Text Message Intervention (TEACH) Improves Quality of Life and Patient Activation in Celiac Disease: A Randomized Clinical Trial

Kelly Haas, MD[1], Andrew Martin, PhD[2], and KT Park, MD, MS[1]

Objective To determine the impact of the Text Message Educational Automated Compliance Help (TEACH) text message intervention as a pragmatic approach for patient engagement among adolescents with celiac disease (CD) as measured by gluten-free diet (GFD) adherence, patient activation, and quality of life (QOL).

Study design Randomized controlled trial with patient recruitment at a pediatric, university-based hospital and through social media; 61 participants ages 12-24 years with CD diagnosed at least 1 year were enrolled. The TEACH intervention cohort received 45 unique text messages over a 3-month study period while the control group received standard of care treatment. Primary outcome measures included objective markers of GFD adherence included serum tissue transglutaminase IgA and deamidated gliadin peptide IgA levels. Secondary patient-reported outcomes collected via online survey included the Celiac Dietary Adherence Test, National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) Global Short Form measure of QOL, Celiac Symptom Index, and Patient Activation Measure. All measures were assessed at enrollment and after the 3-month study period. Statistical analysis performed using the 2-tailed paired Student *t* test.

Results Among the TEACH intervention group, there was significant improvement comparing enrollment scores with 3-month follow-up scores in patient activation (Patient Activation Measure score 63.1 vs 72.5, $P = .01$) and QOL (NIH PROMIS Global Mental Health 50.8 vs 53.3, $P = .01$ and NIH PROMIS Global Physical Health 50.8 vs 57.7, $P = .03$). There was no statistically significant difference in patient-reported or objectively measured GFD adherence.

Conclusions TEACH is an effective intervention among patients with CD to improve patient activation and QOL, even among a cohort with GFD adherence at baseline. *(J Pediatr 2017;185:62-7).*

Trial registration ClinicalTrials.gov: NCT02458898.

Celiac disease (CD) is an immune-mediated enteropathy caused by gluten ingestion that results in increased intestinal permeability and nutrient malabsorption. There are nearly 3 million people with CD in the US, the majority of whom are undiagnosed or untreated, with an estimated prevalence of 3-13:1000 among the pediatric population.[1-4] Uncontrolled CD can lead to poor quality of life (QOL) and morbidity, including infertility, nontraumatic fractures, and malignancy.[1-4] The only treatment for CD at this time is strict elimination of gluten from the diet.

Although the management of CD is simple in theory, lifelong adherence to a gluten-free diet (GFD) can be challenging. The adolescent and young adult population is at increased risk for poor adherence in the management of chronic illnesses.[5-7] Barriers to adherence identified among patients with chronic disease include a desire for normality and freedom, poor physical or mental well-being, and lack of support from peers, parents, or healthcare providers.[6] Adolescents with CD are more likely to be nonadherent to GFD compared with younger children or adults, particularly in social settings outside the home or when transitioning to college where they have greater independence in preparing meals and are more susceptible to peer pressure.[8-11] Patients with nonadherence in the management of chronic disease are at risk for poor QOL, adverse health outcomes, and increased healthcare costs.[7,12]

Studies among adults with CD show improvement in GFD adherence using online behavioral interventions,[13] yet there is a paucity of research among the adolescent population with CD to address GFD adherence. Growing evidence suggests that

CD	Celiac disease
CDAT	Celiac Dietary Adherence Test
CSI	Celiac Symptom Index
DGP	Deamidated gliadin peptide
GFD	Gluten-free diet
NIH	National Institutes of Health
PAM	Patient Activation Measure
PROMIS	Patient-Reported Outcomes Measurement Information System
QOL	Quality of life
REDCap	Research Electronic Data Capture
TEACH	Text Message Educational Automated Compliance Help
TTG	Tissue transglutaminase

From the [1]Department of Pediatrics, Division of Gastroenterology; and [2]Center for Clinical Informatics, Stanford University School of Medicine, Stanford University, Palo Alto, CA

Funding provided by National Institutes of Health (NIH) (T32DK007056-39), the Elizabeth and Russell Siegelman Postdoctoral Fellowship through the Child Health Research Institute, and the Stanford CTSA (UL1 TR001085) to K.H. REDCap funding from NIH/NCRR (UL1 RR025744). K.P. supported by NIH (NIDDK094868). The authors declare no conflicts of interest.

0022-3476/$ - see front matter. © 2017 Elsevier Inc. All rights reserved.

http://dx.doi.org10.1016/j.jpeds.2017.02.062

patients with chronic disease may adopt health-conscious co-management skills through online behavioral intervention or mobile technology such as text messaging.[14-17] Text messaging is a familiar form of communication among adolescents; 91% of teens with a cell phone use text messaging to communicate with an average of 30 messages sent and received per day.[18] Emerging adult[19-23] and pediatric[24-31] data from the current self-monitoring mobile health movement show that well-designed phone text messaging interventions reduce adverse health outcomes, improve adherence to therapy plans, increase patient activation, and improve overall QOL among patients with chronic disease. However, there are no studies showing similar utility of text messaging among adolescents or young adults with CD.

We hypothesize that our Text Message Educational Automated Compliance Help (TEACH) program may be a novel text message intervention to engage and educate adolescents and young adults with CD. Intended as an automated text messaging tool, we designed the components of TEACH to be a pragmatic way to improve GFD adherence, patient activation, and QOL among adolescents and young adults with CD. The primary objective of this study was to determine whether enrollment in TEACH will improve GFD adherence as measured by percent change in serum tissue transglutaminase (TTG) IgA and deamidated gliadin peptide (DGP) IgA over the 3-month study period. The secondary objective was to determine TEACH's impact on patient-reported GFD adherence, patient activation, disease symptomatology, and QOL.

Methods

The TEACH Program study (ClinicalTrials.gov: NCT02458898) is a block randomized controlled clinical trial among 61 patients ages 12-24 years with CD. The study protocol and ethical considerations were approved by the Stanford Human Subjects Research and Institutional Review Board. Informed telephone consent was obtained from parents for children <18 years of age with online assent or consent provided by study participants depending on age. Participant referral, consent, and data collection were performed through an integrated, secure Stanford Research Electronic Data Capture (REDCap) database. After obtaining consent and child assent when indicated, participants were randomized into the TEACH intervention group receiving text messages or the control group with standard of care management by their primary gastroenterologist. The control group was aware of their enrollment in a text message reminder study through the informed consent process. All participants completed 4 surveys including the Celiac Dietary Adherence Test (CDAT), National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) Global Short Form, Celiac Symptom Index (CSI), and Patient Activation Measure (PAM) online through the secure REDCap database upon enrollment and after completion of the 3-month study intervention period. Serum TTG IgA and DGP IgA were obtained at the time of enrollment and after the 3-month study intervention through Stanford or LabCorp laboratory. Total IgA levels were obtained with enrollment laboratories to evaluate for IgA deficiency.

Participants were referred from Stanford Children's Health network, Oakland Children's Hospital, or through online social media recruitment from across the US using our REDCap patient referral website and were screened for eligibility by the principle investigator over the phone. Enrollment criteria included age 12-24 years, CD diagnosed at least 1 year prior to study enrollment, access to a mobile phone and email, and the ability to read English. Sixty-one participants were enrolled of 194 participant referrals (**Figure 1**; available at www.jpeds.com).

Block randomization was performed based on enrollment TTG IgA level (<4, 4-10, or >10). Randomization algorithm was generated by coin flip and was integrated into the REDCap database programming to occur once consent and baseline outcome measures were obtained by study coordinator.

TEACH intervention was comprised of 45 unique messages developed by our study team and CD dietician (**Table I**; available at www.jpeds.com). Automated text messages were sent to the TEACH intervention cohort 2-3 times per week in the evenings over the 3-month study period via Twilio interface with REDCap study website. Text message content included 15 links to online resources such as gluten-free recipes, restaurant search tools, or CD organization websites, 15 humorous reminders to stay gluten-free, and 15 bidirectional quiz questions. A complete list of text messages sent to participants is shown in **Table I**.

Demographic information was obtained upon enrollment (**Table II**). Participants completed 4 validated patient-reported survey outcome measures (CDAT, NIH PROMIS Global Short Form, CSI, and PAM) at enrollment and after the 3-month study period. The CDAT is a measure of GFD adherence validated among adults,[32] though it has been used in a research setting among patients age 16 and above.[13] It is composed of 7 questions with scores ranging from 7 to 35; scores, <13 indicate good GFD adherence.[32] The NIH PROMIS Global Short Form is a 10-question measure of QOL validated among adults 18 years of age and above with physical and mental health components; higher scores indicate better QOL.[33] The CSI is a 16-question measure of CD activity validated among adults 18 years of age and above with scores ranging from 16 to 80; scores <30 indicate good disease control and scores >45 indicate poor disease control.[34] PAM is a 13-item measure of patient activation validated among adults age 18 years and above, though it has been used in a research setting among patients as young as 12 years of age.[35] Scores range from 0 to 100; higher scores indicate greater patient activation with an improvement by 4 points thought to be clinically meaningful.[36] Objective serum markers (TTG IgA and DGP IgA) were obtained at enrollment and after the 3-month study period through Stanford or LabCorp. The same laboratory system was used for enrollment and follow-up labs for each participant. Logs of text messages sent and participant responses were collected via REDCap study website, and anonymous participant feedback was obtained upon study completion.

Download English Version:

https://daneshyari.com/en/article/5719116

Download Persian Version:

https://daneshyari.com/article/5719116

Daneshyari.com