Evaluating the Efficacy of a Bundled Chronic Condition Management Program

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ABSTRACT

OBJECTIVES: Chronic disease management solutions have been difficult to implement at scale and in real-world clinical settings. We report on the preliminary results of an intervention designed to address these issues.

STUDY DESIGN: We performed a prospective analysis on data collected during the early trials of our intervention to assess its effectiveness and feasibility.

METHODS: We partnered with 2 physicians to recruit adults with diabetes or prediabetes. A health advisor from our team engaged each participant for 12 weeks with print information and individually tailored telephonic and text message–based counseling according to the participant's preference(s). The primary measure recorded was glycated hemoglobin (A1C), in addition to several secondary clinical and behavioral measures and participant satisfaction. All measures, except participant satisfaction, were recorded at baseline and 12 weeks, and changes were measured with non–variance-assuming *t* tests.

RESULTS: We recruited 167 participants and received participant-reported data from 122 (73%). For A1C, we recorded data for 56 participants (34%); of these, we saw a mean decrease in A1C of 0.91% (95% confidence interval [CI], 0.44%-1.38%; *P* = .0053). For participants with diabetes, the decrease in A1C was 1.53% (95% CI, 0.77%-2.28%; *P* = .0009), and for participants with prediabetes, we saw no progression toward diabetes (*P* = .2282). We saw significant improvements in most secondary measures (for most, *P* <.0001) and favorable participant feedback (mean satisfaction rating = 2.97 of 3 [95% CI, 2.91-3.00]).

CONCLUSIONS: This management model shows some promise in improving disease management in a scalable manner.

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Chronic disease in the 21st century United States has increased in prevalence for the past 15 years, and its management and treatment now consume the majority of healthcare spending.[1-3] Intensive behavioral counseling is one strategy that has been deemed both necessary and cost-effective in the effort to combat this trend. Per the guidelines of the US Preventive Services Task Force and the Affordable Care Act, intensive behavioral counseling can be covered as a preventive measure against cardiovascular disease for obese or otherwise at-risk individuals.[4,5] Although cost-effectiveness estimates vary widely, they are all well within the commonly accepted intervention threshold of $50,000 per quality-adjusted life-year added—below which, an intervention is considered to be worth the cost.[6,7]

However, several issues threaten its scalability and efficacy. One, is availability of time on the part of physicians and patients. Team-based coordination has been suggested as a solution to increase the time available to physicians, but only the most qualified clinicians (ie medical doctors, physician assistants, certified registered nurse practitioners, certified clinical nurse specialists) can be reimbursed for counseling; furthermore, patient time constraints remain a barrier even when clinician time constraints are accounted for.[8-12] Telephonic counseling has also been suggested as an option, but recent results have not shown promise.[13]

To address this issue, we set out to develop, implement, and test an innovative remote intensive counseling intervention for type 2 diabetes (T2D) as a model for other chronic disease management interventions. Utilizing "processes of change" from the Transtheoretical model and motivational interviewing techniques, we delivered a multi-channel (mail, phone, text, and/or e-mail), 12-week intensive behavioral counseling intervention to individuals with diagnoses of diabetes or prediabetes. The aim was 4-fold: 1) deliver the intervention to the participant in a comfortable environment and timeframe to improve participant engagement, 2) act as an extension of the patient's primary care provider to provide a coordinated care intervention (not an intervention delivered in parallel), 3) deliver an intervention that produces lasting results in value-based outcomes, and 4) deliver an intervention that is scalable to a large patient-per-advisor ratio.

Here, we present our preliminary results and implications to those attempting similar interventions or to those searching for novel management interventions.

METHODS

Study Design

Our design was prospective and followed a cohort receiving the intervention over 12 weeks. We had 3 main hypotheses: 1) participants would engage and find the experience favorable due to their ability to select the time and method of engagement; 2) clinicians would find the experience favorable due to our ease of enrollment, mainte-

nance of contact with them, and our contributions to their patients' value-based outcomes; and 3) it would produce significant positive results in clinical and behavioral measures of diabetes management.

Setting, Participants, Enrollment

Participants receiving the intervention were being served by 2 Alabama primary care physicians—one in an urban center and the other in a rural area—so as to test the intervention independent of geography. The physicians served as the enrollers and recruiters, and eligibility criteria for participants were as follows: 1) the clinician felt that the participant would benefit from intensive behavioral counseling for diabetes management or prevention; 2) the participant felt that he or she would benefit from intensive behavioral counseling for diabetes management or prevention; 3) the participant's last glycated hemoglobin (A1C) measurement was at, or above, 5.7; and 4) the participant was aged at least 18 years. The principle of participant opt-in was paramount, as we hypothesized that individuals who wanted intensive behavioral counseling would benefit more than those who simply followed the advice of their clinicians. All identifying information was stored in a HIPAA-secured database. Enrollment for this sample began on June 16, 2014, and ended June 17, 2015, with the last postintervention assessment occurring on September 29, 2015. In all, 167 individuals were identified and consented to participate in the intervention.

Intervention

The duration of the intervention was 12 weeks. Every participant was given standard print information and management-assisting tools in addition to being assigned to a personal health advisor, who was in weekly communication with the participant to provide support, motivation, additional education, and accountability.

The provided print material and tools were as follows: 1) 2 informational booklets—1 on diabetes self-management and 1 on healthy eating principles; 2) 1 interactive booklet encouraging participants to contemplate their goals, external facilitators, and external barriers; 3) booklets in which individuals were asked to track medication adherence, diet, and physical activity for personal and clinician viewing; 4) a blood glucose logbook; 5) a pedometer; 6) an informational card (to be carried in a purse or wallet) on suggested procedures for others to follow in the event of hypoglycemia; 7) a refrigerator magnet reinforcing healthy eating principles discussed throughout the program; and 8) 1-page informational cards, termed "mailers," focusing on individual topics of diabetes management, sent once every 1 to 2 weeks depending on the depth of the topic.

The health advisor engagement procedure was as follows. First, the participant would be engaged through mail and phone, and could choose text message and/or e-mail based on availability and preference. The participant would receive telephone sessions once per week, at a time chosen by the participant, to discuss the topic of the week, in addition to the information they had already received. The health advisor would use motivational interviewing techniques to discover participant barriers and foster the participant's creation of solutions that worked for them.[14] Various processes of change from the Transtheoretical model would be taught and/or suggested as strategies to overcome barriers and achieve health behaviors, as needed.[15]

One small goal for the upcoming week would be decided by the participant at the end of each session. In order to assist participants in staying on track, 3 text messages would be sent to the participant per week; all of which would be based on standard aspects of the week's topic or on personal matters discussed with the health advisor in the previous counseling session. The aim was usually to encourage, remind, or hold the participant accountable to their goal for the week and in the long term. Alternatively, if the participant chose e-mail but not text message as their preferred method of communication, 2 to 3 e-mails would be sent each week to accomplish the same purpose as the text messages. Any inbound communication (eg, an additional question outside of the scheduled interactions) from the participant to their health advisor was received and responded to. For matters potentially of clinical concern, the participant was encouraged to contact their enrolling clinician, and the health advisor followed up on the matter the following week.

Measures

All primary and secondary measures were recorded via participant report at baseline and again at the 12-week program completion date. The primary measure used to assess the efficacy of the intervention was A1C, measured in percent glycation.

Secondary measures were based on individual aspects of diabetes management, which were covered throughout the intervention. We were interested in testing whether comprehensive education and counseling on diabetes management made a clinically relevant difference, as well as whether counseling on individual management behaviors changed those behaviors. There were 12 secondary measures, with the first 2 being: 1) body mass index (BMI) and 2) knowledge regarding diabetes management. Knowledge was identified by our team in 4 key components of diabetes understanding: that diabetes involves higher than normal blood sugar, that diabetes is a chronic condition, the causes of elevated blood sugar, and the potential complications if left unmanaged. Participants were asked to describe their understanding of diabetes at baseline and 12 weeks, and whether a participant accurately understood all 4 concepts was measured binarily.

Other secondary measures included: 3) health self-efficacy, which was measured—for participant convenience—by 1 item, which read thus: "On a scale of 1-5, with 5 being the highest, how confident are you in your ability to improve your health?" We measured binarily whether a participant rated their confidence as 5; 4) skipped doses of medication per week (number); 5) if a participant skipped any number of doses of medication per week (binary: 0 times per week or ≥1 time per week); 6) if a participant was engaging in moderate to vigorous physical activity 2 or more times per week; 7) if a participant was eating at least 7 healthy meals per week, defined as half nonstarchy vegetables, a quarter starchy vegetables and/or grains, a quarter protein, an optional small portion of fruit, and an unsweetened beverage; 8) whether a participant had received at least 1 formal eye exam in the past 12 months; 9) whether a participant had received at least 1 formal

foot exam in the past 12 months; and 10) the number of emergency department (ED) visits a participant had in the past 3 months.

The final 2 secondary measures were: 11) the participant's understanding of healthcare cost management, identified with 4 key strategies for maintaining low healthcare costs: managing diabetes (lowering A1C), utilizing generic medications whenever possible, getting appropriate insurance, and appropriate use of the clinician's office and ED—with "appropriate" defined as understanding what was a wise use of each and what was an unnecessary use of each. We measured binarily whether a participant understood all 4 concepts by asking them to explain what they understood about these strategies. Finally: 12) satisfaction—each participant was asked at the end of the intervention to rate their satisfaction with the program by circling a smiling face, a neutral face, or a frowning face, then providing personal comments.

Statistical Analyses

For all numerical measures, the mean and 95% confidence intervals (CIs) were calculated at baseline and at 12 weeks. For all measures described above as binary, a score of 1 or 0 was given to the participant, and the percentage scoring a 1 was presented. Then, all 12-week means were compared with baseline means using 1-sided *t* tests, not assuming equal variance, to discover or disprove statistically significant differences. One-sided *t* tests were used in place of 2-sided because all of our outcomes had an ideal direction of improvement (either up or down), except for prediabetes A1C, in which we wanted to either affect a decrease or affect the prevention of an increase. Weight change, although not necessarily directionally tied to diabetes management, was also measured directionally for a decrease because the average BMI of our participants was above 30. In the future, we would like to perform and report analyses of variance and covariance between our behavioral and clinical measures; however, for this preliminary report, we only wanted to examine the efficacy of the intervention on each measure individually. All analyses were conducted using Microsoft Excel and Google Spreadsheets.

RESULTS

Of 167 individuals consenting to participate in the intervention, 122 were retained and provided data on 1 or more secondary measures throughout the program (73.05% participant retention), with 101 providing baseline data on the primary measure (A1C). Of those 101, 56 self-reported the 12-weeks' primary assessment (55.45% primary reporting retention). Participants were inconsistent in their responsiveness to secondary measures. Numerical measures are presented in **Table 1** and management threshold measures are presented in **Table 2**. Where CIs passed the minimum or maximum value possible, they were presented as the minimum or maximum.

DISCUSSION

Intervention participants saw significantly improved behavioral and clinical measures. In the context of our model condition, A1C and diabetes management behaviors significantly improved, signifying better glycemic control. Although this decrease was seen mostly in participants with diabetes, we did not detect a significant change (2-sided *t* test $P = .2282$) in A1C for participants with prediabetes, signifying that the progression to diabetes may have been delayed or prevented. Also of note is that intervention participants saw a meaningful improvement in A1C, but not in weight. We believe this to be due to the fact that we did not focus on rapid weight loss, but rather on small and sustainable goals that would increase self-efficacy and reduce blood sugar, such as appropriate medication adherence and moderate physical activity. Longer-term iterations of this intervention may indeed yield weight loss, but that remains to be seen and was not a focus of our intervention.

For our secondary measures on individual aspects of diabetes management, results were quite favorable. We saw significant differences post intervention in the percent of participants meeting management thresholds for all related aspects except cost management understanding and ED use reduction. These results seem promising to our hypothesis that our intensive counseling intervention would produce positive behavioral and clinical results. Although we hypothesized that self-efficacy, medication adherence, diet, and physical activity were the arms of our intervention most correlated with clinical improvement, in a future formal study, we hope to test the covariance between all secondary values and A1C.

Limitations and Strengths

Our hope was that, in providing the participant with the authority to choose his or her time of contact and making the intervention 12 weeks (instead of the common 24-week intensive behavioral counseling intervention), we would see high engagement and retention throughout the intervention. However, health advisors were unable to systematically connect with participants at previously agreed-upon times and by previously agreed-upon means; thus, some participants consented with the physician to enroll, and then were unreachable by health advisors. In these cases, information was delivered and participant-reported measures were requested by mail, but response rates were low. Qualitatively, health advisors determined that common reasons for this were the lack of a static schedule and that baseline measures were collected during the same call in which the program was explained, resulting in sometimes long initial calls. Although we thought this would make the data-collecting process more personal, and we explained that ensuing calls would be much shorter, this could have been a factor in the loss to follow-up.

Another method to be improved on was that we did not ask participants to ensure they had up-to-date A1C scores preceding baseline and shortly following 12 weeks. This may have increased our sample size for the primary measure, and is now standard protocol for all interventions following this analysis. A final limitation was that we did not conduct follow-up assessments at 24 and 48 weeks (approximately 6 months and 12 months) to assess the sustainability hypothesis. Since this iteration of the intervention was completed, all of these changes have been implemented with the intent to strengthen the efficacy of the intervention and our power to measure that efficacy.

Despite the aforementioned limitations, our feasibility study had several promising strengths. One is that, for the participants that did engage, we were able to provide extremely personalized

Table 1. Numerical Measures at Baseline and 12 Weeks

Measure/ Population	N	Baseline: μ (95% CI)	12 Weeks: μ (95% CI)	Change: μ (95% CI)	*P*
A1C (% glycosylation)					
Total	56	7.78 (7.19 - 8.37)	6.87 (6.53-7.21)	−0.91 (−0.44 to −1.38)	.0053[a]
With diabetes at baseline	32	9.07 (8.28-9.85)	7.54 (7.07-8.01)	−1.53 (−0.77 to −2.28)	.0009[a]
With prediabetes at baseline	24	6.07 (5.97-6.16)	5.98 (5.88-6.08)	−0.09 (−0.01 to −0.7)	1-sided = .1141 2-sided = .2282
Body mass index	90	34.41 (32.67-36.15)	33.41 (31.64-35.17)	−1.00 (−0.65 to −1.36)	.2138
ED visits within the last 3 months	70	0.26 (0.13-0.39)	0.16 (0.00-0.38)	−0.10 (0.17 to −0.37)	.2284
Skipped medications per week	96	0.52 (0.28-0.76)	0.02 (0.00-0.05)	−0.50 (−0.26 to −0.74)	.0001[a]
Participant satisfaction	32	N/A	2.97 (2.91-3.00)	N/A	N/A

A1C indicates glycated hemoglobin; ED, emergency department; N/A, not applicable.
[a]Using a threshold of P <.05, we determined this difference to be statistically significant.

Table 2. Management Threshold Measures at Baseline and 12 Weeks

Management Concept	Threshold for Management	N	% Meeting Threshold at Baseline	% Meeting Threshold at 12 Weeks	% Change (95% CI)	*P*
Medication adherence	0 doses skipped per week	96	78.12	97.92	+19.7 (11.27-28.31)	<.0001[a]
Healthy eating	7 healthy meals per week	48	50.00	91.67	+41.67 (26.41-56.92)	<.0001[a]
Physical activity	≥2 times per week	99	35.35	76.77	+41.41 (30.51-52.32)	<.0001[a]
Disease understanding	4 key concepts taught back	99	47.96	88.78	+40.82 (30.68-50.95)	<.0001[a]
Cost management understanding	4 key concepts taught back	50	70.00	82.00	+12.00 (1.32-22.68)	.0817
Self-efficacy	Self-reported 5 on the Likert scale	89	49.44	79.78	+30.34 (18.45-42.22)	<.0001[a]
Foot care	1 formal foot exam received in the past 12 months	94	43.62	69.15	+25.53 (15.73-35.34)	.0002[a]
Eye care	1 formal eye exam received in the last 12 months	86	55.81	83.72	+27.91 (17.33-38.49)	<.0001[a]

[a]Using a threshold of *P* <.05, we determined this difference to be statistically significant.

counseling with multiple contact points and a conversational environment. Participants routinely commented in an unsolicited fashion that they appreciated the accountability, the nonjudgmental setting in which to voice problems and brainstorm solutions, and the empathy and compassion of the health advisor, and they rated satisfaction with the program an average at 2.97 of 3 stars. Another advantage of the intervention was that it demonstrated successful outcomes for a meaningful percentage of participants. This is meaningfully different than fee-for-service reimbursements, such as the Chronic Care Management codes that focus on activity and process rather than effectively driving for better outcomes. Our cost per intervention per participant was approximately $300, which is 37.5% less than the annual cost of reimbursement for face-to-face chronic condition management programs sponsored by CMS.[10] Furthermore, the clinicians received regular reports on participant outcomes, but put forth no extra time outside the participant's normal visits. If we can replicate these results from remote counseling in a larger study group, we believe we can prove the scalability of remote counseling over face-to-face counseling in terms of clinician time spent and cost-effectiveness.

CONCLUSIONS

Our preliminary results from a remote intensive behavioral counseling intervention to improve diabetes management showed significant clinical and behavioral results at lower than usual financial cost while requiring less time on the part of the clinician. Although loss to follow-up and sustainability are being addressed in current iterations of the intervention, the preliminary results, in terms of clinical differences and scalability, are promising. A full-scale study comparing the intervention with usual care is underway.

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