and standardizes patient instruction and data collection. In addition, the functionality is generalizable across institutions and EHR portals. Thus, while in this study TRIM was personalized to patients with GERD, the multidisciplinary and electronic design and structure is such that it can be, and should be, incorporated into broader obesity programs, especially when obesity is specifically tied to a specific disease state (e.g., nonalcoholic fatty liver disease).

Although multidisciplinary care, education and engagement are considered key elements to weight management programs for GERD, the supportive literature is limited by small sample sizes and lack of follow-up or real-world generalizability^{16,17}. In this study we followed patients for six months during intervention and up to an additional six months after

the end of intervention. The positive longitudinal results in this study emphasize the sustainability of TRIM with regards to self-management strategies and patient accountability. Of note, symptom improvement remained stable at 3 and 6 months despite and ongoing overall weight reduction, suggesting that mild persistent symptoms may be independent of weight change.

The qualitative layer in this study adds an additional strength and novelty that cannot be measured through quantitative analysis alone. Patients were extremely positive about the TRIM experience, and particularly valued the multidisciplinary approach and the relationship they developed with the health educators. Furthermore, patient feedback identified key areas for future assessment such as addressing barriers faced in the work setting and cultural differences related to healthy behaviors. Patients were enthusiastic about sharing experiences and learning from others, and requested more resources related to group intervention and support forums. Overall patients were accepting of digital programs (e.g., a smartphone application) as a more accessible, long-term solution.

Through the focus groups we uncovered that many patients were unaware of and did not independently recognize the link between weight and GERD prior to TRIM participation. Yet, patients shared a strong desire to alleviate symptoms and reduce PPI use. Results from our mixed methods study suggest that weight loss becomes a more desirable and attainable goal once patients associate weight loss with symptom relief, further underscoring the value of health education. The idea that symptom relief is a powerful facilitator of healthy behaviors is intriguing and likely transcends symptom based disorders across medicine.

There are important limitations in this study, many of which are inherent to feasibility studies. Despite several attempts to reach participants, more than half of the group was lost to follow-up, introducing bias related to incomplete follow-up. We believe that the loss in follow-up relates to the work hour constraints of education sessions. In addition, the qualitative data suggests that the referring provider's enthusiasm and encouragement may drive patient participation. In fact, it is possible that some patients simply needed to be told to "lose" weight and/or the association between obesity and GERD and then decided to proceed with weight loss on their own. Similarly, the 6-month program length may not be appropriate for all patients; some patients may require a longer duration of follow-up and some may feel they have the "tools" to succeed after 1–2 visits. Future iterations of the program should maintain the flexibility to adapt to individual patient needs. Although a loss in sample size, we limited the analysis to measured data and did not impute missing data from incomplete follow-up. Given the risk of variability and potentially reduced reliability of weights derived from two sources we performed an *a priori* planned sensitivity analysis which demonstrated significantly high correlation between different weight collection types. We did not include waist measurement as an outcome in this feasibility study; however, we hope to provide participants with tape measures and instructions in order to incorporate anthropometric measurements in future studies. In addition, this was a pragmatic quality improvement study aimed to assess the effectiveness of implementing several best practice interventions simultaneously in order to minimize provider confusion and ease incorporation into the healthcare workflow (18). Although we recognize that the lack of a graded approach limits the ability to discern independent impacts, we inferred from our qualitative analysis

that two aspects were of critical importance: (1) education that increased the awareness that weight loss can improve symptoms, particularly as reflux symptoms were described as life threatening, quality impairing, and troublesome at night and at work; and (2) the frequent monitoring and patient –reporting required patients to be accountable. Recognizing that our interventions were higher quality than the current standard, our intention was to provide this best practice to all eligible patients. Finally, the comparator cohort (-TRIM) consisted of patients that self-declined participation in TRIM. There likely exist inherent differences in patients and their circumstances which impact selection to participate such as motivation, literacy, and access; this introduces a potential selection bias from unmeasurable or unaccounted confounders. The sample size limited our ability to perform propensity score matching as an alternate analysis. In addition, GerdQ scores were only collected for the +TRIM cohort, and thus we were unable to compare patient-reported outcomes between the +TRIM and -TRIM cohorts. Similarly, there is likely a bias towards TRIM participants positively reporting outcomes. However, improvements in objective outcomes, especially excess weightloss, are consistent with the symptom improvement. Future studies should include a predefined control group and collect standardized data from both intervention and control groups.

The results from this work have generated further research ideas. Simultaneous to the TRIM program we implemented a PPI tapering program for patients who derived symptom improvement while participating in TRIM. While 12-month follow-up of the PPI tapering initiative is ongoing, initial results suggest that a third of patients are willing to taper their PPI therapy, and of those over 70% are able to withdraw PPIs completely. From a health services perspective, it is essential to understand why a significant portion of patients declined TRIM enrollment and why some clinicians declined patient referral to TRIM. Future intervention designs should explore mechanisms to further automate the referral process and examine the external generalizability and viability of TRIM.

In conclusion, this prospective mixed methods feasibility study highlights the positive effects of TRIM. Patients participating in TRIM had significant symptom reduction and when compared to patients not participating in TRIM, significant weight loss. Strengths of TRIM include optimized EHR functionality, minimal interference with clinician workflow, multidisciplinary care coordination, and a patient-centered approach. Lifestyle management programs tailored to obese patients with GERD, such as TRIM, should be integrated into health promotion practices.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding: RY: Supported by NIH T32DK101363.

Research reported in this publication was supported, in part, by the National Institutes of Health's National Center for Advancing Translational Sciences, Grant Number UL1TR001422. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Abbreviations

GERD	Gastroesophageal reflux disease
TRIM	The Reflux Improvement Monitoring
EBW	Excess body weight
%EBW	percent excess body weight
NU-IRB	Northwestern University Institutional Review Board
EHR	Electronic health record
EDW	enterprise data warehouse

References

1. Park SK, Lee T, Yang HJ, et al. Weight loss and waist reduction is associated with improvement in gastroesophageal disease reflux symptoms: A longitudinal study of 15 295 subjects undergoing health checkups. *Neurogastroenterol Motil.* 2016
2. El-Serag HB, Graham DY, Satia JA, Rabeneck L. Obesity is an independent risk factor for GERD symptoms and erosive esophagitis. *Am J Gastroenterol.* 2005; 100:1243–50. [PubMed: 15929752]
3. Ness-Jensen E, Hveem K, El-Serag H, Lagergren J. Lifestyle Intervention in Gastroesophageal Reflux Disease. *Clin Gastroenterol Hepatol.* 2016; 14:175–82. e1–3. [PubMed: 25956834]
4. de Bortoli N, Guidi G, Martinucci I, et al. Voluntary and controlled weight loss can reduce symptoms and proton pump inhibitor use and dosage in patients with gastroesophageal reflux disease: a comparative study. *Dis Esophagus.* 2016; 29:197–204. [PubMed: 25516110]
5. Boeckxstaens G, El-Serag HB, Smout AJ, Kahrilas PJ. Symptomatic reflux disease: the present, the past and the future. *Gut.* 2014; 63:1185–93. [PubMed: 24607936]
6. Consensus Core Set: ACO and PCMH / Primary Care Measures Version 1.0. 2016. (Accessed January 18, 2017, at Consensus Core Set: ACO and PCMH / Primary Care Measures.)
7. Moyer VA. Force USPST. Screening for and management of obesity in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2012; 157:373–8. [PubMed: 22733087]
8. Yadlapati R, Gawron AJ, Bilimoria K, et al. Development of quality measures for the care of patients with gastroesophageal reflux disease. *Clin Gastroenterol Hepatol.* 2015; 13:874–83. e2. [PubMed: 25460560]
9. Salyers WJ Jr, Mansour A, El-Haddad B, Golbeck AL, Kallail KJ. Lifestyle modification counseling in patients with gastroesophageal reflux disease. *Gastroenterol Nurs.* 2007; 30:302–4. [PubMed: 17724407]
10. Woodruff RC, Schauer GL, Addison AR, Gehlot A, Kegler MC. Barriers to weight loss among community health center patients: qualitative insights from primary care providers. *BMC Obes.* 2016; 3:43. [PubMed: 27785364]
11. Acosta A, Streett S, Kroh MD, et al. White Paper AGA: POWER - Practice Guide on Obesity and Weight Management, Education and Resources. *Clin Gastroenterol Hepatol.* 2017
12. Yadlapati R, Pandolfino JE, O A, et al. A Weight Management Program for Obese Reflux Patients is Effective and Improves Symptoms. *Gastroenterology.* 2016
13. Jones R, Junghard O, Dent J, et al. Development of the GerdQ, a tool for the diagnosis and management of gastro-oesophageal reflux disease in primary care. *Aliment Pharmacol Ther.* 2009; 30:1030–8. [PubMed: 19737151]
14. Leavitt F. The health belief model and utilization of ambulatory care services. *Soc Sci Med Med Psychol Med Sociol.* 1979; 13A:105–12. [PubMed: 551519]

15. Brill JV, Ashmore JA, Brengman ML, et al. White Paper AGA: An Episode-of-Care Framework for the Management of Obesity-Moving Toward High Value, High Quality Care: A Report From the American Gastroenterological Association Institute Obesity Episode of Care and Bundle Initiative Work Group. *Clin Gastroenterol Hepatol*. 2017
16. Dibley LB, Norton C, Jones R. Non-pharmacological intervention for gastro-oesophageal reflux disease in primary care. *Br J Gen Pract*. 2010; 60:e459–65. [PubMed: 21144190]
17. Finley K, Giannamore M, Bennett M, Hall L. Assessing the impact of lifestyle modification education on knowledge and behavior changes in gastroesophageal reflux disease patients on proton pump inhibitors. *J Am Pharm Assoc* (2003). 2009; 49:544–8. [PubMed: 19589767]

Study Highlights

1. WHAT IS CURRENT KNOWLEDGE

- Obesity is an independent risk factor for gastroesophageal reflux disease (GERD).
- Effective weight management programs for obese patients with GERD are needed.
- The Reflux Improvement & Monitoring (TRIM) program provides multidisciplinary lifestyle education and monitoring over six months.

2. WHAT IS NEW HERE

- TRIM is associated with improvement in patient-reported symptom severity, quality of life, and weight.
- Healthcare models should consider incorporating programs such as TRIM into the management of obese patients with GERD.

Figure 1.

Structure of The Reflux Improvement & Monitoring (TRIM) program. Eligible patient is identified through electronic clinical decision support and recruited via electronic prompts and provider approval. Patient receives automated instruction to participate in TRIM. TRIM involves participation up to 6 months with health education in the form of digital, print, and verbal instruction and resources.

Figure 2.
Change in GerdQ and GerdQ-DI Scores During TRIM Intervention Among +TRIM Cohort

	Baseline	3 Months	6 Months	12 Months
No. of +TRIM participants with available data	52	52	25	12
No. of –TRIM participants with available data	89	89	56	19
P value		0.04	<0.0001	0.005

Figure 3. Change in % excess body weight (%EBW) over time in the +TRIM and –TRIM Cohorts. Model is unadjusted. P-values based on a longitudinal mixed model analysis clustered by participant (1-X observations/participant), measured in units of patient-month, and analyzed at 3, 6, and 12 month intervals.

Table 1

Baseline data for patients in the TRIM and No TRIM cohorts.

	TRIM (n=52)	No TRIM (n=89)	P-value
Age, years	54.4 ± 12.8	54.0 ± 13.4	0.85
Female sex	40 (77%)	55 (62%)	0.06
Race *			0.26
White	23 (51%)	34 (43%)	
African- American	18 (40%)	27 (34%)	
Hispanic	2 (4%)	12 (15%)	
Other	2 (4%)	6 (8%)	
Referring clinician type *			0.32
General Internal Medicine	20 (45%)	29 (36%)	
Gastroenterology	24 (55%)	51 (64%)	
Baseline weight, kg	101.8 ± 19.1	105.8 ± 22.0	0.28
Baseline excess body weight, kg	43.9 ± 18.7	44.1 ± 19.0	0.96
Baseline % excess body weight	41.8 ± 10.1	40.5 ± 10.0	0.47

* Variables missing 17 observations

Table 2

Multivariable longitudinal regression model adjusted for all covariates.

Covariates	β coefficient for +TRIM	95% CI	P-value
Gender (Female)	-0.1	-1.0, 0.7	0.72
Age	-0.0	-0.0, 0.0	0.81
Race (Referenced to White)			
Non-Hispanic Black	0.5	-0.3, 1.2	0.23
Hispanic	0.2	-0.9, 1.3	0.70
Other	0.7	-0.6, 2.0	0.27
Baseline %EBW	0.0	-0.0, 0.1	0.46
Referring clinician (Gastroenterology)	-0.2	-0.8, 0.4	0.52
Time interval	β coefficient for +TRIM	95% CI	P-value
Month 3	-1.1	-2.1, -0.0	0.05
Month 6	-2.7	-4.0, -1.4	<0.01

Confidence Interval (CI); Excess Body Weight (EBW); The Reflux Improvement and Monitoring Program (TRIM)