AbleTo

Clinical Outcomes & Value Metrics

April 2022

AbleTo

AbleTo Outcomes Studies

Summary of peer-reviewed publications and white papers

Financial outcomes

Impact of AbleTo on Per Capita Resource Utilization and Health Spending among Beneficiaries from a Large National Health Plan (performed by Veracity Health Analytics)

AbleTo completed a propensity-matched analysis of resource use and total health care spending in a large group of AbleTo program graduates (N=1864) from a national health plan. The study demonstrated a 45% reduction in inpatient hospitalization and >$4000 per patient reduction in medical expenses at 12 months (with significant reductions as early as 8 weeks) resulting in an ROI of >1.5 for program graduates. The analysis was conducted by an experienced third party analytics company, Veracity Health Analytics, in collaboration with a large national health plan.

Leveraging Remote Behavioral Health Interventions to Improve Medical Outcomes and Reduce Costs. Pande RL, Morris M, Peters A, Spettell CM, Feifer R, Gillis W, American Journal of Managed Care. 2015;21:e141-e151.

This study documented a statistically significant 31% lower inpatient hospitalization rate and a significant 48% fewer inpatient days at 6 months among AbleTo cardiac program participants versus a well-matched comparison group.

Medical and behavioral health outcomes

Clinical and Workplace Outcomes From a Virtually Delivered Cognitive Behavioral Therapy Program for Pain. Mochari-Greenberger, H., Andreopoulos, E., Peters, A. and Pande, R.L. (2020), Pain Pract. doi:10.1111/papr.12867

This study evaluated clinical and workplace outcomes from 1086 AbleTo graduates with pain and behavioral health issues. Pain severity and pain interference improved by 17% and 27% respectively over 8 weeks (p<.0001). Reductions in depression, anxiety, and stress symptoms were significant and associated with reductions in pain interference (p<.0001). Absenteeism, presenteeism, and activity impairment each improved by more than 25% (p<.0001).

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Published Study
Page 36 – 40

Using Telehealth to Implement Cognitive-Behavioral Therapy. Dent L, Peters, A, Kerr PL, Mochari-Greenberger H, Pande RL. Using Telehealth to Implement Cognitive-Behavioral Therapy. Psychiatric Services. 2018. 69(4):370-373.https://doi.org/10.1176/appi.ps.201700477

This study looked at the use of telehealth to implement cognitive-behavioral therapy. Evaluation of the AbleTo program demonstrated high participant satisfaction, and significant reductions in depression, anxiety, and stress symptoms during the program period.

Published Study
Page 41 – 50

A Nationally Scaled Telebehavioral Health Program for Chronic Pain: Characteristics, Goals, and Psychological Outcomes. Mochari-Greenberger H, Peters A, Vue L, Pande RL. Telemed J E Health. 2017;23:640-648.

This study described the common characteristics (back pain, arthritis, fibromyalgia) and mood triggers (severe pain, health concerns, interpersonal relationship challenges) reported among consecutive AbleTo chronic pain program prescription use (53%). Clinically meaningful improvements in behavioral health symptoms were observed in the cohort at 8 weeks including a 52% response rate for depression symptoms.

Published Study
Page 51 – 58

A Tele-Behavioral Health Intervention to Reduce Depression, Anxiety, and Stress and Improve Diabetes Self-Management. Mochari-Greenberger H, Vue L, Luka A, Peters A, Pande RL. Telemed J E Health. 2016;22:624-630.

This study demonstrated clinically meaningful and statistically significant improvements in depression (-51%), anxiety (-45%) and stress (-45%) symptoms; blood glucose levels (-12mg/dL); and blood glucose self-testing behaviors (15% increase in frequency of self-testing) among a cohort of consecutive participants in AbleTo's diabetes program.

Published Scientific Abstract
Page 59

Prevalence of and Change in Loneliness among Older Adults Engaged in Telebehavioral Healthcare. Kashine N, Pande RL, Mochari-Greenberger H. Ann Behav Med. 2021; 55:S1–S618.

Loneliness and social isolation have increasingly been recognized as significant public health issues that can impact mental and physical health. AbleTo evaluated the prevalence of loneliness and social isolation among >1000 AbleTo participants from a national Medicare Advantage plan and found among participantslonely at baseline, mean within-person loneliness score was 35% lower at 8 weeksn (p< .0001).

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Published Scientific Abstract Page 60

Improved Medication Adherence among Diverse Participants in a Virtual Behavioral Therapy Program for Adults with Diabetes. Mochari-Greenberger H, Andreopoulos E, Bell SA, Pande RL. Improved Medication Adherence among Diverse Participants in a Virtual Behavioral Therapy Program for Adults with Diabetes. Diabetes. 2019; 68 (Supplement 1)

In this retrospective study of AbleTo participants with diabetes, medication non-adherence significantly improved by 42% over 8 weeks. Improvement was observed overall and also within sub-groups, including among those with polypharmacy (> 5 prescription medications).

Published Scientific Abstract Page 61

Improved Heart Failure Self-Care In A Medicare Population Receiving Virtual Behavioral Therapy: A Health Plan-Provider Collaboration. Mochari Greenberger H, Dennis C, Andreopoulos E, Pollock A, Peters A, Pande RL. American Heart Association Scientific Sessions 2019.

In collaboration with Humana, AbleTo demonstrated that participants with heart failure experienced improved adherence to physician instructions and heart failure self-care. A retrospective review of data from over 175 consecutive cardiac program participants with heart failure showed validated Self-Care of Heart Failure Index maintenance behavior and confidence scales were both significantly improved; awareness of physician instructions increased by 25% at 8 weeks.

Research Report Page 62

Self-Rated Health Improves over 8 Weeks among AbleTo Participants

General self-rated health is a predictor of future health care costs. AbleTo conducted a retrospective evaluation of >3,500 consecutive AbleTo participants and observed statistically significant within-person improvements in self-rated health among participants during the program period: fewer participants rated their health as poor or fair, and more rated their health as good, very good or excellent at week 8 versus week 0 (SF-36 Question 1; p<.0001).

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Digital behavioral health and impact

Published Study
Page 63-76

Evaluation of a Commercial Mobile Health App for Depression and Anxiety (AbleTo Digital+): Retrospective Cohort Study. JMIR Form Res 2021;5(9):e27570. Doi: 10.2196/27570. Anton MT, Greenberger HM, Andreopoulos E, Pande RL.

A retrospective cohort study evaluating Digital+, AbleTo's digital self-paced well-being program with cognitive behavioral therapy activities and one-on-one motivational coaching, documented significant reductions in depression, generalized anxiety, and social anxiety symptoms throughout the program.

Published Study
Page 77-90

Evaluation of an Open-Access CBT-Based Internet Program for Social Anxiety: Patterns of Use, Retention and Outcomes. Dryman MT, McTeague LM, Olino TM, Heimberg RG. Journal of Consulting and Clinical Psychology. 2017. 85 (10): 988-999

This study looked at the impact of the digital CBT program Joyable on participants with social anxiety. The Social Phobia Inventory was used to evaluate outcomes for participants over a two year period. Participants engaged in the program experienced a significant reduction in social anxiety symptoms across a wide range of symptom severity.

Research Presentation
Page 91

Prevalence and Change in Work Productivity and Activity Impairment among Employed U.S. Adults Completing a Cognitive Behavioral Telehealth Treatment for Depression and Anxiety. Anxiety and Depression Association of America, Denver, CO. Anton, M.T., Andreopoulos, E., Mochari-Greenberger, H., & Pande, R.L. (2022).

This study observed association between change in depression and anxiety symptoms and work and activity impairment at the final session among employed U.S. adults who completed an 8-week protocolized cognitive behavioral telehealth treatment for depression and anxiety.

Peer Reviewed Publication
Page 92-96

Prevalence and Change in Work-Related Impairment Among Users of a Guided Digital Intervention for Depression and Anxiety: A Retrospective Cohort Analysis. Anton, M. T., Pande, R. L., & Mochari-Greenberger, H. (2021). Retrieved from https://tmb.apaopen.org/pub/r4d8qqtx

Examination of the impact of AbleTo's Digital+ program on work-related impairment by measuring impairment in addition to mental health symptom severity.

AbleTo

Workplace productivity

White Paper Page

97-106

An Innovative Technology-Enabled Behavioral Health Solution to Improve Employee Productivity: Outcomes from a National Real-World Population. Behavioral Therapy for U.S. Workers with Comorbid Medical and Mental Health Conditions. AbleTo, Inc. (2017). New York, NY.

This paper describes the significant improvements in work productivity (including reductions in absenteeism (-55%), presenteeism (-43%) and activity impairment (-47%) observed over the 8-week program period among a diverse cohort of consecutively enrolled, employed, AbleTo participants with work productivity impairment at week 0.

Research Report Page 107-108

Work-related burnout among Digital+ users during COVID-19.

Burnout can result from unsuccessfully managed chronic workplace stress, driving adverse health and workplace outcomes. This study evaluated the distribution of work-related burnout among healthcare system employees using Digital+ pre COVID-19 cohort versus COVID-19 cohort as measured by the Copenhagen Burnout Inventory. Study results indicated that 2 in 3 users reported work related burnout during the pandemic. Users presenting with burnout at baseline experienced an average of 30% reduction in burnout score by the end of their Digital+ program participation.

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Access to care

Whiite Paper
Page 109-116

Barriers to Behavioral Health Care: Consumer Insights Reveal Low Engagement and Unmet Needs Persist. AbleTo, Inc. (2018). Mochari-Greenberger H, Pande RL. New York, NY.

This paper describes research AbleTo conducted in a nationally drawn sample of U.S. adults with employer-sponsored health insurance and elevated levels of depression, anxiety and/or stress. The study found that well established barriers to behavioral health care, including financial and stigma-related concerns, still persist today; virtually provided behavioral health care is a solution to overcome these barriers.

Value of telebehavioral health care

White Paper
Page 117-139

Telebehavioral Health Care: A Solution to Improve Cost, Access, and Quality of Care. AbleTo, Inc. and The Association for Behavioral Health and Wellness (2018). Greenberger H, Greenberg P, Huth T, Klein RM, Pande RL. New York, NY.

This comprehensive literature review, written in collaboration with the Association for Behavioral Health and Wellness, summarizes the value of virtually provided behavioral health care to improve costs, access and quality of care.

Measurement

Published Study
Page 140-147

Comparison of the DASS-21, the PHQ-8, and the GAD-7 in the Virtual Behavioral Health Care Setting. Peters L, Mochari Greenberger H, Andreopoulos E, Pollock A, Peters A, Pande RL. Heliyon; 2021:7(3).

AbleTo compared the performance of commonly used depression and anxiety symptom assessment tools, DASS-21 (Depression Anxiety Stress Scales 21), PHQ-8 (Patient Health Questionnaire-8), and GAD-7 (Generalized Anxiety Disorder-7) in an adult population with medical and behavioral health issues being treated in a virtual behavioral health care setting. The DASS-Depression and PHQ-8 and the DASS-Anxiety and GAD-7 similarly ranked symptom severity. The PHQ-8 and GAD-7 were more likely than the DASS-21 Depression or Anxiety scales to classify individuals as having above-threshold symptom severity.

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Impacts of COVID-19 on mental health

Published Study
Page 148-153

Behavioral Health in America During the COVID-19 Pandemic: Meeting Increased Needs Through Access to High Quality Virtual Care. Mochari-Greenberger H, Pande RL. Am J Health Promot. 2021 Feb;35(2):312-317. doi: 10.1177/0890117120983982d. PMID: 33554622.

The COVID-19 pandemic resulted in significant demand for mental health services, especially teletherapy. AbleTo analyzed data from initial patient clinical assessments completed during the pandemic to understand the prevalence and distribution of COVID-19 related primary concerns, and the association with depression, anxiety and stress symptom severity and found of 2,356 adults with depression symptoms consecutively enrolled in AbleTo programs between April 1 and June 30 2020, mean reduction in symptom severity was greater than 50% overall and within demographic

Published Study
Page 154-169

Prevalence of COVID-19 Related Concerns and the Association with Psychological Symptom Severity Among U.S. Adults Engaged in Telebehavioral Therapy During the Pandemic. Kashine NL, Mochari-Greenberger H, Andreopoulos E, Pande RL. Soc Work Ment Health. Epub Ahead of Print July 30 2021.

"This study looked at the links between pandemic-related sterssors and mental health observing symptom severity among a cohort of adults consecutively enrolled in a telebehavioral therapy program during the COVID-19 pandemic (N = 2,588). Anxious feelings (14.5%), work-related stressors (10.2%), and isolation (10.1%) were the most prevalent concerns, while COVID-19 concern was associated with significantly higher stress symptom scores."

By Veracity Healthcare Analytics

AbleTo Impact Analysis

Summary of Prior AbleTo Financial Outcomes Study

Study Overview

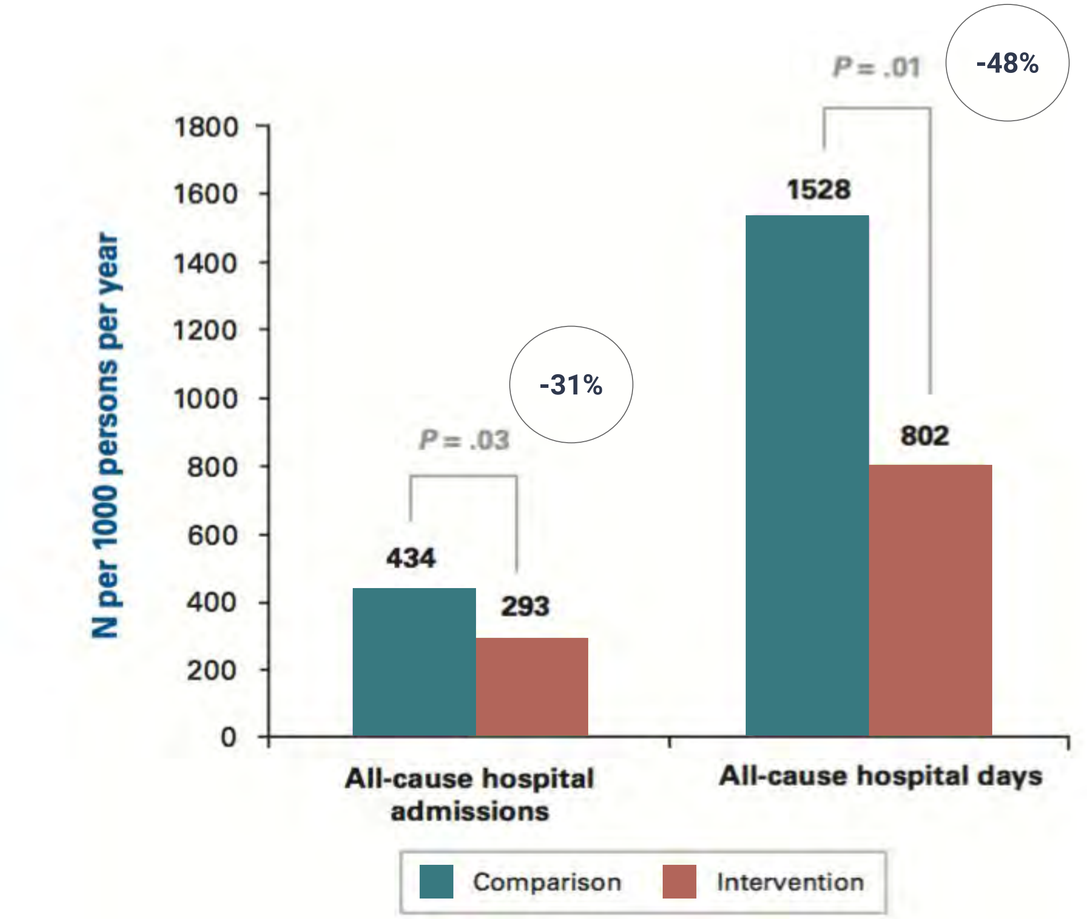
Study Design and Participants:

- Retrospective, observational cohort study
- Intervention group = 201 AbleTo cardiac program participants with cardiac disease
- Comparison group = 180 patients who were minimally exposed (engaged with AbleTo but received no more than 2 weeks of care)
- All patients with continuous coverage 6 months pre- and post- intake

Study Limitations:

- Participation bias
- Cardiac patients only
- 6 months follow up only
- Small sample size
- No examination of total medical expenses

Significantly Reduced Inpatient Utilization



Pande, RL, Morris, M, Peters, A, Spettell, C, Feifer R, and Gillis W. *Am J Manag Care*. 2015;21(2)

Expert analysis on program savings and ROI

Niteesh Choudhry, MD, PhD

- Professor, Harvard Medical School, School of Public Health
  - MD (University of Toronto); PhD Health Policy [Evaluate Sciences and Statistics] (Harvard University)
- Director, Center for Healthcare Delivery Sciences, Brigham and Women's Hospital
  - 200+ publications focused on patient engagement and predictive analytics

Veracity HEALTHCARE ANALYTICS

Veracity's Clients and Study Partners:

Rigorous analysis methodology to ensure validity of results

Commercially-insured, propensity-matched members from a national health plan with at least 6 months of pre-treatment and post treatment data

1,864

Members Not Offered AbleTo

Propensity matched on targeting characteristics that might impact spending/resource use

vs.

1,864

AbleTo Graduates

Completed 7+ weeks of the intervention, excluding those who received a second program

AbleTo

The analysis reveals substantial resource and cost outcomes

Significant reduction in IP utilization, appropriate increase in BH utilization/cost. Early significant savings sustained at month 12.

	2 Months	6 Months	12 Months
Inpatient Reduction	↓ 78%	↓ 57%	↓ 45%
Difference in Medical Spend (Non BH)	-$3,658	-$4,100	-$4,798
ROI on Average Program Cost	1.46	1.64	1.92

p-value	<.01	<.05	0.10

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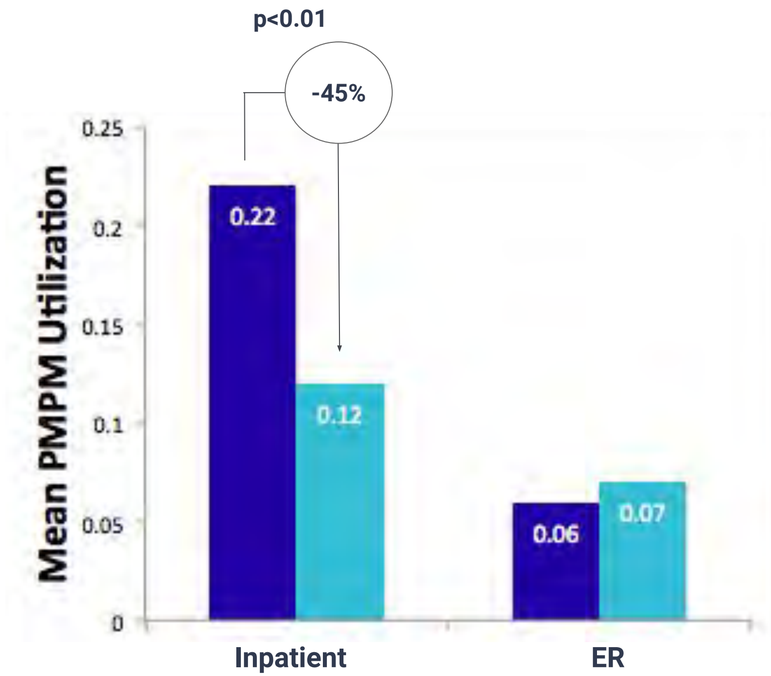
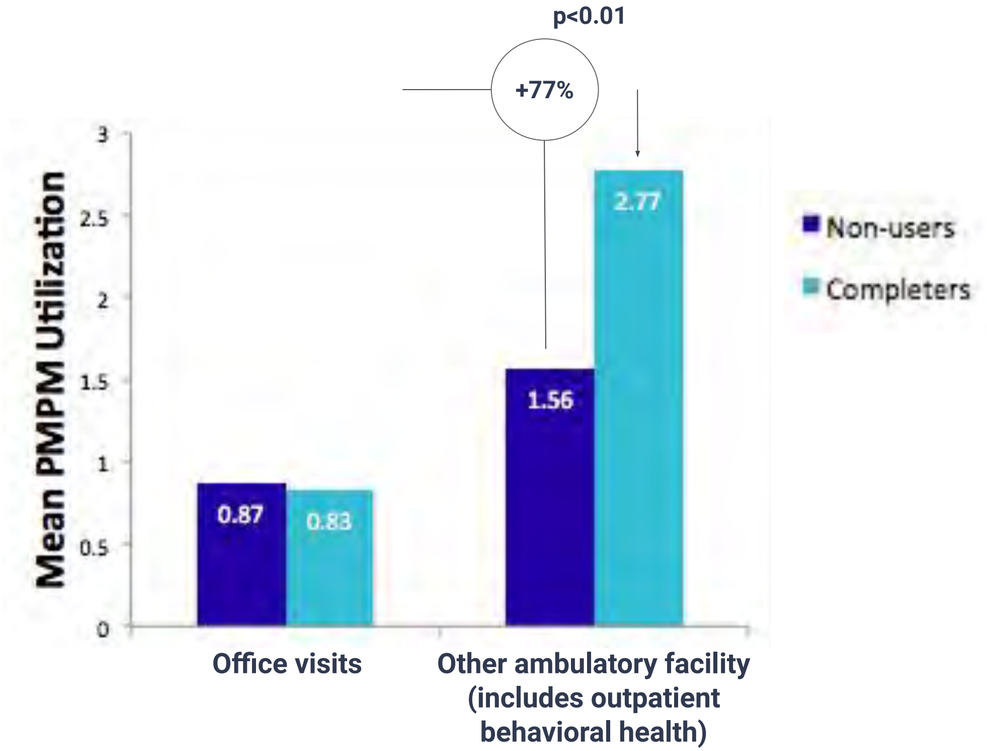
Statistically Significant Reduction in IP utilization at 12 Months Balanced with Increase in BH Encounters





AbleTo

Leveraging Remote Behavioral Health Interventions to Improve Medical Outcomes and Reduce Costs

American Journal of Managed Care

Summary

Adult members of a large U.S. commercial health plan who experienced a recent cardiovascular event were referred to participate in AbleTo's 8-week virtual behavioral health program. At 6-months post-enrollment, participants had significantly fewer all-cause hospital admissions, and significantly fewer total hospital days versus a comparison group. These research results suggest that bridging the gaps between behavioral health and medical health serves as an effective and achievable population health strategy to improve quality and lower cost of care.

Demographics

- 381 Adults
- Average age 56.3 years
- 70% male/ 30% female

Key Outcomes

- **31% reduction** in all-cause hospital
- admissions in 6 months
- **48% fewer** hospital stays at 6 months
- **Clinically meaningful reductions** in
- depression, anxiety and stress symptoms.

Successful patient engagement in a national, remotely delivered behavioral health intervention can reduce medical utilization in a targeted cardiac population.

Full Study: Pande RL, Morris M, Peters A, Spettell CM, Feifer R, Gillis W. Leveraging Remote Behavioral Health Interventions to Improve Medical Outcomes and Reduce Costs. Am J Manag Care. 2015;21: e141-e151. https://www.ajmc.com/journals/issue/2015/2015-vol21-n2/leveraging-remote-behavioral-health-interventions-to-improve-medical-outcomes-and-reduce-costs/

COMMENTARY

Précis: Successful patient engagement in a nationally available, remotely delivered behavioral health intervention can significantly improve medical outcomes and lower healthcare costs.

Leveraging Remote Behavioral Health Interventions to Improve Medical Outcomes and Reduce Costs

Reena L. Pande, MD, MSc; Michael Morris; Aimee Peters, LCSW; Claire M. Spettell, PhD; Richard Feifer, MD, MPH; William Gillis, PsyD

ABSTRACT

Objective:

The dramatic rise in healthcare expenditures calls for innovative and scalable strategies to achieve measurable, near-term improvements in health. Our objective was to determine whether a remotely delivered behavioral health intervention could improve medical health, reduce hospital admissions, and lower cost of care for individuals with a recent cardiovascular event.

Study Design:

This retrospective observational cohort study included members of a commercial health plan referred to participate in AbilTo's Cardiac Health Program. AbilTo is a national provider of tele-health, behavioral change programs for high risk medical populations.

Methods:

The program is an 8-week behavioral health intervention delivered by a licensed clinical social worker and a behavioral coach via phone or secure video.

Results:

Among the 201 intervention and 180 comparison subjects, the study found that program participants had significantly fewer all-cause hospital admissions in 6 months (293 per 1000 persons/year vs 493 per 1000 persons/year in the comparison group) resulting in an adjusted percent reduction of 31% ($P = .03$), and significantly fewer total hospital days (1455 days per 1000 persons/year vs 3933 per 1000 persons/year with an adjusted percent decline of 48% [$P = .01$]). This resulted in an overall savings in the cost of care even after accounting for total program costs.

Conclusions:

Successful patient engagement in a national, remotely delivered behavioral health intervention can reduce medical utilization in a targeted cardiac population. A restored focus on tackling barriers to behavior change to improve medical health is an effective, achievable population health strategy for reducing health costs in the United States.

Am J Manag Care. 2015;21(2):e000-e000

Despite tremendous progress in improving morbidity and mortality in patients with high-risk medical conditions, such as cardiovascular disease, healthcare expenditures continue to rise at a dramatic pace.[1,2] Innovative population health strategies that focus not only on disease but also on sustainable improvements in health and well-being are sorely needed. The anticipated benefits include happier, healthier patients, ultimately leading to lower healthcare costs. Existing strategies to improve health have unfortunately not adequately focused on addressing the behavioral determinants of health, which when adequately treated may lead to tangible optimization of medical health and reductions in medical utilization.

For many individuals with medical conditions such as cardiovascular disease, concomitant behavioral health issues—such as depression, stress, and anxiety—are common and pose substantial challenges to recovery from medical illness.[3] Even in those individuals who do not meet the clinical criteria for behavioral health concerns, inadequate resiliency to cope with the challenges posed in the face of a medical or life event can significantly impact health. In patients with a recent cardiovascular event, such as myocardial infarction (MI), coronary artery bypass surgery, or congestive heart failure, major depression is known to affect as many as 1 in 4 individuals and can lead to adverse cardiac outcomes, greater all-cause mortality, and significantly greater healthcare utilization.[4-11] Addressing these behavioral health issues and helping patients develop the life skills needed to overcome barriers to self-care and self-management are necessary prerequisites to improving medical health and lowering healthcare costs.

Aetna, a national health benefits company, enhanced its care management programs in 2011 by collaborating with AbilTo, a network of behavioral health providers, to provide structured, condition-specific behavioral health programs to its members identified with specific medical

conditions. We hypothesized that an intervention that successfully engages patients to address the behavioral health issues that commonly accompany high-risk medical conditions, such as cardiovascular disease, would lead to improved health resource utilization and lower healthcare costs. Accordingly, we conducted a retrospective study to assess the impact of AbilTo's Cardiac Health program, a remotely delivered behavioral health intervention, on all-cause hospital readmissions and total hospital days during the 6-month follow-up period in a commercially insured population of individuals with cardiovascular disease.

METHODS

Study Design

A retrospective, observational study design was used to compare individuals who had completed at least 7 weeks out of the 8-week AbilTo program with those who had completed the initial assessment and 2 weeks or fewer of the program. Individuals with partial program completion (ending anytime between week 3 and week 6) were not included in this analysis.

Study Groups

Commercially insured patients were included in the study if they met the following inclusion criteria: 1) referral from Aetna to AbilTo's Cardiac Health Program based on evidence of a recent cardiovascular event; 2) completion of an initial consultation with an AbilTo therapist; and 3) availability of continuous enrollment with Aetna 6 months prior to and 6 months post AbilTo program intake. This approach was selected so that baseline behavioral health symptom scores were available for all individuals, as these symptoms can independently affect the utilization and cost outcome measures. All participants had Aetna as primary healthcare benefits provider. Cardiovascular events were defined on the basis of hospitalization or outpatient claims submitted with a principal diagnosis code from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) for myocardial infarction (410.xx), intermediate coronary syndrome (411.xx), or cardiac dysrhythmia (427.xx), or with a principal procedural code from Current Procedural Terminology-10 (CPT-10) for coronary artery bypass surgery, valve surgery, coronary stenting, or angioplasty.

Participants

Between September 2011 and May 2013, 552 participants were referred to AbilTo's Cardiac Health program and completed an initial consultation. Of these, 251 individuals completed 7 weeks or more, 241 completed 2 weeks or fewer of the program, and 60 participants were excluded on the basis of partial program completion (completing between 3 and 6 weeks). After applying the requirement for 6 months pre-intake and 6 months post intake eligibility for Aetna medical benefits, there were 201 individuals remaining in the intervention group and 180 individuals in the comparison group.

Intervention

AbilTo's programs are based on widely accepted behavior change tools, including cognitive behavioral therapy (CBT), acceptance and commitment therapy (ACT), mindfulness, motivational interviewing, and other related, evidence-based, best-practice approaches. All protocols are crafted by AbilTo's clinical team in collaboration with an advisory group consisting of psychiatrists, psychologists, and other medical professionals. All programs are delivered remotely by telephone or secure video, and the care is administered by a specially trained provider team consisting of a behavioral health provider (a licensed clinical social worker [LCSW] or equivalent) and a behavioral coach. All providers receive American Social Work Board-certified training administered specifically by AbilTo in order to ensure delivery of AbilTo's best-practices treatment protocols. The programs are all 8 weeks in duration and consist of 16 sessions in total. Program participants undergo a one-time clinical intake session ("initial consultation") with a LCSW followed by separate weekly one-on-one sessions with both a LCSW and a behavioral coach for a total of 8 weeks. Providers participate in case conferences under the guidance of a LCSW clinical supervisor during the course of each program to review the participant's progress. The clinical supervisor also reviews all case notes on a weekly basis to ensure high quality and adherence to the treatment protocols. A proprietary content management system ensures consistent delivery of program content and provides a secure platform in compliance with the Health Insurance Portability and Accountability Act, to allow sharing of clinical notes among the LCSW, behavioral coach, and clinical supervisor.

Primary Outcome Measures

The primary outcome measures were all-cause hospital admissions and total hospital days in the 6-month period from the date of initial consultation. Additional outcome measures included: total emergency department (ED) visits; outpatient visits, including behavioral health

(BH) visits; and cardiac-specific hospital readmissions and hospital days. Outcome measures were derived from Aetna medical claims data that included facility and professional services. Claims for AbilTo sessions were adjudicated as behavioral health visits by the participants' health plan, and were included in the overall BH outcome metric.

Secondary Outcome Measures

Severity of depression, anxiety, and stress were evaluated using the Depression Anxiety Stress Scale 21 (DASS-21), a scale to measure these behavioral health dimensions that has been widely validated in multiple clinical populations.[12-14] The DASS-21 was administered by an LCSW at baseline (for both groups) and at program completion (intervention group only). Baseline demographics and presence of clinical conditions were collected from Aetna's administrative databases. Scores representing each participant's risk of future healthcare usage was calculated using Ingenix Episode Risk Group software.[15]

Statistical Methods

The descriptive analyses of baseline differences used t tests for continuous variables and $\chi 2$ tests for categorical variables. Multivariable logistic regression was used to test the odds of binary outcomes, such as likelihood of an inpatient admission or ED visit, controlling for demographic and baseline differences between the groups. Poisson or negative binomial multivariable regression was used to test the differences in count data such as inpatient admissions, ED visits, and office visits between the groups. All analyses were conducted using SAS 9.2 software (SAS Institute Inc, Cary, North Carolina).

RESULTS

Patient Population and Engagement

Participant identification for the AbilTo program intervention was made on the basis of a triggering cardiac event. Individuals included in this study were primarily referred by nurses evaluating individuals as part of care management programs led by the health plan. Participants were additionally identified by targeted outreach to at-risk eligible individuals known to have a recent cardiovascular event identified on the basis of relevant *ICD-9-CM* or CPT-10 codes as described above. Of these, 552 individuals were referred for participation, completed an initial consultation, and were eligible for this analysis. As shown in **Figure 1**, of the 552 individuals referred who completed an initial consultation, 394 individuals (71%) enrolled (ie, completed week 1), and of these 394 individuals, 242 (61%) completed the program. To ensure completeness of data for analysis, individuals were required to have been enrolled in the health plan for the 6-month pre and post periods. Therefore, we were left with 201 individuals in the intervention group and 180 individuals in the comparison group for the final study population.

Baseline characteristics

The baseline characteristics were very well balanced between the 2 study groups (**Table 1**). The average age was 56 years in both groups, and a similar proportion of both groups were male (70% in the intervention group and 67% in the comparison group). Although there were slightly more individuals in the intervention group from the Northeast region and fewer from Midwest ($P = .04$), the groups were well balanced with respect to the proportion of participants residing in rural, suburban, and urban community settings. The prevalence of baseline comorbid clinical conditions was similar in the 2 groups, including rates of diabetes, hypertension, and hyperlipidemia (Table 1). There were no significant differences in average baseline maximal DASS-21 scores for depression, anxiety, and stress (Table 1), and more than 60% of participants in both groups fell into the normal subclinical depression range on the DASS-21 scale (**Figure 2**). In addition, there was a nonsignificant trend towards more individuals in the comparison group (43.3%) falling in the normal range on all 3 dimensions of the DASS-21 scale compared with the intervention group (32.2%). There was no significant difference in the prospective risk scores between the 2 groups (6.39 ± 5.2 in the intervention group vs 6.85 ± 6.2 in the control group; $P = .43$), and baseline medical utilization (in the 6-month period prior to clinical intake) showed no significant differences between the 2 groups with similar rates of pre-period total medical expenditures, total inpatient expenditures, inpatient admissions, cardiac-specific inpatient admissions, ED visits, and total outpatient services (**Table 2**). The only difference noted was higher utilization of outpatient behavioral health services in the comparison group at baseline (1544 per 1000 persons per year vs 842 per 1000 persons per year in the intervention group; $P < .0001$).

Outcomes

Individuals in the AbilTo intervention group had significant reductions in severity of all components of the DASS-21 score, including depression, anxiety, and

stress (Figure 3). During the 6-month follow-up period, the intervention group had 38% fewer total hospital admissions (386 admissions per 1000 persons per year vs 622 per 1000 persons per year in the comparison group) (Table 3). After multivariable adjustment for demographic variables, baseline risk score, and baseline depression score, as well as pre-period medical utilization, the intervention group had a statistically significantly 31% fewer hospital admissions ($P = .03$) during the 6-month follow-up period (Figure 4). Interestingly, a similar proportion of individuals in each group were hospitalized during the 6-month period (15% in the intervention group vs 21% in the comparison group, $P = .19$). However, there was a trend ($P = .16$) towards more individuals in the comparison group with multiple (2 or more) admissions (7.2%) compared with fewer multiple admissions in the intervention group (3.5%).

Individuals in the AbilTo intervention group had 63% fewer total inpatient hospital days in the 6-month follow-up period (1455 days per 1000 persons per year in the intervention group compared with 3933 days per 1000 persons per year in the comparison group). These data were statistically significant with an adjusted percent reduction of 48% ($P = .01$) even after accounting for demographics, baseline risk, baseline depression scores, and pre-period medical utilization.

There was no significant difference in utilization of ED services in the 2 groups, although there was a trend towards fewer ED visits in the intervention group (505 per 1000 persons per year vs 689 per 1000 persons per year in the comparison group; adjusted $P = .40$). The intervention group had significantly more behavioral health visits, almost entirely accounted for by participation in the AbilTo program itself (19,713 visits per 1000 persons per year vs 2822 per 1000 persons per year in the comparison group; adjusted $P < .0001$). Excluding behavioral health visits, there were no differences in utilization of all outpatient services (34,634 visits per 1000 persons per year vs 31,167 per 1000 persons per year; adjusted $P = .19$), nor were there any differences in cardiac-specific outpatient visits ($P = .33$).

Healthcare Expenditures

To determine the potential cost savings derived from program participation, we calculated the potential cost savings attributable to the significant reduction in total days in the hospital. To estimate the potential savings, we first determined the average total cost of an inpatient hospital day (including facility, professional, and ancillary charges) for the comparison group in the 6-month follow-up period using claims data for this population. Individuals in the comparison group averaged 1.88 inpatient hospital days in the 6-month follow-up period, and the average cost was $4500 per hospital day. Using the adjusted percent difference in total inpatient hospital days of 48% between the comparison group and the AbilTo intervention group, each individual completing the AbilTo program would be expected to avoid an average of 0.95 inpatient hospital days. Thus, the 202 individuals in the intervention group were estimated to have saved 191.9 hospital days. Applying the average cost per hospital day of $4500, we estimated the individuals who fully participated in the AbilTo program saved $864,000 in the 6-month follow-up period. Comparing this cost saving with the estimated total program cost demonstrated an overall total cost savings as early as 6 months.

DISCUSSION

We demonstrated that an 8-week remotely delivered behavioral change intervention was associated with a cost savings, driven by an adjusted 48% reduction in total inpatient days and 31% reduction in all-cause hospital admissions in the 6-month follow-up period. These substantial reductions in healthcare utilization and associated cost savings were attributable to the delivery of a high-quality behavioral health program for this high-risk group of patients with cardiovascular disease. This study shows that focused targeting of patients with high-risk clinical conditions coupled with highly successful engagement strategies can lead not only to meaningful behavioral health improvements but also to improved medical outcomes and lower healthcare expenditures.

It has been long recognized that behavioral health issues can be both a cause and a consequence of medical disease.[16] In individuals with cardiovascular disease, comorbid behavioral health concerns are common, affecting up to 25% of patients,[11,17] and result in poorer adherence to medications and lifestyle recommendations and worse overall clinical outcomes, including increased hospital readmissions and higher mortality.[4-8,18-20] Taken together, inadequate management of behavioral health issues can lead to unnecessarily greater medical utilization and as much as a doubling in the cost of care.[21] It stands to reason that a program that successfully influences behavioral health could have a profound impact on overall health, medical utilization, and total health expenditures. However, prior studies to assess the effect of behavioral health interventions in cardiovascular disease have met with mixed results. For example,

the Enhancing Recovery in Coronary Heart Disease (ENRICHD) trial investigated the effects of CBT, with or without pharmacologic intervention, on post-MI patients with depression, and found no difference in the primary end point of event-free survival at an average follow-up of 29 months.[22] On the other hand, a follow-up evaluation of the ENRICHD study data showed that the intervention led to reduced late-term mortality with the benefits corresponding to the degree of improvement in depression.[23] Other studies using purely a pharmacologic intervention for depression have not shown an impact on cardiovascular outcomes or mortality.[24-26] A few recent studies have employed a remote or Internet-based approach to reach patients with cardiovascular disease and have demonstrated improvements in depression, adherence, and quality of life.[27-29]

Our study and our intervention differ from the existing literature in several important ways. First, we did not design our intervention to focus only on improvements in behavioral health or cardiac outcomes. Instead, our goal was to demonstrate that successful targeting and engagement of high-risk cardiac patients in a behavioral health intervention would impact 2 specific outcomes: 1) medical utilization and 2) healthcare expenditures. The impact of treating behavioral health on these critical components of the healthcare continuum has not previously been well studied in cardiovascular disease. Second, our intervention differs from usual behavioral healthcare or pharmacotherapy in several unique ways that promote greater engagement and ultimately more successful outcomes. The studied intervention features a collaborative care model utilizing the expertise of a licensed clinical social worker and a behavioral coach. These providers work in partnership with one another in the care of each individual patient and also receive clinical oversight by a LCSW supervisor. Moreover, the protocoled nature of the intervention using "best practices" ensures high quality and consistent program content delivery across the United States.

Finally, acknowledging that engagement itself may be a barrier to care for patients with comorbid medical and behavioral health conditions, the program uses remote care delivery by phone or video to simplify engagement and maximize participation. The success of this approach is highlighted by a high 61% completion rate among those who enroll in the program after initial clinical intake. The importance of ease of engagement is highlighted by recent studies demonstrating the value of home-based or phone-based support in improving quality of life in patients with cardiac disease.[27-30] It has become increasingly clear that outcomes can be best optimized when utilizing a strategy that combines both successful engagement and high-quality care programs that focus on meaningful behavior change skills.

While prior studies have solely focused on individuals with depression and cardiovascular disease, our study is unique in that more than 60% of individuals in both the intervention and comparison groups had scores on the depression dimension of the DASS-21 scale below the clinical threshold for depression, and between 30% to 40% had normal scores in all 3 dimensions of the scale. This underscores the fact that even individuals who do not meet the formal criteria for clinical depression may benefit from a behavioral health intervention focused on addressing and overcoming barriers to change. As described above, this intervention utilizes a combination of evidence-based, rigorously evaluated approaches, including CBT, ACT, motivational interviewing, and mindfulness, among others. As demonstrated here, these approaches have significant benefit not only for individuals with clinical depression but also for individuals with stress, anxiety/panic, and medical health conditions, as is the case in this cardiac population, or a variety of other situations where therapy and coaching can help build the life skills needed for better self-care and improved overall health.

By targeting individuals at a moment when they may be particularly receptive to change (ie, after a recent medical event), by focusing on achieving successful patient engagement, and by ensuring high-quality and consistent program delivery, our intervention was able to reduce all-cause hospital admissions and total days spent in the hospital, and produce a corresponding significant cost savings. That actual healthcare savings that accrue from our behavioral health intervention delivers on the promise that by virtue of improved well-being, high-quality behavioral healthcare can indeed lead to measurable improvements in medical health and lower healthcare costs. These results serve as a reminder that helping patients to overcome their barriers to change can improve overall health and well-being and reduce the cost of care simultaneously.

Limitations

There are several limitations to this study that should be considered. The study was designed as a retrospective observational study, and as such we cannot exclude the possibility of participation bias. However, the comparison population had completed the initial intake consultation and was remarkably similar to the intervention

group with respect to almost all baseline measurements: demographics; comorbid clinical conditions; baseline medical utilizations and medical expenditures; and baseline depression, stress, and anxiety scores. One significant difference noted in baseline characteristics was a differential in utilization of outpatient behavioral health services in the 6-month period prior to intervention. We theorize that this difference might have been one of the reasons why individuals in the comparison group chose not to participate in the AbilTo intervention. However, it is important to consider the impact that this difference might have had on utilization in the follow-up period. Given that baseline utilization of behavioral health services in many medical conditions is recognized to result in greater medical utilization, we accounted for these differences in several ways in our analysis.

First, all regression analyses were adjusted for this baseline utilization data. Second, analyses also adjusted for a prospective risk score, a measure to predict current and future healthcare usage,[15] and this score was no different at baseline between the 2 groups. Moreover, the absolute rate of pre-period utilization (1544 per 1000 members per year) was small in comparison to the utilization in the post period (19,713 per 1000 members per year), which was largely accounted for by AbilTo program participation. As such, while there were statistical differences, the absolute rates may not have been large enough to have a clinically meaningful impact on outcomes. Even after adjusting for these differences, our analysis shows significant reductions in hospital admissions and total days in the hospital even after full multivariable adjustment for many potentially confounding factors.

Second, though the sample size allowed adequate power to see significant reductions in the primary end point, the small sample size may have limited the ability to detect differences in secondary end points. Finally, the study included only individuals with primary commercial insurance and did not include individuals with Medicaid or Medicare, or the dual-eligible population. While we anticipate that similar benefits would accrue in these populations, the study does not allow us to generalize to this wider population.

CONCLUSIONS

These data demonstrate that a high-quality, short-duration, remotely delivered population health strategy utilizing a behavioral health intervention can lead to demonstrable benefits in behavioral health, medical health outcomes, and overall cost of care. A scalable intervention of this nature has the potential to reach a wide population of individuals in need. Successful patient engagement and the meaningful behavior change that results are necessary prerequisites to improving medical health and reducing the burgeoning costs of healthcare in the United States.

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AbilTo and Aetna were both directly involved in the design and conduct of the study, as well as in collection, analysis, and interpretation of the data. All authors contributed to study concept and design.

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Author Disclosures: Dr Pande reports being an employee of and holding an equity interest in AbilTo. She serves as AbilTo's Chief Medical Officer. She is also a physician in the Cardiovascular Division at Brigham and Women's Hospital and instructor at Harvard Medical School. Ms Peters reports being an employee of and holding an equity interest in AbilTo. She serves as AbilTo's Chief Clinical Officer. Dr Feifer reports being an employee and shareholder of Aetna, where he serves as National Medical Director and leads the Department of Clinical Consulting, Strategy, and Analysis. Ms Spettell reports being an employee and shareholder of Aetna, where she serves as Executive Director in the Data Science department. Mr Gillis, reports being an employee and shareholder of Aetna and serves as the Director of Clinical Health Services. Mr Morris reports being an employee and shareholder of Aetna, where he holds the position of Senior Informatics Manager in the Data Science department. No other potential conflicts of interest relevant to this article were reported.

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Take-Away Points

- Inadequately addressed behavioral health issues commonly accompany medical conditions and account for worse medical outcomes and greater healthcare utilization.
- This study demonstrates that a remotely delivered behavioral health intervention targeted to individuals with high-risk medical conditions can indeed reduce medical resource utilization and lower healthcare costs within 6 months.
- This study confirms that a collaborative strategy to bridge the gaps between behavioral health and medical health serves as an effective and achievable population health strategy to improve quality and lower cost of care.

Table 1. Baseline Characteristics of the Study Populations

	Comparison	Intervention	*P*
Total population (n)	**180**	**201**	
Demographic characteristics			
Age in years, mean ± SD	56.6 ± 6.8	56.3 ± 7.3	.68
Male gender (%)	67%	70%	.45
Employee (vs spouse); %)	72%	67%	.36
Region			.048
Northeast (%)	38%	48%	
Midwest (%)	18%	9%	
Southeast (%)	23%	20%	
West (%)	21%	23%	
Community designation			.88
Urban	31%	30%	
Suburban	33%	35%	
Rural	36%	35%	
Baseline medical conditions			
Ischemic heart disease	82.2%	84.7%	.52
Heart failure	32.8%	31.2%	.74
Diabetes mellitus	30.6%	35.6%	.29
Hyperlipidemia	82.2%	87.6%	.14
Hypertension	71.7%	77.7%	.17
Obesity	13.3%	14.4%	.77
Cerebrovascular disease	6.7%	13.4%	.03
Peripheral artery disease	9.4%	12.4%	.36
Atrial fibrillation	20.6%	14.9%	.14
Ventricular arrhythmia	14.4%	9.4%	.13
COPD	9.4%	7.9%	.60
Chronic renal failure	8.3%	7.9%	.88
Anxiety	8.3%	6.4%	.48
Depression	16.7%	13.4%	.37
Low back pain	18.9%	15.3%	.36

COPD indicates chronic obstructive pulmonary disease.

Table 2. Baseline Medical Resource Utilization (in the preceding 6-month period)

	Comparison	Intervention	*P*
Total inpatient admissions, n (%)	156 (86.7%)	178 (88.1%)	.67
Emergency department visits, n (%)	62 (34.4%)	56 (27.7%)	.16
Inpatient utilization (n per 1000 persons/year)			
All-cause hospital admissions	2444	2406	.81
All-cause hospital days	11,578	10,277	.30
Cardiac-specific admissions	1578	1634	.67
Cardiac-specific hospital days	7367	7198	.85
Emergency department utilization (n per 1000 persons/year)	922	762	0.29
Outpatient utilization (n per 1000 persons/year)			
Total outpatient visits	21,956	20,851	.55
Behavioral health-specific outpatient visits	1544	842	<.0001

Table 3. Medical Resource Utilization in the 6-Month Follow-up Period

	Unadjusted			Adjusted[a]			
	Comparison	Intervention	% Difference	Comparison	Intervention	% Difference	*P*[a]
Inpatient utilization (n per 1000 persons/year)							
All-cause hospital admissions	622	386	–38%	434	293	–31%	.03
All-cause hospital days	3933	1455	–63%	1528	802	–48%	.01
Cardiac-specific admissions	144	109	–24%	91	65	–28%	.17
Emergency department utilization (n per 1000 persons/year)	689	505	–26%	468	394	–15%	.40
Outpatient utilization (n per 1000 persons/year							
Total outpatient visits (excluding behavioral health)	31,167	34,634	+11%	29,918	33,959	+13.5%	.19
Cardiac-specific outpatient visits	4400	4347	–1.2%	3811	4207	+10%	.33
Behavioral health-specific outpatient visits	2822	19,515	+592%	2591	19,713	+660%	<.0001

[a]After multivariable adjustment for age, gender, prospective Episode Risk Group score at baseline, employee versus spouse, depression risk score at baseline, HMO versus PPO, 6-month pre-period medical utilization, and geographic designation (rural, urban, suburban)

Figure 1. Program Participation Waterfall Diagram

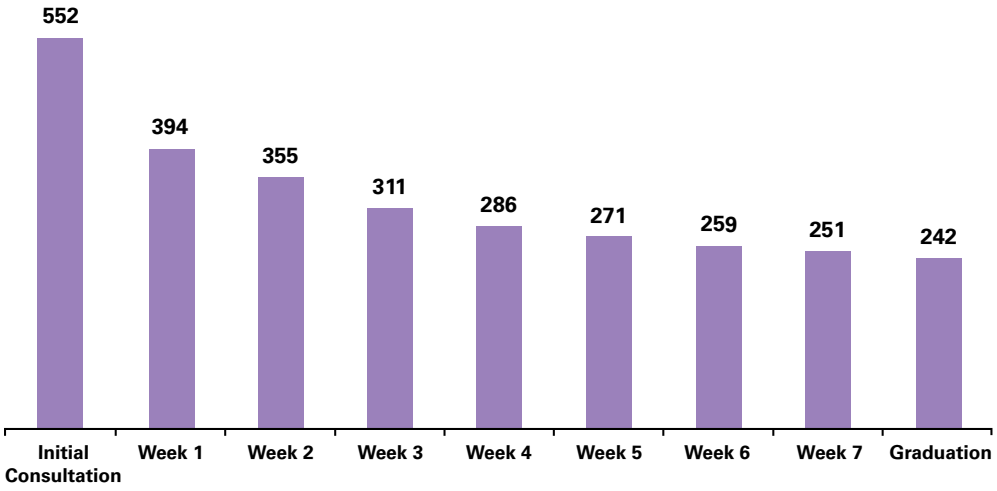
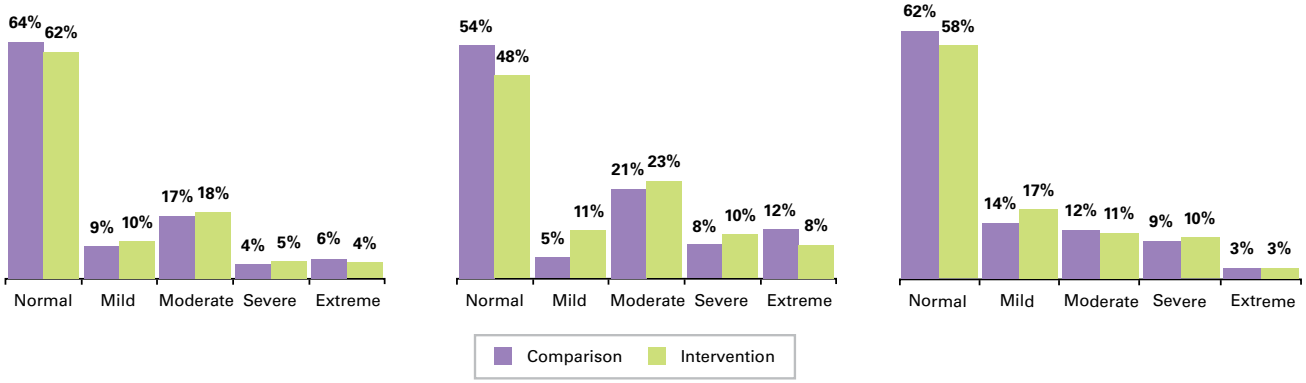
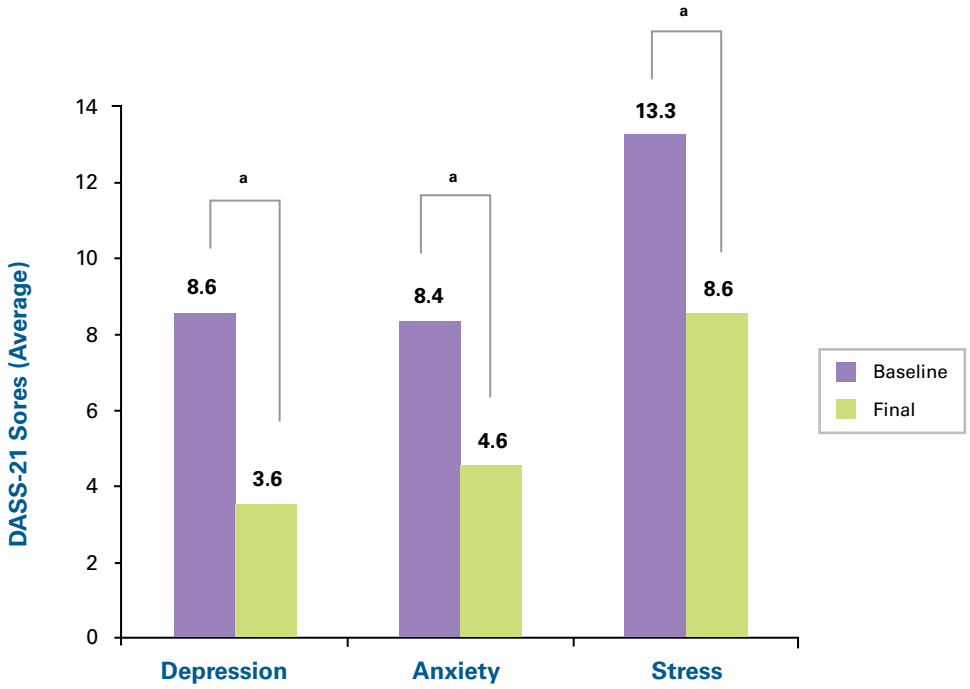


Figure 2. Baseline Depression, Anxiety, and Stress Scores (DASS-21)



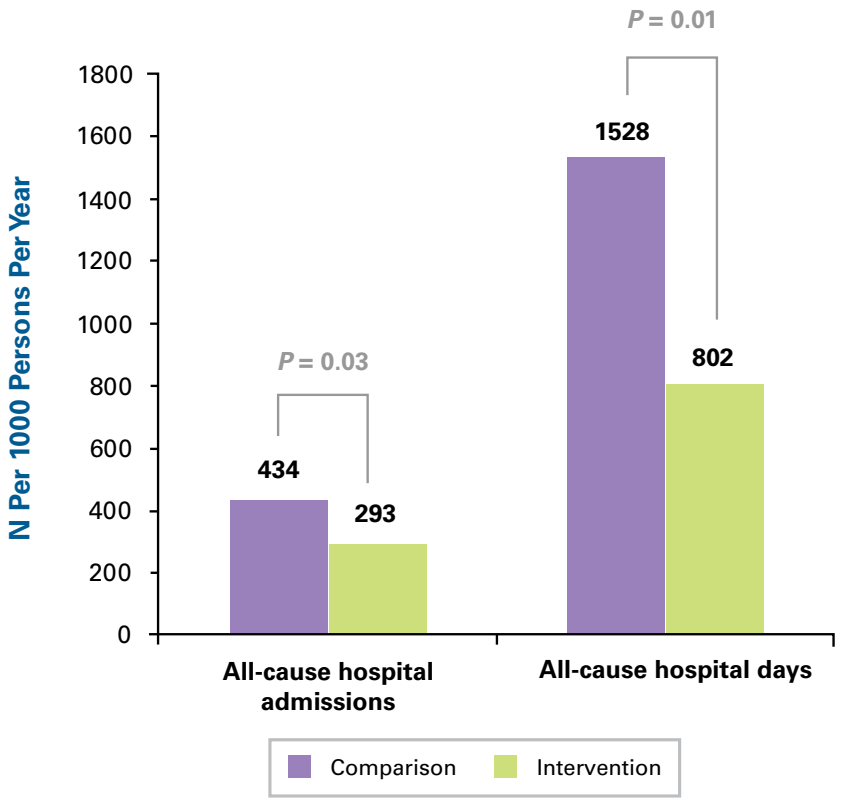
P = not significant for all comparisons.

Figure 3. Improvements in Behavioral Health Scores (DASS-21) in the Intervention Group in the 6-Month Follow-up Period



[a]*P* <.0001.

■ **Figure 4.** Regression-Adjusted Differences in Annualized Inpatient Utilization in the 6-Month Follow-up Period



Analyses are adjusted for age, gender, prospective Episode Risk Group score at baseline, employee versus spouse, depression risk score at baseline, health maintenance organization versus preferred provider organization, 6-month pre-period medical utilization, and geographic designation (rural, urban, suburban).

AbleTo

Clinical and Workplace Outcomes from a Virtually Delivered Cognitive Behavioral Therapy Program for Pain

Pain Practice

Summary

AbleTo conducted a retrospective analysis of the experience more than 1,000 participants who completed our structured, evidence-based telebehavioral therapy program. Results showed that individuals living with pain and behavioral health needs who completed a high-quality behavioral health treatment program had improved pain, emotional and functional symptoms. This new research provides compelling evidence that by treating the behavioral health needs of individuals living with pain we can effectively improve physical, mental and workplace function.

Demographics

- 1,086 participants
- Average age 53 years
- 61% male/ 29% female

Key Outcomes

- **17% reduction** in pain severity
- **27% mean reduction** in pain interference, representing clinically meaningful improvement among 54.5% of participants
- **Reductions** in depression, anxiety, and/or stress symptoms were significant and associated with reductions in pain interference
- **>25% improved** absenteeism, presenteeism, and activity impairment

High-quality, structured behavioral health care delivers significant positive results on the emotional and physical health and function of people living with chronic pain.

Full Study: Mochari Greenberger, H., Andreopoulos, E., Peters, A. and Pande, R.L. (2020), Clinical and Workplace Outcomes From a Virtually Delivered Cognitive Behavioral Therapy Program for Pain. Pain Pract. doi:10.1111/papr.12867 https://onlinelibrary.wiley.com/doi/abs/10.1111/papr.12867

ORIGINAL ARTICLE

Clinical and Workplace Outcomes From a Virtually Delivered Cognitive Behavioral Therapy Program for Pain

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■ **Abstract**

Objectives: To evaluate clinical and workplace outcomes from an evidence-based virtual behavioral therapy program for individuals with pain and behavioral health issues.

Methods: This was a retrospective de-identified data analysis among a cohort of 1,086 participants enrolled in a standardized, evidence-based telebehavioral therapy program between September 1, 2016, and August 31, 2017 (mean age 53 ± 11.5 years; 29% male). The program was delivered over approximately 8 weeks by licensed therapists and behavior coaches by telephone or video, and tailored to the pain management and behavioral health goals of each participant. Structured measurements were documented in the electronic clinical record, including demographics, comorbidities, pain severity (Pain Intensity, Enjoyment of Life, General Activity tool), behavioral health symptoms (Depression, Anxiety and Stress Scale short form), and productivity (Work Productivity and Activity Impairment survey).

Results: At baseline, participants had high average pain severity (5.8/10 points), high frequencies of behavioral health symptoms (68%), and activity impairment (90%); absenteeism (34%) and presenteeism (75%) were observed among employed individuals. Pain severity and pain interference improved by 17% and 27%, respectively, over 8 weeks ($P < 0.0001$). Reductions in depression, anxiety, and stress symptoms were significant and associated with reductions in pain interference ($P < 0.0001$). Absenteeism, presenteeism, and activity impairment ratings each improved by more than 25% ($P < 0.0001$).

Discussion: Participants in a virtually delivered behavioral therapy program for pain experienced significant improvements in pain intensity, pain interference, behavioral health symptoms, and work productivity. ■

Key Words: behavioral medicine, pain, coping skills, psychology, depression, anxiety

INTRODUCTION

More than 40% of the U.S. adult population reports having 1 or more painful health conditions.[1] For 1 in 5 adults (approximately 50 million), pain is chronic and frequently associated with medical comorbidity and disability.[2] Beyond the recognized clinical burden associated with pain, the incremental fiscal burden is also large and estimated to be as high as $635 billion annually, composed of medical costs, disability days, lost wages, and impaired productivity.[3]

Behavioral health conditions, which commonly co-occur with pain, are a known contributor to adverse clinical and workplace outcomes. For example, major depression may be identified in more than 20% of pain patients in primary care settings, and at even

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higher rates in pain clinics and orthopedic and rheumatology settings.[4] Acknowledging and addressing the link between pain and behavioral health is a growing national priority, especially with the high rates of opioid use and the increased recognition of the link between psychiatric disorders and opioid misuse.[5,6]

Behavioral therapy is a well-accepted non-medication-based treatment strategy for both pain and common behavioral health conditions such as depression and anxiety.[7] However, fewer than 50% of U.S. adults diagnosed with a mental illness receive treatment at all.[8] Common access barriers, including health limitations, transportation issues, and lack of available high-quality evidence-based care, prevent many from getting needed treatment.[9,10]

Solutions to established access barriers could lead to improved clinical and workplace outcomes for the millions living with chronic pain and/or behavioral health conditions. Virtual behavioral therapy (ie, evidence-based behavioral therapy provided by a licensed therapist over secure telephone or video) has gained recognition as an effective and noninferior treatment delivery mechanism for depression and chronic pain that can address these known challenges.[11–14]

Few data describe real-world outcomes from standardized virtual behavioral therapy programs for chronic pain delivered at a national scale. The purpose of this study was to describe clinical and workplace outcomes from an evidence-based, virtual behavioral therapy program for individuals with pain and behavioral health issues in the United States.

METHODS

This retrospective program evaluation study was approved by the Sterling Institutional Review Board of Atlanta, Georgia. A waiver of informed consent was approved for analysis of previously collected and de-identified clinical data.

Data Source

This was a retrospective study of de-identified data from a cohort of 1,086 adults who completed AbleTo, a standardized and quality-assured telebehavioral therapy program for pain, consecutively enrolled during the 1-year period between September 1, 2016, and August 31, 2017. The program comprised a U.S.-based nationwide network of trained and supervised licensed therapists and health behavior coaches who provided evidence-based, condition-specific, protocolized behavioral therapy for adults with comorbid pain and behavioral health issues. Care was delivered over the telephone or by secure videoconference supported by a secure technology platform.

Participants

Engagement methodology and criteria for program participation have been previously described.[15–18] Briefly, participants entered the program either by referral from a healthcare or health insurance plan provider (including care management teams), or via proactive outreach and engagement guided by clinical algorithms to identify adults with pain conditions at risk for behavioral health issues. Participants were ≥18 years old and required to have access to a telephone. Individuals were excluded from participation if determined to be more clinically appropriate for in-person, community-based care based on an initial clinical assessment performed by a licensed therapist. Examples of conditions with an indication for in-person care referral included imminent risk for harm to self or others, symptoms of psychosis, and significant neurocognitive impairment. Emergency protocols were in place to manage acute or imminent suicide risk and/or other symptoms of severe mental illness.

Program Description

The program was designed to support adults to better manage their pain and behavioral health symptoms through cognitive behavioral therapy strategies and improved adherence to medications, physician recommendations, and prescribed lifestyle behaviors. Content was developed using clinical treatment guidelines and evidence-based approaches, including cognitive behavioral therapy, acceptance and commitment therapy, motivational interviewing, and mindfulness and distress tolerance practice.

The program included an initial clinical consultation and 8 subsequent weekly behavioral therapy sessions with a licensed therapist. The initial consultation included a baseline mental health and psychosocial interview, including risk assessment, standardized psychometric assessment, and pain assessment. Each therapy session was paired with a weekly coaching session with a behavior coach (master's level clinician with 2 or

more years of experience in behavioral health) to support each participant to make progress towards attaining goals established in therapy.

Therapy and coaching sessions were each approximately 45 minutes long and delivered through a Health Insurance Portability and Accountability Act–compliant telephone and/or secure video platform based on participant preference. Therapists and coaches used a customized technology platform to access manualized evidence-based protocols to guide each session, write session notes, and communicate securely with each other. Therapists tailored the structured and protocolized treatment modules to each individual participant's goals and needs in order to promote skill development, behavior change, and action steps towards personal goal achievement.[18] Participants received homework assignments to complement and reinforce each therapy session; examples of homework included pain and mood monitoring, breathing and meditation exercises, and journaling about pain and daily experiences. The program was time-limited to 8 weeks; if a longer course of therapy or other clinical needs were identified/indicated during the 8-week treatment period, the therapist coordinated care with community-based providers and resources. Treatment fidelity was overseen through case conferences led by clinical program advisors. The program advisors also conducted clinical note review to quality assure the care delivery process and to assess treatment protocol adherence.

Measurements

Sociodemographics. Self-reported sociodemographic and clinical characteristics (age, sex, U.S. region, past medical history, past psychiatric history, opioid prescription) were systematically collected as part of the standardized interview at the initial consultation. Self-rated health was measured using a standardized question adapted from the SF-36 Quality of Life survey: "In general, would you say your health is: (1) excellent, (2) very good, (3) good, (4) fair, (5) poor."[19]

Pain and Pain Symptoms. The presence of chronic pain (vs. less frequent/shorter duration pain) was assessed at the initial consultation using the following standardized question: "In the past 6 months, how often did you have pain?" As recommended in the U.S. National Institutes of Health 2016 National Pain Strategy, chronic pain was defined as pain for greater than or equal to half the days over the preceding 6 months.[20]

Pain severity and pain interference were measured at the initial consultation and again at the final therapy session (8 weeks) among participants reporting chronic pain (responses 3 to 5 to the chronic pain assessment question above) using 2 pain items from the Pain Intensity, Enjoyment of Life, General Activity (PEG) assessment tool: (1) "In the past 7 days, how would you rate your pain on average? 0 = No pain 10 = Worst imaginable pain," and (2) "In the past 7 days, how much did pain interfere with your day-to-day activities? 0 = No interference 10 = Completely interferes."[20,21] Any score above 0 was defined as abnormal.

Behavioral Health Symptoms. Psychiatric symptoms were measured at the initial consultation and again at the final therapy session (8 weeks) using the Depression, Anxiety and Stress Scale short form (DASS-21).[22] The DASS-21 is a 21-item self-report inventory across 3 domains: depression, anxiety, and stress. Reliability and validity of the DASS-21 have been documented in diverse clinical and nonclinical populations.[23–25] Scores range from 0 to 42 points in each domain; higher scores indicate greater symptom severity. Above-normal symptom severity was categorized using a depression score of >9, an anxiety score of >7, and/or a stress score of >14.[22]

Workplace Productivity and Daily Activity. Employment status (yes/no), absenteeism (work missed due to health/behavioral health problem), presenteeism (reduced productivity at work due to health/behavioral health problem), and activity impairment (degree to which a health/behavioral health problem interfered with daily activities) were assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire at baseline and again at 8 weeks.[26] The 6-item WPAI questionnaire assesses impairment during the preceding 7 days and has been validated and used broadly in medical and behavioral health populations, including among adults living and working with chronic pain.[26–28] Above-normal scores were defined as absenteeism or presenteeism scores > 0% (among participants employed during the program), and activity impairment > 0%.

Statistical Methods

Baseline demographic, medical, psychiatric, pain, and workplace characteristics of the sample were

summarized using descriptive statistics. Changes in clinical and workplace metrics (pain intensity, pain interference, DASS-21, WPAI) during the program period were calculated as absolute and mean percentage change from the initial consultation to week 8 among participants with above-normal scores at initial consultation using paired *t*-tests. A clinically meaningful change in pain intensity and/or pain interference was defined as ≥30%.[29] Stratified analyses were conducted to evaluate changes in pain intensity and pain interference by sociodemographic and clinical characteristics. Logistic regression was utilized to assess independence of observed differences adjusting for baseline pain intensity and pain interference. The correlation between changes in pain intensity and pain interference and concurrent changes in DASS-21 and WPAI metrics from initial consultation to the week 8 therapy visit was assessed among participants with chronic pain who presented with above-normal symptoms/impairment at initial consultation using Spearman's rank correlation. SAS version 9.4 software (SAS Institute, Cary, NC, U.S.A.) was used for the analyses; statistical tests were 2-sided, with $\alpha = 0.05$.

RESULTS

Baseline Characteristics

The distribution of pain frequency among participants in the 6 months prior to their initial consultation is presented in Figure 1. Greater than 90% of participants were classified as having chronic pain. The balance reported having pain less than half the days (7%) or no pain (2%) in the preceding 6 months.

Baseline demographic and clinical characteristics are described in Table 1. Almost one third of the participant cohort was male, median age was 55 years, and 9.5% of participants were 65 years of age or older. More than 2 out of 3 participants (68.9%) reported a past psychiatric history of depression, anxiety, or post-traumatic stress disorder. Above-normal depression, anxiety, and/or stress symptom scores were observed at baseline among 67.7% of participants. The majority of participants (90%) reported daily activity impairment. Among those who were employed, more than 3 out of 4 were experiencing absenteeism or presenteeism at baseline.

No differences in sex or age distributions were observed between participants with chronic pain vs. nonchronic pain. Participants with chronic pain were more likely than those with nonchronic pain to report having been prescribed an opioid medication (31% vs. 9%; $P < 0.01$). They also more frequently rated themselves as having poor or fair health status (46% vs. 25%) and were more likely to have above-normal depression and anxiety symptom scores vs. their counterparts with nonchronic pain ($P < 0.05$). Participants with chronic pain were less frequently employed (45% vs. 57%), had greater levels of absenteeism, and were more likely to experience daily activity impairment vs. their counterparts (see Table 1).

Pain Severity and Interference

Significant reductions in pain intensity and pain interference were observed over the 8-week treatment period (Figure 2). The average reduction in pain intensity was 16.7%, and 40.1% of participants experienced a clinically meaningful reduction of ≥30% at 8 weeks. There

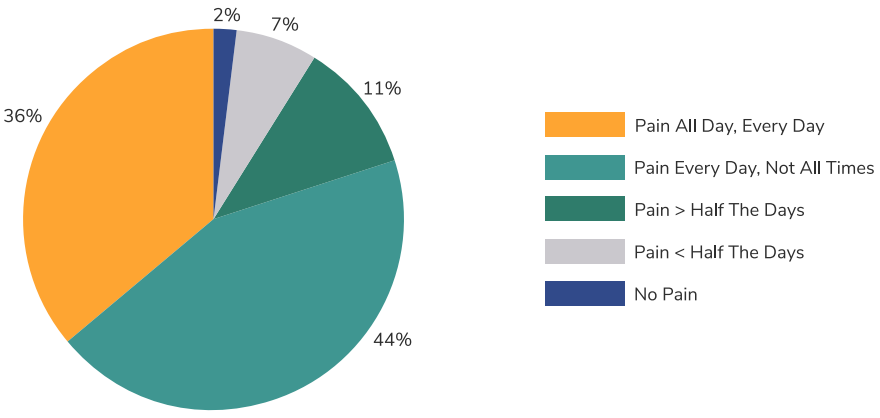

Figure 1. Baseline distribution of pain frequency and duration among a 1-year consecutive sample of participants in a virtual behavioral therapy program for pain and behavioral health. Figure represents data from 1,084 participants with complete data (*n* = 2 missing chronic pain assessment).

Table 1. Baseline Characteristics Among a 1-year Consecutive Sample of Participants in a Virtual Behavioral Therapy Program for Pain and Behavioral Health (*N* = 1,086)

	Overall *N* = 1,086	Pain Is Chronic* *N* = 985	Pain Is Not Chronic* *N* = 99	*P*
Demographics				
Age, mean (SD)	52.5 (11.5)	52.7 (11.3)	50.5 (13.8)	0.12
Male, *n* (%)	315 (29.0)	286 (29.0)	29 (29.3)	0.96
U.S. region, *n* (%)				
Middle America	120 (11.2)	112 (11.5)	8 (8.1)	0.02
Northeast	516 (48.0)	452 (45.9)	62 (62.6)	
Southeast	162 (15.1)	153 (15.5)	9 (9.1)	
West	288 (26.5)	268 (27.2)	20 (20.2)	
Past medical history, *n* (%)				
Heart condition	149 (13.7)	138 (14.0)	11 (11.1)	0.42
Diabetes	201 (18.5)	184 (18.7)	17 (17.2)	0.71
Past psychiatric history, *n* (%)				
Depression	600 (55.2)	551 (55.9)	48 (48.5)	0.16
Anxiety	537 (49.4)	488 (49.5)	48 (48.5)	0.84
Post-traumatic stress disorder	125 (11.5)	117 (11.9)	8 (8.1)	0.26
Opioid prescription, *n* (% yes)	314 (28.9)	304 (30.9)	9 (9.1)	<0.01
Self-rated health, *n* (%)				
Fair or poor	479 (44.1)	453 (46.0)	25 (25.3)	<0.01
DASS-21 symptom severity, *n* (%)†				
Depression score > 9†	535 (49.4)	501 (51.0)	33 (33.3)	<0.01
Anxiety score > 7†	466 (43.0)	433 (44.0)	32 (32.3)	0.02
Stress score > 14	467 (43.0)	433 (44.0)	33 (33.3)	0.04
Work productivity impairment, *n* (%)‡				
Employed	498 (46.1)	442 (45.0)	56 (57.1)	0.02
Absenteeism	170 (34.1)	158 (35.7)	12 (21.4)	0.03
Presenteeism	374 (75.1)	336 (76.0)	38 (67.9)	0.18
Activity impairment, *n* (%)§				
Daily activity is impaired	981 (90.4)	901 (91.6)	79 (79.8)	<0.01

*n = 2 excluded from stratified analysis due to missing chronic pain assessment. †n = 4 excluded due to missing DASS-21 scores. ‡n = 5 excluded due to missing WPAI data; absenteeism and presenteeism distribution estimates were among participants with data who were employed at baseline (n = 498). §n = 3 excluded due to missing activity impairment data.

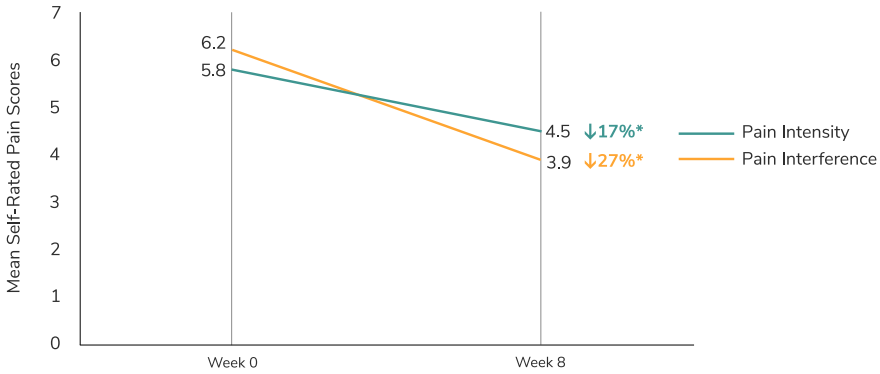

Figure 2. Changes in pain intensity and pain interference over 8 weeks among virtual behavioral therapy with chronic pain. Figure represents data from participants with chronic pain and a pain rating >0 at initial consultation; *N* = 976/985 (99%) for pain intensity and *N* = 911/985 (92%) for pain interference. **P* < 0.0001 for the mean within-person changes in pain intensity and pain interference.

was no statistical difference in the proportion of participants reporting ≥30% reduction in pain intensity by age group (≥55 years 39% vs. <55 years 41%; $P = 0.55$), sex (males 44% vs. females 39%; $P = 0.12$), or among those prescribed vs. not prescribed an opioid medication (36% vs. 42%, respectively; $P = 0.09$). Employment status was associated with changes in pain intensity, with individuals not employed at the time of participation significantly less likely than those who were employed to report clinically meaningful reductions in pain (34% vs. 47%, respectively; $P < 0.0001$); this lower odds of clinically meaningful reduction

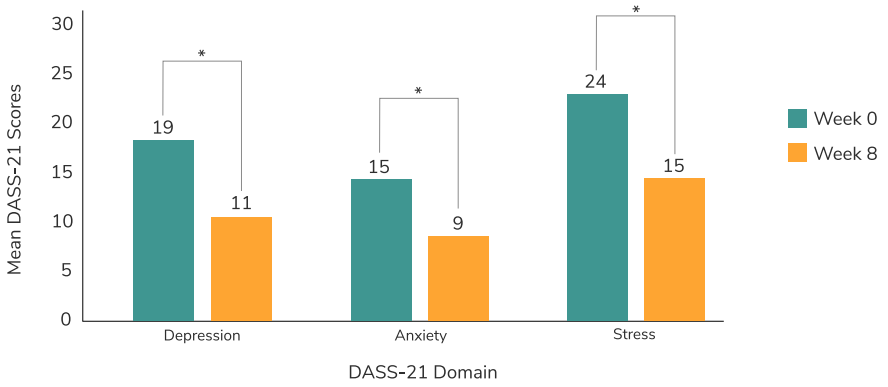

Figure 3. Changes in depression, anxiety and stress symptoms over 8 weeks among participants in a virtual behavioral therapy program for pain and behavioral health. DASS-21, Depression, Anxiety and Stress Scale short form. Figure represents data among participants with above-normal symptom scores at initial consultation within each domain: depression n = 533, anxiety n = 465, stress n = 466. *P < 0.0001 for the mean within-person changes in depression, anxiety and stress symptoms.

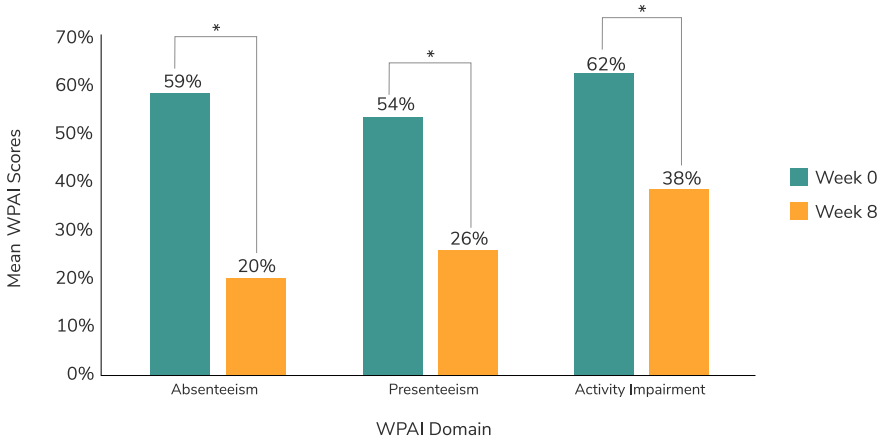

Figure 4. Changes in Work Productivity and Activity Impairment (WPAI) scores over 8 weeks among participants in a virtual behavioral therapy program for pain and behavioral health. Figure represents observed change in work productivity and activity impairment among participants with absenteeism, presenteeism and/or activity impairment at baseline. *P < 0.0001 for the mean within-person changes in absenteeism, presenteeism and activity impairment.

persisted after controlling for baseline pain intensity (odds ratio [OR] = 0.55; 95% confidence interval [CI] = 0.43 to 0.72).

A 26.5% mean reduction in pain interference was observed during the program period, representing a clinically meaningful improvement among more than half (54.5%) of participants. No significant difference in the odds of achieving clinically meaningful reduction in pain interference was observed by age group (≥55 years 55% vs. <55 years 54%; P = 0.97) or sex (males 58% vs. females 53%; P = 0.20). Participants with an opioid prescription were less likely than those without an opioid prescription to experience ≥30% reduction in pain interference during the program (48% vs. 57%, respectively; P = 0.01); this association remained significant after adjustment for baseline pain interference (OR = 0.60; 95% CI = 0.45 to 0.81). Participants not employed during program participation were less likely than those employed to experience a ≥30% reduction in pain interference (51% vs. 59%, respectively; P = 0.02); this association persisted after adjustment for baseline pain interference (OR = 0.60; 95% CI = 0.46 to 0.80).

Behavioral Health Symptoms

Depression, anxiety, and/or stress symptom scores significantly improved during the program period (Figure 3). A direct correlation was observed between reductions in depression and pain intensity scores (Spearman r = 0.22; P < 0.0001) and pain interference scores (Spearman r = 0.35; P < 0.0001). Similar correlations were observed between changes in anxiety and

stress scores and changes in pain interference and intensity measures.

Workplace Productivity and Daily Activity

Among participants employed at the time of treatment (46%), significant reductions in absenteeism and presenteeism were observed over 8 weeks (Figure 4). Ninety-one percent of participants reported activity impairment at baseline (see Table 1); among those individuals, activity impairment improved by more than 25% during the program period. Significant correlation was observed between reductions in activity impairment and reductions in pain intensity (Spearman $r = 0.42$; $P < 0.0001$) and pain interference (Spearman $r = 0.61$; $P < 0.0001$), respectively.

DISCUSSION

This article has described a retrospective observational data analysis among participants in an 8-week virtual behavioral therapy program for pain. The results documented significant, concurrent, and clinically meaningful improvements in pain intensity and interference, behavioral health symptoms, work productivity, and activity impairment during the program period.

In this analysis, the pre- to post-treatment reductions in pain intensity and pain interference observed were consistent with those demonstrated in other behavioral therapy interventions in chronic pain populations at or around 8 weeks. In a 2018 randomized controlled clinical trial, Rutledge et al. documented that cognitive behavioral therapy for lower back pain delivered by telephone was associated with significant improvement in pain interference and an approximately 1.2-point (24%) reduction in pain intensity, with more than 33% of participants achieving a ≥30% reduction in pain intensity on a numeric rating scale of 0 to 10 at 8 weeks.[14] Similar reductions in pain intensity and pain interference have also been shown in randomized trials of behavioral therapy for pain in other settings and via other delivery modalities (eg, nurses vs. therapists, group vs. individual, face-to-face vs. virtual).[30–33] The improvements in behavioral health symptoms experienced by this cohort were correlated with reductions in pain; this co-occurrence is of clinical importance because improvements in behavioral health symptoms predict better pain outcomes.[34,35]

Extending the reach of evidence-based, nonpharmacologic therapies for chronic pain is of particular importance given the pervasiveness of chronic pain and the concurrent and growing epidemic of opioid misuse. Nonpharmacologic clinical therapies, as well as non-opioid drug therapies, are favored approaches for the management of chronic pain[36]; nonetheless, there has been an increase in opioid prescription as a first-line treatment of chronic pain, which has contributed to rising rates of opioid use disorder and overdose. In the present study, a significant proportion (30.9%) of participants with chronic pain reported use of a prescription opioid medication at baseline. Though the impact of this program on opioid use rates was not assessed, other studies have demonstrated that behavioral therapy may reduce or avoid opioid use altogether. Moreover, participants in this study without prescribed opioids were more likely to experience clinically meaningful reductions in pain interference, even after adjustment for baseline levels of interference. As such, improved access to high-quality behavioral therapy delivered via virtual approaches has the potential to play an essential role in tackling the opioid epidemic and helping more individuals living with chronic pain.

The interrelationship among pain, behavioral health, functional impairment, and work productivity is well recognized and has motivated employers to focus attention on strategies to address the costs related to medical spending and lost productivity. In this study, patients with chronic pain were less likely to be employed altogether, but among those who were employed, we observed high baseline rates of absenteeism (36%) and presenteeism (76%). Effectiveness of virtual behavioral therapy to improve work productivity has been previously shown, but this evaluation may be one of the first to specifically show improvements among adults who received virtually delivered behavioral therapy for chronic pain.[37] Further, that improvements in psychological symptoms, workplace productivity, and activity impairment were observed in the same participants supports the interplay of these variables and suggests that behavioral therapy can have synergistic effects on these interdependent outcomes metrics. These results suggest that enabling access to a virtual behavioral therapy program may be a valuable strategy for employers seeking to address the high burden of pain and related conditions among employees.

The limitations of these data should be acknowledged when interpreting these study results. First, due to the single-arm observational study design, we cannot make causal inferences or attribute observed improvements solely to the intervention vs. natural progression of the

disease. However, the improvements in pain metrics mirror the improvements previously demonstrated in clinical trials of behavioral therapy for pain. Second, we recognize the inherent limitations in self-reported clinical data given that there may be response biases. Validated questions commonly used in measurement-based practice to assess clinical outcomes were utilized, allowing comparison to similar data collected in other patient populations. Third, standardized data on treatment delivery mode (telephone vs. video) for each session were not included in the research data set, which prevented us from conducting a stratified analysis to examine outcomes by delivery modality. Finally, we acknowledge that there is heterogeneity in the location, etiology, and clinical presentations of chronic pain that could not be characterized with the data available for this analysis; nonetheless, per protocol, the program was tailored by each therapist to meet the individual pain-related behavioral health needs of the participant.

Evidence-based behavioral therapy is a well-established treatment strategy for chronic pain and behavioral health comorbidity in adults.[7,38–40] Virtual delivery of this care by a licensed clinician can reach more individuals in need. Consecutive participants in this virtual behavioral therapy program experienced significant improvements in pain, behavioral health symptoms, as well as functional impairment and work productivity. This study demonstrated successful implementation of evidence-based practice at scale and adds to our knowledge about virtual behavioral therapy outcomes among adults with chronic pain conditions. Moreover, these data provide evidence that the magnitude of improvement in pain intensity and pain interference observed in the clinical trial setting may be expected with real-world deployment, as measured by validated tools utilized as standard clinical practice. Cost-effectiveness evaluation will be an important next step in longer-term program evaluation. Improving access to such care is paramount, particularly in the context of the high rates of chronic pain, the ongoing and growing opioid epidemic, and the desire on the part of payers and employers to find scalable solutions to address the cost and comorbidity burden associated with chronic pain.

CONFLICTS OF INTEREST

Dr. Mochari-Greenberger is an employee of and holds an equity interest in AbleTo. Ms. Andreopoulos is an employee of AbleTo. Ms. Peters is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Clinical Officer. Dr. Pande is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Medical Officer.

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AbleTo

Using Telehealth to Implement Cognitive-Behavioral Therapy

Psychiatric Services

Summary

AbleTo's quality-assured evidence-based virtual behavioral therapy programs are designed to overcome barriers to identification and enrollment into behavioral health care among adults with medical comorbidities or major life events. The AbleTo model identifies individuals at a time of increased risk for psychological comorbidity, and provides outreach to coordinate enrollment into remotely delivered standardized behavioral therapy programs tailored to meet individual's clinical needs. Evaluation of the program demonstrated high participant satisfaction, and significant reductions in depression, anxiety, and stress symptoms during the program period.

Demographics

- 1,482 adults
- Average age: 54 years
- 36% male/ 64% female

Key Outcomes

Clinically meaningful improvements in psychological symptoms over 8-weeks:

- 64% of patients experienced a ≥50% reduction in depression symptoms score
- 45% of patients completed the program with ≥70% depression symptom score reduction
- Similar improvements in anxiety and stress scores

High participant satisfaction scores

- 98% of participants rated their satisfaction as 6 or higher on a zero to eight point scale

AbleTo provides targeted and proactive behavioral telehealth programs that demonstrate national reach, high patient satisfaction, and significant reductions in symptoms of depression, anxiety, and stress.

Full Study: Dent L, Peters, A, Kerr PL, Mochari-Greenberger H, Pande RL. Using Telehealth to Implement Cognitive-Behavioral Therapy. Psychiatric Services. 2018. 69(4):370-373. https://doi.org/10.1176/appi.ps.201700477

Using Telehealth to Implement Cognitive-Behavioral Therapy

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Behavioral health issues are common among patients with comorbid medical conditions but often go unrecognized or untreated, resulting in worse clinical outcomes and avoidable medical expenditures. This column describes an innovative telehealth solution that includes proactive and targeted patient identification and engagement and nationwide delivery of a technology-enabled, standardized, and evidence-based behavioral health program delivered via phone or video. A retrospective before-after evaluation of the program demonstrated national reach, high patient satisfaction, and significant reductions in symptoms of depression, anxiety, and stress.

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Depression and other behavioral health issues are prevalent among patients with complex medical conditions and often go unrecognized and untreated in primary or acute care settings (1). Lack of treatment is associated with poorer outcomes and increased health care costs (2). Even when patients are recognized to have behavioral health issues, there is a dearth of high-quality, consistently delivered, and easily accessible behavioral health service options (3). Moreover, individuals with coexisting behavioral and general medical challenges may have difficulties with psychotherapy initiation and adherence (4).

As such, innovative solutions are needed to optimize patient identification and access to care, to deliver high-quality behavioral health care with consistent application of evidence-based best practices, and to sustain patient engagement. A creative combination of data analytics, technology, and interpersonal care delivery via telehealth may bridge these gaps.

Trials have demonstrated that telehealth interventions, such as psychotherapy delivered by telephone or video, are effective and comparable in efficacy to face-to-face treatment of depression (5,6). Advantages of remotely delivered therapy include reduced geographic, physical, or time-related constraints for patients, potential cost savings to the health care system, and enhanced opportunities for collaborative care (7). In this column we describe a novel behavioral health solution designed to identify, engage, and treat patients with behavioral health comorbidities.

The Model

AbleTo is a national technology-enabled behavioral health care provider that delivers proactive evidence-based and quality-assured behavioral therapy programs to individuals living with comorbid general medical and behavioral health conditions or experiencing life challenges. All care is delivered remotely by phone or secure video and supported by digital tools. [A figure in the online supplement illustrates the process.]

Participants. Potential participants are identified by outbound engagement via telephone or by direct inbound referral from community or health plan providers, including care management teams. Targeted outreach is guided by clinical algorithms applied to medical and pharmacy claims and other data sources to identify individuals with higher risk of behavioral health issues, high resource utilization, and high-risk medical comorbidities. Trained engagement specialists perform outreach. Clinically appropriate, interested individuals are registered after completing privacy and safety procedures (including HIPAA practices). Participants are required to be ≥18 years old and to have access to a telephone.

Providers. All care is delivered by AbleTo's national network of recruited, trained, and supervised therapists (licensed clinical social workers [LCSWs] or state-recognized equivalent positions) and behavior coaches. Therapists are required to be experienced in cognitive-behavioral therapy, adept at telehealth care delivery, and knowledgeable about the care of high-risk populations with general medical conditions and behavioral health issues or who are navigating life transitions. Behavior coaches are master's-level clinicians, with a degree in psychology, nursing, or a related field, and have at least two years of clinical behavioral health experience. All clinicians

are formally trained to deliver AbleTo's evidence-based programs and are supervised by senior clinicians (LCSWs with prior experience supervising evidence-based psychotherapy) who perform case note review, hold case conferences for each patient, provide emergency consultation, and direct care coordination.

Initial consultation. Initial consultation with a therapist is completed via telephone and includes a full behavioral health clinical evaluation and risk assessment, including assignment of a provisional *DSM-5* diagnosis. Individuals are ineligible for the program if their clinical presentations are deemed to be too risky and if in-person community-based resources are determined to be more clinically appropriate. To ensure the safety of the patient and others at risk, the intervention uses strict emergency protocols to manage acute or imminent suicide risk and symptoms of severe mental illness. Patients ineligible for the intervention are referred to a community provider by following a standardized protocol.

Program overview. The program consists of the initial consultation followed by 15 modular sessions delivered over approximately eight weeks that alternate between psychotherapy sessions and behavioral coaching. Each participant is assigned to a program protocol matched to his or her specific health conditions, including behavioral health conditions (such as postpartum depression, anxiety with or without panic attacks, depression, and substance misuse), self-reported life challenges (such as bereavement and caregiving), and acute and chronic medical conditions with which comorbid behavioral health issues are highly prevalent (including diabetes, cardiovascular disease, chronic pain, cancer, gastrointestinal conditions, and respiratory conditions). The assigned program protocol is selected on the basis of the participant's chief complaints and primary concerns, general medical and psychiatric diagnoses, symptom presentation, and the therapist's assessment and recommendation at initial consultation. Treatment modules are based on empirical research integrating standard and third-wave cognitive-behavioral therapy models. Session content is standardized and focused on identified areas for behavior change, but each participant's experience is personalized to identify and address barriers and specific goals. Coordination of care with the participant's providers occurs throughout the engagement and treatment and is a standard component of discharge.

Cost. AbleTo partners with health plans, self-insured employers, and provider organizations to provide behavioral health services as an in-network benefit. Participants have modest to no out-of-pocket cost depending on their health plan benefits and associated copayments or deductibles.

Quality Assurance

Consistent delivery of high-quality care is facilitated in multiple ways. First, providers are required to have extensive didactic and practical training, demonstrated experience, and additional training specific to the AbleTo program, HIPAA, privacy and data security, and best practices for telehealth care delivery [see online supplement]. Providers are evaluated regularly by a clinical supervisor. Second, the program is delivered via a customized technology platform that provides clinicians access to standardized session protocols. The platform serves as a protected electronic record for session notes and supports secure electronic communication among the clinical team and with participants. Third, the intervention includes standardized collection of patient-reported outcomes and progress completing behavioral goals. Therapists participate in case conferences with a clinical supervisor to discuss case conceptualization, treatment planning and progress, safety, discharge planning, and protocol adherence.

Evaluation

We conducted a retrospective evaluation of AbleTo's program reach and experience by using a deidentified clinical data set from a sample of 1,482 consecutive program graduates with elevated pretreatment DASS-21 scores and who completed the program between January 1, 2014, and June 30, 2015 (8) [see flow diagram in online supplement]. Participant demographic characteristics, general medical and psychiatric history, and medication use were systematically collected. Program satisfaction was assessed posttreatment on a scale (scores range from 0 to 8) adapted from the Net Promoter Score (9). This research was approved by the Sterling Institutional Review Board.

The program had national reach in the United States, spanning the Northeast, Southeast, Midwest, and West nondifferentially [see table in online supplement]. Participants were predominantly female (64%, N=952) with an average age of 53.7±9.5 years. Common comorbid medical conditions included hypertension and diabetes. Almost one in three (29%, N=300 of 1,023) participants presenting with elevated depressive symptoms did not report a history of diagnosed depression, and close to half (43%, N=458 of 1,072) with elevated anxiety symptoms did not report a prior diagnosis of anxiety.

Median DASS-21 depression scores decreased pre- to posttreatment, from 18 (interquartile range [IQR] 12–24) to 6 points (IQR 2–12), among participants with elevated baseline depression scale scores (69%, N=1,023). The median within-person decrease from pretreatment to posttreatment of 10 points (IQR –6 to –16) was significant (Wilcoxon signed-rank test; $p<.001$), with a large effect size ($r=-.53$). Overall, 64% (N=658) of patients exhibited symptom reduction (≥50% score reduction), and 45% (N=459) completed the program with ≥70% score reduction. Similar clinically meaningful, statistically significant changes were observed in anxiety and stress scores [see graph in online supplement].

In a stratified analysis using Wilcoxon rank-sum two-sample tests to determine whether changes in DASS-21 scores differed among those who started an antidepressant during the treatment period (N=100), no significant differences were observed. Median changes in depression, anxiety, and stress scores were similar among those who initiated antidepressant therapy and those who did not.

At graduation, more than 95% (N=1,408) of participants completed the program satisfaction assessment. Among them, 98% (N=1,379) rated their satisfaction as 6 or higher, with 84% (N=1,187) rating their satisfaction as 8 out of 8 (highest rating).

Discussion

We have described an innovative telehealth model that addresses three nationally recognized barriers to behavioral health care: patient identification and proactive engagement, access to care, and quality-assured delivery of best-practice care. The model was designed to identify individuals at a time of increased risk for psychological comorbidity and to provide outreach to coordinate enrollment into a remotely delivered standardized therapy program tailored to meet individual clinical needs. We demonstrated wide reach of the program and identification of symptomatic participants who did not report a history of diagnosed depression or anxiety in their lifetime. Program satisfaction was high, and participants experienced significant reduction in depression, anxiety, and stress symptoms during the program period. Symptom reductions were observed among participants irrespective of whether antidepressants were initiated during treatment.

The approach we describe expands the current evidence regarding behavioral telehealth programs in several ways, including data-driven methodology applied in partnership with health plans and providers to identify individuals who may be in need of behavioral health care; proactive outreach to identified individuals to screen for behavioral health conditions, including high-risk symptoms, and facilitate access and enrollment; national reach of the quality-assured evidence-based program; and program standardization with modular design to meet individual treatment and care coordination needs of the participant.

The modular nature of the program allows for dynamic adjustment to patient and clinician needs while retaining an evidence-based protocol. The program also includes protocols to meet the needs of diverse patient populations who may benefit from behavioral therapy. This tailored and inclusive approach represents translation of telehealth research into scaled clinical practice and diverges from published telehealth evaluations that, by design, are limited to strict inclusion of homogeneous samples.

The program evaluation documented scalability of a high-quality technology-enabled program with the potential to reach many patients otherwise unable to receive traditional mental health care services. This model focuses on the treatment of behavioral health symptoms as a means to improve adherence to general medical treatment and overall physical health outcomes and reduce total cost of care (10,11). Thus, if proven to be effective, an innovative behavioral health care model of this nature stands to benefit a variety of health care stakeholders, from patients to employers and payers.

There are limitations to the inferences that can be drawn from the evaluation data. First, the lack of a control group precludes formal determination of causality. But data from other telehealth intervention trials support the consistency and feasibility of findings (5,6). Second, midtreatment and longer-term follow-up data are not yet available to evaluate treatment "dose" versus response and longevity of symptom decreases. However, follow-up studies of this program have demonstrated improvement in medical outcomes and reduction in medical utilization (11). Third, the program evaluation data presented herein are for commercially insured adults; it is unknown whether these results generalize to other populations. A strength of the data is the large patient sample, representative of "real world" telehealth care seekers.

Conclusions

Behavioral health conditions are prevalent among patients with medical comorbidities and often go unrecognized or untreated because of barriers, including inadequate identification of patients in need and insufficient access to high-quality behavioral health care. We have described a nationally scaled telehealth model designed to overcome barriers to identification and enrollment into therapy. Participants were highly satisfied and experienced clinically meaningful improvements in behavioral health outcomes, further underscoring the potential impact that a telehealth solution could have in optimizing treatment outcomes.

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Dr. Dent has served as a program developer and consultant for AbleTo, Ms. Peters is chief clinical officer and holds equity interest in AbleTo, Dr. Kerr is a paid consultant for AbleTo, Dr. Mochari-Greenberger is director of clinical research at and holds equity interest in AbleTo, and Dr. Pande is chief medical officer and holds equity interest in AbleTo.

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AbleTo

A Nationally Scaled Telebehavioral Health Program for Chronic Pain: Characteristics, Goals, and Psychological Outcomes

Telemedicine and e-Health

Summary

This study demonstrated the observed clinical impact of a scaled virtual behavioral health program for chronic pain designed to address comorbidities and primary concerns commonly encountered by the millions of U.S. adults living and working with pain. Participants shared common sources of pain, behavioral health goals, and mood triggers, with more than half having elevated depression, anxiety, and/or stress scores at baseline. After completing the 8-week program, participants experienced clinically meaningful reductions in depression, anxiety and stress symptom severity; more than half experienced a greater than 50% reduction in depression severity.

Demographics

- 170 participants
- Average age: 53 years
- 24% male/76% female

Key Outcomes

Significant improvement in behavioral health symptom scores:

- **48% fewer** hospital stays at 6 months
- **Clinically meaningful reductions** in
- depression, anxiety and stress symptoms.

Depression, anxiety, and stress symptoms improved in the majority of symptomatic participants; these outcomes did not vary by participant sex.

Common Mood Triggers:

- Pain
- Health concerns
- Relationship challenges
- Work-related Issues
- Financial concerns

Shared Goals:

- Pain management
- Weight loss
- Increased physical activity
- Mood management
- Improved diet

Full Study: Mochari-Greenberger H, Peters A, Vue L, Pande RL. A Behavioral Telehealth Program for Chronic Pain: Participant Characteristics, Goals, and Psychosocial Outcomes. Telemed J E Health. 2017;23:640-648. http://doi.org/10.1089/tmj.2016.0188

Original Research

A Nationally Scaled Telebehavioral Health Program for Chronic Pain: Characteristics, Goals, and Psychological Outcomes

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Abstract

Background: *Millions of U.S. adults suffer from chronic pain with a high prevalence of comorbid mental health issues. Telehealth-delivered behavioral therapy for chronic pain has been evaluated in the research setting. The purpose of this study was 1) to describe a nationally scaled, standardized, telebehavioral therapy program for patients with chronic pain and behavioral comorbidities, and 2) evaluate characteristics, goals, and psychosocial outcomes among program participants.*

Materials and Methods: *This was mixed-methods retrospective cohort analysis among consecutive program graduates (mean age 53y; 24% male). The 8-week program was delivered by a licensed therapist and a behavior coach through telephone/secure video and tailored to each participant's behavioral health needs and goals. Participant chief complaints, behavioral goals, and mood triggers were abstracted by deidentified clinical record review using structured qualitative research methods. Depression, anxiety, and stress symptom data were collected at baseline and program graduation using the validated Depression Anxiety Stress Scales 21.*

Results: *Back pain (42%) and hip/leg/knee pain (28%) comprised the most common chief complaints. Pain management (44%) and weight loss (43%) were the most frequently cited goals. At baseline, approximately half of participants had elevated depression (59%), anxiety (54%), and/or stress (48%) scores. Triggers for depressed, anxious, or stressed mood included severe pain (47%), health concerns (46%), and interpersonal relationship challenges (45%). At graduation, significant improvement in median depression (−54%), anxiety (−50%), and stress (−33%) symptom scores was observed among those with non-normal baseline values ($p < 0.001$); degree of improvement did not vary by participant age or sex.*

Conclusions: *Participants in a nationally scaled telebehavioral health program for chronic pain experienced significant improvement in depression, anxiety, and stress symptoms and shared several complaints, goals, and mood triggers.*

Keywords: *telemedicine, telehealth, behavioral therapy, evidence-based practice, depression, chronic pain*

Introduction

Over 100 million American men and women live with chronic pain, including one-third of adults aged 45 years and older.[1,2] Chronic pain is associated with more frequent physician visits and medication prescription.[3] Depression co-occurs with chronic pain in more than 20% of patients and is associated with increased pain severity, higher healthcare utilization (including greater frequency of hospitalizations, emergency room visits, and hospital outpatient procedures), and poorer outcomes after surgical intervention.[1–9]

Behavioral therapy is effective in treating both pain and depression[5,10–12] and has demonstrated cost-utility in the chronic pain setting.[11,13] However, a myriad of barriers, including challenges related to patient health and the healthcare system, is known to limit initiation of and adherence to behavioral therapy.[12] Moreover, not all patients who might benefit from behavioral therapy are identified, and as many as two-thirds of patients referred to therapy do not complete treatment.[14]

Telebehavioral therapy (behavioral therapy delivered by telephone or videoconference) has gained attention as a mechanism through which these barriers to therapy can be overcome.[12,15–19] Availability of telebehavioral health services for chronic pain has increased in response to national need and recognition that technology-enabled solutions have potential to substantially increase access to quality behavioral healthcare for pain, depression, and associated substance use disorders.[20,21] However, little is known about the clinical outcomes of scaled and standardized evidence-based telebehavioral therapy programs for chronic pain or about the clinical and psychological characteristics among individuals who participate in programs of this nature. The purpose of this study was to describe a nationally scaled

technology-enabled telebehavioral therapy program to identify and treat individuals with chronic pain and behavioral comorbidities and examine characteristics and psychological outcomes (depression, anxiety, and stress) among participants, overall and by sex. The second aim of the research was to characterize participant chief complaints, health goals, and mood triggers.

Materials and Methods

DATA SOURCE

This was a retrospective study of deidentified records from a cohort of 170 consecutive graduates from a nationally scaled technology-enabled telebehavioral therapy program for chronic pain (AbleTo). AbleTo is a behavioral healthcare provider that offers condition-specific behavioral health services through telephone or secure video to patients across the United States (U.S.). AbleTo programs are tailored to meet the needs of several specific patient populations, including but not limited to chronic pain patients and patients with medical conditions such as cardiac disease[22] or diabetes.[23]

PROGRAM PARTICIPANTS

In collaboration with health plan partners, persons with preexisting chronic pain conditions at risk for behavioral health issues were identified using data-driven clinical algorithms, and proactive outreach was performed. Participants could also be referred directly by health plan nurse or other healthcare provider. Potential participants were eligible to enroll in the chronic pain program if they had a documented chronic pain-related diagnosis, recent pain-related procedure, or a high level of physical therapy or overall medical resource utilization. The following exclusion criteria rendered potential participants ineligible for enrollment: psychiatric hospitalization in the past year; active suicidal ideation with plan and intent; nonsuicidal self-injury; bipolar disorder with active manic or hypomanic symptoms or not medication stable; severe substance use disorder, active intoxication, or withdrawal; psychotic symptoms; currently experiencing physical domestic violence; and violent ideation that suggested an imminent risk of violence or homicidal ideation. If an individual being screened met any exclusion criteria, he or she was referred to the appropriate level of care in his or her community, and the referring party was informed following a standardized protocol. If indicated, direct connections were made to crisis resources. Eligible persons completed pretreatment procedures, including registration and Health Insurance Portability and Accountability Act (HIPAA) review and acknowledgement, and then scheduled their first telebehavioral therapy session.

This analysis included participants enrolled in the chronic pain program during the 1-year period between July 29, 2014 and July 28, 2015. Among 309 participants who completed their first therapy visit, 235 (75%) completed at least half of the program and 176 completed the full program. Of these graduates, 170 graduated by September 2015, when the deidentified dataset was locked, and were included in this analysis. HIPAA-trained research staff conducted retrospective record review to abstract data for analysis. This research was approved by the Sterling Institutional Review Board.

PROGRAM DESCRIPTION

The technology-enabled behavioral therapy program for chronic pain was designed to support individuals to better manage pain and comorbid depressive symptoms through behavioral strategies, medical adherence, and positive lifestyle changes. The program was built using evidence-based approaches, including cognitive behavioral therapy; acceptance and commitment therapy; clinical guidelines to reduce depression, anxiety, and stress; mindfulness; distress tolerance; and motivational interviewing.[24–27] The program was developed by the AbleTo clinical team, in collaboration with an interdisciplinary advisory group of medical professionals, psychologists, and senior clinical social workers.

Program delivery occurred through HIPAA-compliant telephone or secure video platform, based on participant preference. The program was administered by a "care team" composed of a behavioral health provider (licensed clinical social worker [LCSW] or equivalent) and a behavior coach (Master's level clinicians, often with a degree in psychology, nursing, or other related field with at least 2 years of clinical experience in behavioral health). Standardized training and continuing education (certified by the Association of Social Work Board) were provided to ensure consistent and quality delivery of AbleTo's best practices chronic pain program protocol.

The chronic pain program consisted of an initial consultation followed by 15 sessions completed within an ~8-week period. The initial consultation was conducted by a LCSW and included a baseline mental health and psychosocial interview, including psychiatric and medical history and standardized quantitative measures (such as the Depression Anxiety and Stress Scales 21 [DASS-21] and other validated scales). The initial consultation was followed by eight therapy sessions with an LCSW and seven coaching sessions with a behavioral

coach. All sessions were ~45 min in duration. The program was delivered using a customized technology platform that provided access to evidence-based protocols to guide each session. The clinical content delivered through individual therapist and coaching sessions was standardized, but each participant's program was personalized to identify and address his or her concerns, goals, and barriers. The best practice interventions for depression, anxiety, and stress varied, and individualized treatments were tailored based on the presence and severity in these three domains.

During the first therapy session, the therapists worked with each participant to collaboratively identify and agree on treatment goals. These individualized treatment goals were developed to be focused and achievable and to support improvement in the chief complaint that brought the participant to the program. In addition, some participants set goals related to return to work, increased social participation, or management of other comorbid conditions such as cardiac disease or diabetes.

Throughout the following sessions, the therapist implemented the protocoled cognitive behavioral modules to address psychological and other factors associated with chronic pain conditions. The therapists tailored these modules for each participant to facilitate behavior change, skill development, and action toward personal goal achievement. Topics covered during therapy sessions included modifying self-defeating thoughts, acceptance, behavioral activation, mindfulness, and social support. Therapy sessions were complemented by homework exercises that the therapist customized to each participant's goals and presenting medical and psychological issues. Examples of homework included pain and mood monitoring; breathing and meditation; and journaling about pain and daily experiences.

During the weekly coaching sessions, the behavioral coaches worked with each participant to identify any specific barriers to treatment adherence and to problem solve to overcome these obstacles. Topics of focus during behavioral coaching sessions included self-care, body scan, observing emotions, distress tolerance, and self-advocacy. The behavioral coaches supported each participant to apply these skills, as well as to optimize change by facilitating translation of the cognitive behavioral therapy lessons into actionable activities in each participant's own life.

Over the course of the program period, the LCSW and coach participated in case conferences under the guidance of an LCSW clinical supervisor to review participant progress. The clinical supervisor performed weekly review of session notes to ensure high quality standards and adherence to the treatment protocol. The chronic pain protocol included modules targeted to specific skills and was tailored to each participant's needs and goals.

QUANTITATIVE MEASURES

Baseline sociodemographic and clinical characteristics were systematically documented through standardized interview by the LCSW at the initial consultation and included: age, sex, U.S. region (mid-America, northeast, southeast, and west), medical history (diabetes, heart disease, hypertension, neurological disease, and major surgery), mental health screening (depression and anxiety), and pain medication use (both over the counter medications and prescription medications such as opioids).

The primary clinical outcome was change in depression, anxiety, and stress scores during the program period. These domains were assessed at baseline and at graduation by the provider using the DASS-21, which has been validated and utilized in diverse clinical and community samples, including among chronic pain patients.[28–32] The DASS-21 contains 7 items each to measure depression, anxiety, and stress domains, for a total of 21 items. Each item is measured on a frequency scale ranging from 0 to 3; scores for each domain are summed and then multiplied by a factor of two. Total scores for each domain range from 0 to 42 points, with higher scores indicating more severe symptoms. Non-normal was defined as a score >9 points for depression, >7 points for anxiety, or >14 points for stress.[28,33,34]

QUALITATIVE MEASURES

Systematic chart review was conducted for the 100 most recent consecutive graduates of AbleTo's chronic pain program. Qualitative data were abstracted from free text clinical note fields regarding participant (1) chief complaint(s), (2) long-term goals, and (3) mood triggers. At the initial consultation, participants were asked to cite their chief complaint(s) and other relevant information to describe what brought them to the chronic pain program. During the first therapy and coaching visits, the care team worked with each participant to frame achievable long-term behavioral health and health-related goals. Over the course of the program period, mood triggers (i.e., situations which triggered depressed, anxious, or other mood states) were routinely documented in the session notes as part of the program protocol.

The first author and third authors (the coders) systematically reviewed the charts and identified salient themes in the data relevant to these three categories. Directed content analysis methods were applied to abstract and order the qualitative data; a deductive coding strategy was used, whereby a provisional start list of responses was listed in the

database.[35] This start list was informed by preparatory research, the chronic pain clinical program protocol, and the scientific literature. Inductive coding was then used to add codes that emerged during data collection.[35,36] Folk taxonomy was used to organize codes and to understand their similarities and differences.[35] The coders met to discuss any discrepancies and to reach agreement.

STATISTICAL ANALYSES

Baseline characteristics of the study sample, DASS-21 scores and severity categories, and participant chief complaints, goals, and mood triggers were presented using descriptive statistics. The primary outcome, change in DASS-21 scores over the program period, was presented as (1) the median absolute and percent differences in individual scores at graduation versus at baseline and (2) the proportion of participants who changed DASS-21 severity categories in each domain from baseline to graduation.

Wilcoxon signed-rank tests were used to evaluate within-person median change in DASS-21 scores during the program period, overall and stratified by sex. Wilcoxon rank-sum statistics was used to determine sex differences in baseline and graduation Depression Anxiety Stress Scales (DASS) scores and changes in DASS scores over the program period. Chi-squared tests were used to evaluate differences in proportion of participants with above normal DASS-21 score at baseline and at graduation by participant sex. Analyses were conducted using SAS statistical software, version 9.4 (SAS Institute, Cary, NC). Statistical tests were two-sided with alpha set at 0.05.

Results

Baseline sociodemographic and clinical characteristics of the study population, overall and by sex, are shown in *Table 1*. One in four (24%) participants was male, and mean age was 53.3 ± 8.9 years. Age, U.S. region, and baseline distribution of comorbid medical conditions did not vary by participant sex. Female participants were more likely than males to report prescription pain medications, including opioids (58% vs. 38%; $p = 0.02$), at baseline. Female participants had significantly higher odds of having a psychiatric history of depression compared with males (odds ratio [OR] = 2.5; 95% confidence interval [CI] = 1.2–5.1). More than three out of four participants (77%) had at least one above-normal depression, anxiety, and/or stress score at baseline; the distribution of elevated scores did not significantly differ by sex.

Table 1. Baseline Characteristics of Consecutive Chronic Pain Behavioral Telehealth Program Graduates, Overall and By Sex

CHARACTERISTICS	OVERALL (*N* = 170)	MALES (*N* = 40)	FEMALES (*N* = 130)	*p*
Demographics				
Age, years [Mean ± SD]	53.3 ± 8.9	52.6 ± 11.1	53.5 ± 8.1	0.62
Female [*n* (%)]	130 (76)	–	–	–
U.S. Region				0.91
Mid-America	20 (12)	4 (10)	16 (12)	
Northeast	34 (20)	8 (20)	26 (20)	
Southeast	47 (28)	10 (25)	37 (28)	
West	69 (40)	18 (45)	51 (39)	
Pain medications				
Any pain medication [*n* (%)]	134 (80)	28 (70)	106 (83)	0.06
Prescription pain medication [*n* (%)]	127 (76)	23 (58)	104 (82)	**0.002**
Opioid medication [*n* (%)]	89 (53)	15 (38)	74 (58)	**0.02**
Over the counter pain medication [*n* (%)]	51 (31)	13 (33)	38 (30)	0.78
Medical history				
Diabetes [*n* (%)]	53 (31)	16 (40)	37 (29)	0.17
Heart disease/condition [*n* (%)]	24 (14)	7 (18)	17 (13)	0.48
Hypertension [*n* (%)]	80 (47)	21 (53)	59 (45)	0.43
Neurological disease [*n* (%)]	43 (25)	8 (20)	35 (27)	0.38
Surgery [*n* (%)]	113 (67)	23 (58)	90 (69)	0.17
Psychological health history				
Depression [*n* (%)]	109 (64)	19 (48)	90 (69)	**0.01**
Anxiety [*n* (%)]	88 (52)	18 (45)	70 (54)	0.33
Baseline DASS-21 score severity				
Depression Score >9 [*n* (%)]	101 (59)	19 (48)	82 (63)	0.08
Anxiety Score >7 [*n* (%)]	92 (54)	19 (48)	73 (56)	0.34
Stress Score >14 [*n* (%)]	81 (48)	16 (40)	65 (50)	0.27

Values shown in bold indicate statistical significance at $p < .05$.

DASS-21, Depression Anxiety and Stress Scales 21; SD, standard deviation.

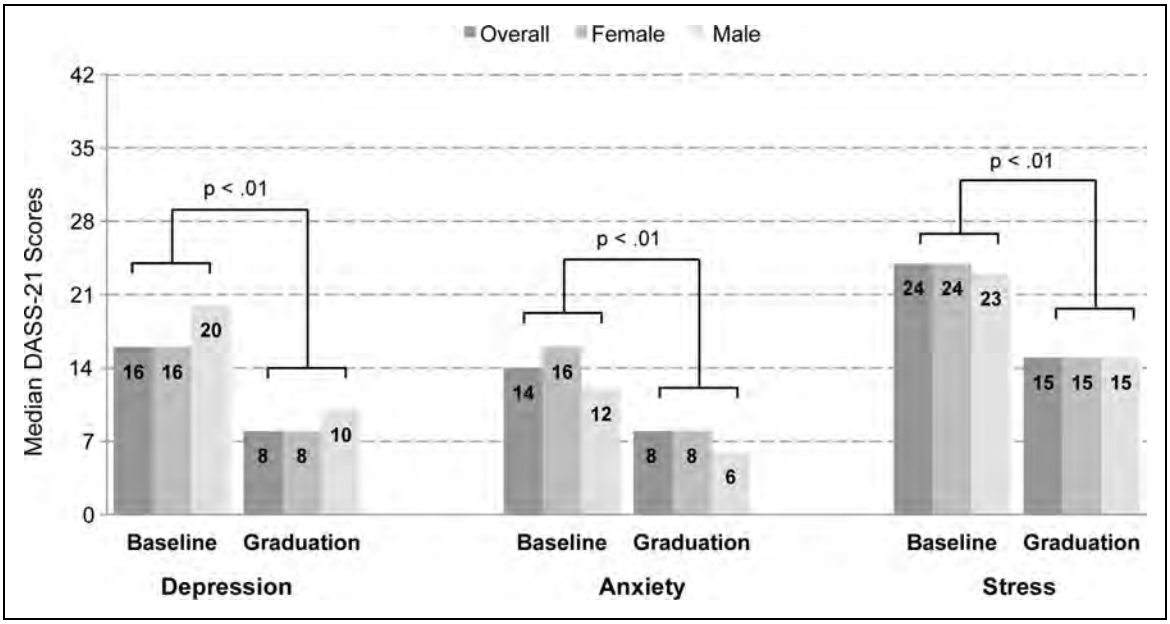

Fig. 1. Depression, anxiety, and stress scores, overall and by sex, among chronic pain telebehavioral health program graduates with elevated baseline scores. Note: Graduation scores exclude 1 participant with an elevated baseline score and a missing end score. *p*-Values indicate statistical significance of mean within person changes in depression, stress, and anxiety scores, overall and by sex. DASS-21, Depression Anxiety and Stress Scales 21.

PROGRAM OUTCOMES: CHANGES IN DEPRESSION, ANXIETY, AND STRESS SCORES

Significant reductions were observed at graduation in median depression (–8 points; –54%), anxiety (–6; –50%), and stress (–8.0; –33%) severity scores among participants with elevated scores at baseline. The magnitude of these changes was not significantly different among men versus women ($p > 0.05$; *Fig. 1*).

The majority of participants with above-normal baseline DASS-21 scores improved to less severe depression (79%), anxiety (73%), and stress (73%) categories by graduation (*Fig. 2*). More than half (52%) of participants with elevated baseline depression scores transitioned to normal scores by graduation, and 57% experienced a ≥50% reduction in depression symptom score. Likewise, 49% of participants with elevated baseline anxiety and 50% of participants with elevated baseline stress scores transitioned to normal scores.

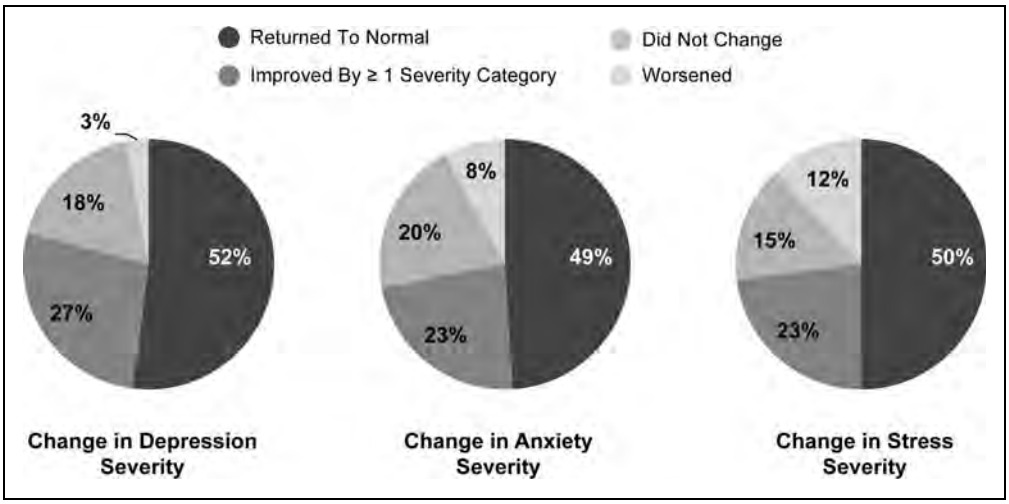

Fig. 2. Change in depression, anxiety, and stress score categories from baseline to graduation. Note: One participant with elevated depression, anxiety, and/or score at baseline was excluded due to missing graduation data.

BASELINE CHIEF COMPLAINTS

The most frequently cited complaint at baseline was back pain (42%). Hip, leg, or knee pain (28%), arthritis (17%), shoulder, arm, wrist or hand pain (17%), fibromyalgia (14%), nerve pain (8%), and headache (6%) were also commonly cited by participants. Females had significantly lower odds of citing back pain as a chief complaint (OR = 0.2; 95%CI = 0.1–0.6), and fibromyalgia-related pain was only reported among female participants (*Table 2*).

Table 2. Most Frequently Cited Chief Complaints and Behavioral Health Goals Among Consecutive Chronic Pain Program Graduates, Overall and by Sex

	OVERALL (*N* = 100), %	MALES (*N* = 25), %	FEMALES (*N* = 75), %	*p*
Chief complaints				
Back pain	42	68	33	**0.002**
Hip, leg, or knee pain	28	44	23	**0.04**
Arthritis pain	17	4	21	0.05
Shoulder, arm, wrist, hand pain	17	12	19	0.44
Fibromyalgia pain	14	0	19	**0.02**
Nerve pain	8	4	9	0.39
Headaches	6	0	8	0.15
Behavioral health and health-related goals				
Pain management	44	40	45	0.64
Weight loss	43	40	44	0.73
Increase in physical activity level	28	32	27	0.61
Learn to manage moods and emotions	25	20	27	0.51
A more healthful diet	15	16	15	0.87
Improve relationships/communication with others	15	8	17	0.26
Take on a hobby/new skill	14	28	9	**0.02**

Overall percentages do not add to 100%; participants were able to cite ≥1 chief complaint and ≥1 goal.

BEHAVIORAL HEALTH AND HEALTH-RELATED GOALS

Pain management (44%), weight loss (43%), and increased physical activity level (28%) were the most commonly set goals set among participants at program onset; the priority or frequency of these goals did not vary by participant sex (*Table 2*). Participants also aimed to develop skills to improve mood management, follow a healthy diet, improve their relationships or communication with others, and to develop other new skills or hobbies. Males were more likely than females to set attainment of a new skill or hobby as a goal (OR = 3.8; 95% CI = 1.2–12.2).

MOOD TRIGGERS

Triggers for depressed, anxious, or other mood states among chronic pain program participants fell into two distinct categories: internal (i.e., those felt or thought by the participant) and external (i.e., environmental or situational). Internal mood triggers included severe pain (47%), health concerns (e.g., uncertainty about future health, upcoming medical appointments/procedures; 46%), and thoughts about someone else (e.g., thinking of someone who died, worry about someone else's well-being; 40%) (*Fig. 3a*). External mood triggers included interpersonal relationship challenges (45%), work (e.g., worry about current work circumstances or return to work; 40%), and financial concerns (34%) (*Fig. 3b*). Frequency of cited mood triggers did not vary by sex.

Discussion

In this longitudinal study, we described the characteristics and behavioral health outcomes among men and women who participated in a nationally scaled, evidence-based behavioral telehealth program for chronic pain. Approximately four out of five participants with elevated baseline scores experienced reduction in symptom severity during the 8-week program period; more than half experienced a ≥50% reduction in depression severity. There were no meaningful differences between male and female participants in the magnitude of changes observed in depression, anxiety, or stress measures. Back pain was the most common chief complaint that brought patients to the program at baseline. At program outset, participants most frequently set goals related to pain management and weight loss.

Cognitive behavioral therapy is a well-established treatment strategy for behavioral health conditions among chronic pain patients, although not all patients have access to high-quality evidence-based care.[10] Telebehavioral therapy has also been well studied and established as noninferior to face-to-face delivery for the treatment of depression.[19] Fewer studies have examined the impact of telebehavioral therapy on depression specifically among chronic pain patients. The reduction in depression scores observed in our patient population was consistent with those documented with telebehavioral therapy protocols for depression in medical populations, including but not limited to patients with chronic pain.[17,19,37–39] For example, in a recent pilot randomized trial of a telephone-delivered depression and disease management program for patients with chronic pain, diabetes and/or hypertension, and depressive symptoms, 24% of participants had experienced a ≥50% reduction in depression score (Beck Depression Inventory II), and 45% of participants experienced a clinically meaningful reduction in Patient Health Questionnaire-9 score at week 10.[17] Our data demonstrating that more than half

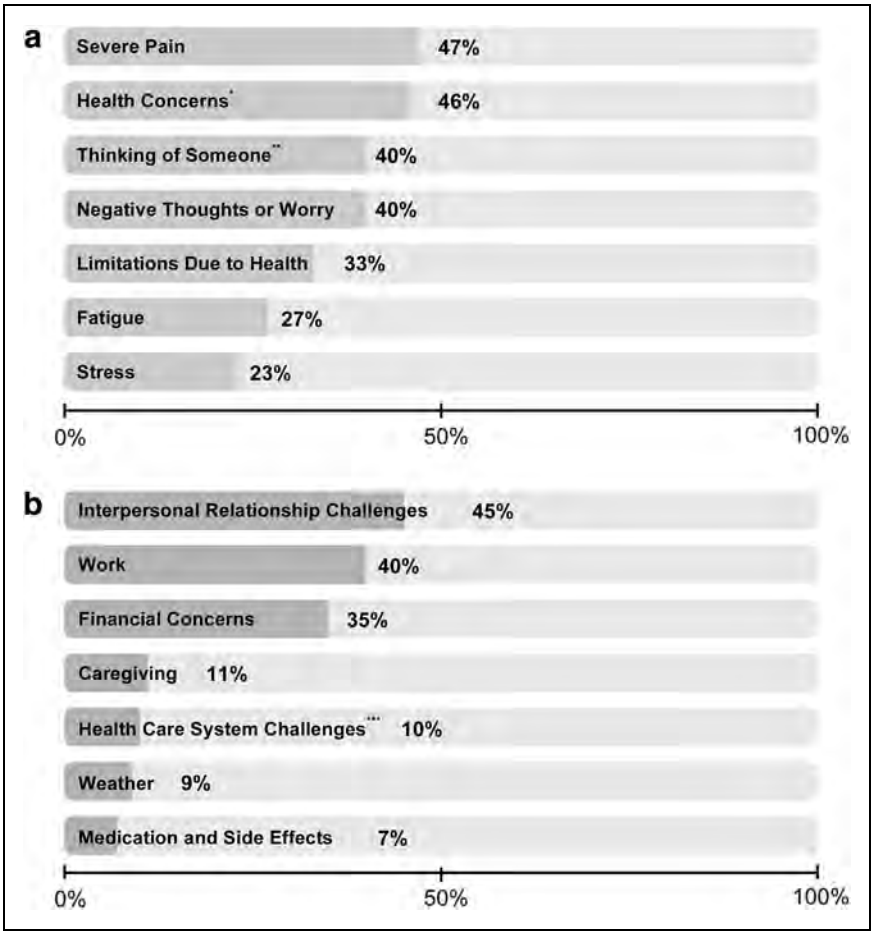

Fig. 3. (a) Internal triggers for depressed, anxious, or stressed mood among chronic pain telebehavioral health program participants. **(b)** External triggers for depressed, anxious, or stressed mood among chronic pain telebehavioral health program participants. *Health concerns include worry about current health, medical issues or medications, uncertainty about future health, and anticipation of upcoming doctor appointments. **Thinking of someone includes thinking of someone who died or who is far away and thinking of someone else's health. ***Healthcare system challenges include concerns about health insurance and frustration with medical team or assessing care.

of participants with depressive symptoms at baseline experienced a greater than 50% decline in DASS-21 depression severity are consistent with these previously published data. This research further contributes to the literature by documenting changes in psychological measures following the implementation of a protocoled, evidence-based technology-enabled behavioral health intervention in a real-world setting.

Novel aspects of this intervention included the (1) national reach and scale of a standardized telebehavioral health treatment program; (2) data-driven approach to identification of patients in need of collaboration with health plans and healthcare providers; (3) proactive identification of and outreach to individuals at increased risk for behavioral health comorbidity associated with chronic pain; and (4) specific tailoring of the program to the individual needs of patients with chronic pain. To our knowledge, this is also one of the first studies to document characteristics, chief complaints, goals, and common mood triggers among patients with chronic pain participating in remotely delivered behavioral treatment. The higher prevalence of female versus male participants, as well as the higher reported opioid prescription rate among female participants, corroborated with the established sex distributions of chronic pain and medication prescription for chronic pain in the U.S.[40,41] The presenting chief complaints among participants in this study were consistent with the most prevalent chronic pain conditions in the U.S. as well (back pain, other orthopedic).[1,42] The behavioral change goals set by participants such as weight loss, increased physical activity, and improving social relationships were aligned with lifestyle factors associated with the development of chronic pain (weight gain and reduced physical activities), as well as with common pain management strategies (weight loss and physical therapy).[1] Taken together, these results support concordance of characteristics between the participants in this telebehavioral health program and U.S. chronic pain patient population and suggest the generalizability of a program of this nature.

The study should be considered within the context of its limitations. We did not have data related to changes in pain severity during the program period; therefore, we were unable to evaluate concurrent changes in pain and psychological symptoms. This was a retrospective analysis of clinical data. As no unexposed control group was available for comparison, we cannot draw causal conclusions between participation and changes in depression, anxiety, and stress symptoms. Nonetheless, participant characteristics and observed changes in clinical symptoms were similar to what has been documented in other clinical and research settings, supporting generalizability of the research results. Aims for future research include assessment of changes in pain severity among program participants, as well as longer term evaluation to determine persistence of symptom reductions gained during the program period.

For the millions of U.S. adults with chronic pain and depressive symptoms, individual or system-level barriers may limit access to behavioral therapy. Participants in a nationally scaled telebehavioral health program shared common sources of pain, behavioral health goals, and mood triggers. Depression, anxiety, and stress symptoms improved in the majority of program graduates, and outcomes did not vary by sex. This study demonstrates the potential clinical impact of a scaled telebehavioral health program for chronic pain designed to address the rising prevalence of chronic pain in the U.S. and the increased comorbidity and healthcare costs associated with untreated mental health and related substance use disorders.

Author Disclosure Statement

Dr. H.M-G. is an employee of and holds an equity interest in AbleTo. Ms. A.P. is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Clinical Officer. Ms. L.V. is an employee of AbleTo. Dr. R.L.P. is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Medical Officer.

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AbleTo

A Tele-Behavioral Health Intervention to Reduce Depression, Anxiety, and Stress and Improve Diabetes Self-Management

Telemedicine and e-Health

Summary

AbleTo's diabetes program was specifically designed to help individuals with diabetes understand and better manage depressive symptoms in support of medical adherence and positive lifestyle changes. Significant reductions in average depression, anxiety, and stress symptoms were observed over the 8-week program period among participants symptomatic at baseline. Increased blood glucose self-testing frequency was documented; participants who tested their blood glucose experienced a reduction in average morning blood glucose levels at 8-weeks versus baseline. These data support the impact of virtually delivered behavioral health interventions to improve mental health and diabetes self-management.

Demographics

- 466 participants
- Average age: 57 years
- 56% female/44% male

Key Outcomes

Among those with elevated baseline scores there were significant reductions in average DASS-21 symptoms scores at 8-weeks:

- Depression (-8.8 points), anxiety (-6.9 points), stress (-9.9 points)
- ≥80% improved to less severe depression, anxiety, or stress categories

Improved glucose self-testing frequency

- (60% vs. 69% tested ≥once per week)

Significant reductions in mean morning glucose levels

Diabetes program graduates experienced significant improvements in behavioral health symptoms and diabetes self-care behaviors.

Full Study: Mochari-Greenberger H, Peters A, Vue L, Pande RL. A Behavioral Telehealth Program for Chronic Pain: Participant Characteristics, Goals, and Psychosocial Outcomes. Telemed J E Health. 2017; 23:640-648. http://doi.org/10.1089/tmj.2016.0188

Original Research

A Tele-Behavioral Health Intervention to Reduce Depression, Anxiety, and Stress and Improve Diabetes Self-Management

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Abstract

Background: *Depression is prevalent among individuals with diabetes and associated with suboptimal self-management. Little is known about the feasibility and potential impact of tele-behavioral therapy to improve depressive symptoms and self-management among diabetes patients.* ***Methods:*** *This was a retrospective observational study of consecutive graduates enrolled in a national 8-week diabetes behavioral telehealth program between August 1, 2014, and January 31, 2015 (N=466; mean age 56.8±5.0 years; 56% female). Participant characteristics (demographics, comorbidities) were obtained by standardized questionnaire. Depression, anxiety, and stress symptoms (DASS; validated Depression Anxiety and Stress Scale 21 survey), and glucose self-testing frequency and values (point-of-care monitor) were measured at program start and completion. Changes in DASS severity and glucose self-testing frequency were assessed by chi-square tests. Changes in DASS and blood glucose levels were evaluated by paired t-tests.* ***Results:*** *At baseline, approximately one in three participants had elevated depression (32%), anxiety (33%), or stress (31%) scores. Significant reductions in average DASS, depression (−8.8), anxiety (−6.9), and stress (−9.9), scores were observed at graduation among those with elevated baseline scores ($p<0.0001$); most (≥80%) improved to less severe depression, anxiety, or stress categories. Improved glucose self-testing frequency (69% vs. 60% tested ≥once per week; $p=0.0005$) and significant reductions in mean morning glucose levels (−12.3 mg/dL; $p=0.0002$) were observed from baseline to graduation. Participants with normal versus non-normal depression scores were more likely to have lower (<mean) glucose levels at graduation (odds ratio=2.0; 95% CI=1.1–3.7).* ***Conclusions:*** *This study documented significant decreases in depression, anxiety, stress, and glucose levels, as well as increased frequency of glucose self-testing, among participants in a diabetes behavioral telehealth program.*

Key words: *behavioral health, telehealth, telemedicine, education*

Introduction

Depression is highly prevalent among individuals with diabetes,[1,2] and more than half may experience less severe depression symptoms.[3] Depression is associated with suboptimal diabetes self-management behaviors such as lower glucose self-monitoring[4,5] as well as with adverse clinical outcomes, including nephropathy, retinopathy, hospitalization, and death.[6–10] Nearly one in ten people in the United States (U.S.) have diabetes,[11] suggesting that widely disseminated programs effective to reduce psychological distress in diabetes patients could have significant public health impact. Moreover, studies suggest that diabetes paired with a comorbid mental health condition is associated with significantly increased cost of care.[12]

Telehealth is a mechanism with the potential to reach the large diverse U.S. diabetes patient population.[13] Although traditional therapeutic strategies have been demonstrated effective to improve depressive symptoms among people with diabetes,[14–16] less is known about the impact of telehealth-delivered behavioral health interventions to improve mental health and diabetes self-management.

The purpose of this study was to evaluate the feasibility and potential impact of a tele-behavioral healthcare program uniquely designed to treat comorbid behavioral health issues associated with diabetes to change participant depression, anxiety, and stress measures. Secondary aims were to (1) determine whether the degree of change in depression, anxiety, or stress scores varied by participant demographic or clinical characteristics and (2) evaluate changes in glucose self-monitoring frequency and glucose levels from program initiation to graduation.

Materials and Methods

STUDY DESIGN AND PARTICIPANTS

AbilTo is a digital healthcare provider that offers behavioral healthcare services through telephone and secure video to patients across the United States. Populations served include individuals with chronic medical conditions, sudden medical

events, or difficult life transitions. This was a retrospective study of deidentified records from 466 consecutive AbilTo diabetes program graduates who enrolled in the program during a 6-month period between August 1, 2014, and January 31, 2015.

Persons were eligible to enroll in the diabetes program if they had a documented diagnosis of having diabetes mellitus in combination with a recent change in medical status, such as an acute event (e.g., hospitalization) or a new medication regimen. Persons with the following criteria were ineligible for enrollment and redirected for clinical consultation and referral: (1) suicide attempt in the past 3 years, (2) psychiatric hospitalization in the past year, (3) current suicidal ideation or nonsuicidal self-injury, (4) bipolar disorder, symptomatic in the past year or not medication stable, (5) severe substance abuse disorder, substance intoxication or withdrawal, or high score on substance use disorder assessment, (6) psychotic symptoms, (7) borderline intellectual functioning; major neurocognitive disorder, (8) domestic violence or homicidal ideation, and (9) end-stage illness. Among 778 persons who completed their first therapy visit, 549 (71%) remained enrolled for at least half way through the program and 494 (63%) graduated (*Supplementary Figure S1*; Supplementary Data are available online at www.liebertpub.com/tmj). Of these graduates, 466 graduated during the prespecified outcomes assessment time frame of October 1, 2014, to March 31, 2015, inclusive, the time period during which blood glucose monitoring data were systematically abstracted from consecutive graduate charts. Health Insurance Privacy and Accountability Act (HIPAA)-trained research staff conducted retrospective record review to abstract deidentified participant data for the analysis. The protocol for this research was approved by the Sterling Institutional Review Board.

PROGRAM DESCRIPTION

AbilTo's diabetes program was specifically designed to help individuals with diabetes understand and better manage depressive symptoms in support of medical compliance and positive lifestyle changes. The program was developed using evidence-based approaches and behavior change tools, including cognitive behavioral therapy, acceptance and commitment therapy, mindfulness, and motivational interviewing, and clinical guidelines to reduce depression, anxiety, and stress and to improve self-management and outcomes among people living with diabetes. The program was designed by the AbilTo clinical team in collaboration with an interdisciplinary advisory group of neuropsychology, clinical psychology, clinical social work, and other medical professionals.

Program delivery occurred through telephone or secure video based on participant preference. The program was administered by a care team, which was made up of a behavioral health provider (licensed clinical social worker or equivalent [LCSW]) and a behavioral coach. Care teams received standardized Association of Social Work Board-certified training provided by AbilTo to ensure consistent and quality delivery of AbilTo's best practice diabetes program protocol.

The AbilTo diabetes program comprised an initial consultation and 15 sessions completed within an ~8-week period. The initial consultation included a baseline interview and was conducted by an LCSW on the care team. The initial consultation was followed by eight sessions with an LCSW and seven sessions with a behavioral coach. During the course of the program, the LCSW and the behavioral coach participated in case conferences under the guidance of an LCSW clinical supervisor to review participant progress. The clinical supervisor also reviewed session notes on a weekly basis to ensure high quality and adherence to the treatment protocol. The protocol comprised modules targeted to specific skills and tailored to the individual participants' needs and goals, drawing from the principles of cognitive behavioral therapy and other evidence-based behavioral health intervention strategies.

The telehealth program protocol was delivered through a customized technology platform. This platform ensured consistent program delivery using a proprietary content management system, which provided a secure system in compliance with HIPAA to allow sharing of session notes among the LCSW, behavioral coach, and the clinical supervisor. Through the platform, the national network of providers had direct access to standardized protocols and online forms to be used to guide each session. Providers also used the platform to input session notes into a protected electronic record, schedule next sessions, and securely message participants.

MEASURES

Participant characteristics, including age (years), sex, U.S. region (west, mid-America, southeast, and northeast), past medical history (cardiac, endocrine, gastrointestinal, gynecological, hepatic, pulmonary, neurological, nutritional, renal, or sexual disease/disorder; history of major surgery, trauma, or tuberculosis), and psychological health history (depression, anxiety), were self-reported and systematically documented by the LCSW on the care team immediately before program initiation as part of the initial consultation.

The primary outcome was change in the severity of depression, anxiety, and stress measures from baseline to program graduation. Depression, anxiety, and stress were measured using the Depression Anxiety Stress Scale 21

(DASS-21).[17] The DASS-21 has been validated to assess depression, anxiety, and stress symptoms in diverse populations.[18–20] The DASS-21 contains seven items each to measure depression, anxiety, and stress for a total of 21 items. For each item, participants were asked to use a 4-point frequency scale to rate the extent to which they experienced the item over the past week (0 = never; 1 = sometimes; 2 = often; 3 = almost always). Depression, anxiety, and stress scale (DASS) scores were calculated by first summing the points for each individual scale score, then multiplying by a factor of two. Non-normal is defined as a depression scale score >9 points, an anxiety scale score >7 points, or a stress scale score >14 points.[17,21] Non-normal DASS scores were further categorized as mild, moderate, severe, or extremely severe based on established guidelines.[22] The DASS-21 was administered immediately before program initiation at the initial consultation and was repeated at program graduation by an LCSW on the care team.

Secondary outcome measures included (1) change in adherence to morning glucose self-testing (self-testing and documenting at least once weekly) and (2) change in morning blood glucose level (weekly average of morning glucose readings recorded by the participant using a point-of-care monitor; mg/dL) from program week 1 to graduation. These data were systematically collected by the care team during week 1 and graduation sessions.

STATISTICAL ANALYSES

Descriptive statistics were used to illustrate characteristics of the study population, the proportion of participants in each DASS category at baseline and at graduation, and the proportion of participants testing morning glucose level at baseline and at graduation. A comorbidity score was calculated by summing the total number of comorbid conditions (of a total of 14); this score was dichotomized at the median (>2 vs. ≤2). Changes in DASS scores for depression, anxiety, and stress, as well as change in mean morning glucose value, were calculated (1) as the absolute difference in value at graduation versus baseline and (2) as the percent change in value from baseline to graduation.

Single-arm paired *t*-tests were used to evaluate change in (1) DASS scores and (2) morning glucose levels from baseline to graduation. Univariate associations between participant characteristics and changes in DASS scores and morning glucose levels were examined using generalized linear regression models. Chi-square tests were used to evaluate differences in the proportion of participants who were testing morning glucose at baseline versus graduation and the associations between above normal (≥100 mg/dL) and high (≥mean) glucose levels and DASS score category (non-normal vs. normal).

Analyses were completed using SAS statistical software (version 9.4; SAS Institute Carey). Statistical tests were two-sided with alpha set at 0.05.

Results

BASELINE CHARACTERISTICS OF DIABETES PROGRAM PARTICIPANTS

Demographic and clinical characteristics of program participants are presented in *Table 1*. More than half of participants were over 55 years old and 44% were male. Participant location varied by U.S. region; the fewest (16%) were from mid-America ($p = 0.0001$). Almost 50% of participants had >2 comorbid medical conditions. Past psychological history of depression or anxiety was reported by 58% of participants and half had an elevated baseline depression, anxiety, and/or stress score. The majority of participants (92%) had a baseline morning glucose level ≥100 mg/dL.

Table 1. Baseline Characteristics of Consecutive AbilTo Diabetes Program Graduates (*N* = 466)

Demographics	
Age, years (mean (SD); [range, median])	(56.8 (5.0); [31–70, 57])
Sex (Female), *n* (%)	259 (56)
Region of the United States.	
West, *n* (%)	142 (30)
Mid-America, *n* (%)	76 (16)
Southeast, *n* (%)	128 (28)
Northeast, *n* (%)	120 (26)
Clinical factors	
Comorbidity score (mean (SD); [range, median])	(2.6 (1.7); [0–8, 2])
Self-reported history of depression, *n* (%)	218 (47)
Self-reported history of anxiety, *n* (%)	165 (35)
Elevated baseline DASS depression scores [>9], *n* (%)	147 (32)
Elevated baseline DASS anxiety score [>7], *n* (%)	153 (33)
Elevated baseline DASS stress score [>14], *n* (%)	145 (31)
Baseline morning glucose ≥100 mg/dL [yes],[a] *n* (%)	257 (92)

DASS, depression, anxiety, and stress scale; SD, standard deviation.

[a]Analysis included *n* = 281 participants with baseline morning glucose values.

Table 2. Association Between Participant Characteristics and Baseline DASS ($n=466$)

	BASELINE DASS SCORES					
	DEPRESSION SCORE		ANXIETY SCORE		STRESS SCORE	
	β	p	β	p	β	p
Demographics						
Age (≥57 vs. <57 years)	0.3	0.68	0.3	0.64	0.1	0.89
Sex (female vs. male)	1.1	0.13	**1.6**	**0.01**	0.7	0.37
U.S. Region[a]						
West	−0.2	0.87	−0.4	0.60	−0.8	0.46
Mid-America	−0.9	0.45	−1.9	0.06	−2.3	0.07
Southeast	−1.1	0.28	−0.4	0.61	−0.4	0.73
Clinical factors						
Comorbidity score (>2 vs. ≤2)	**1.7**	**0.03**	**1.8**	**0.004**	**3.0**	**0.0002**
Self-reported history of depression	**5.3**	**<0.0001**	**2.6**	**<0.0001**	**4.4**	**<0.0001**
Self-reported history of anxiety	**3.6**	**<0.0001**	**2.9**	**<0.0001**	**4.6**	**<0.0001**
Morning glucose (≥100 vs. <100 mg/dL)	−0.3	0.71	0.5	0.41	1.0	0.20

[a]Northeast = reference group.

Values shown in bold indicate statistical significance.

DEPRESSION, ANXIETY, AND STRESS OUTCOMES

No significant associations were observed between participant demographic characteristics and baseline DASS score, except females had on average a 1.6-point higher baseline anxiety score versus males (*Table 2*). Self-reported psychological history of depression and anxiety were each significantly associated with higher baseline DASS scores. Higher comorbidity (comorbidity score >2) was associated with higher baseline depression, anxiety, and stress scores. Elevated morning glucose (≥100 mg/dL) was not associated with baseline DASS scores.

Significant reductions in mean depression (−8.8 points (−51%); $p<0.0001$), anxiety (−6.9 points (−45%); $p<0.0001$), and stress (−9.9 points (−45%); $p<0.0001$) scores were observed from baseline to graduation among participants with elevated scores at baseline. In univariate analyses, age, sex, and higher comorbidity score were not associated with changes in DASS scores.

Among participants with elevated baseline depression scores, 67% transitioned to normal depression scores by graduation. Similarly, 59% of participants with elevated baseline anxiety and 70% of participants with elevated baseline stress scores transitioned to normal scores by graduation (*Fig. 1*). Fewer than 7% of participants experienced worsening in one or more DASS category scores from baseline to graduation, whereas most participants with nonnormal baseline DASS score improved to a less severe depression (81%), anxiety (80%), or stress (86%) category by graduation (*Fig. 2*).

DIABETES SELF-CARE AND OUTCOMES

At baseline, data were available from 281 (60%) participants who had tested and recorded morning glucose levels. The mean baseline morning glucose level among these participants was 146.2 ± 50.9 mg/dL. At graduation, significantly more participants reported glucose self-testing at least once per week (69%; *Fig. 3*); mean morning glucose at graduation was 135.8 ± 43.1 mg/dL.

The mean absolute change in morning glucose from baseline to graduation was −12.3 mg/dL ($p=0.0002$). When the sample was restricted to participants with above normal (≥100 mg/dL) morning glucose at baseline ($n=214$), the absolute change in glucose from baseline to graduation was

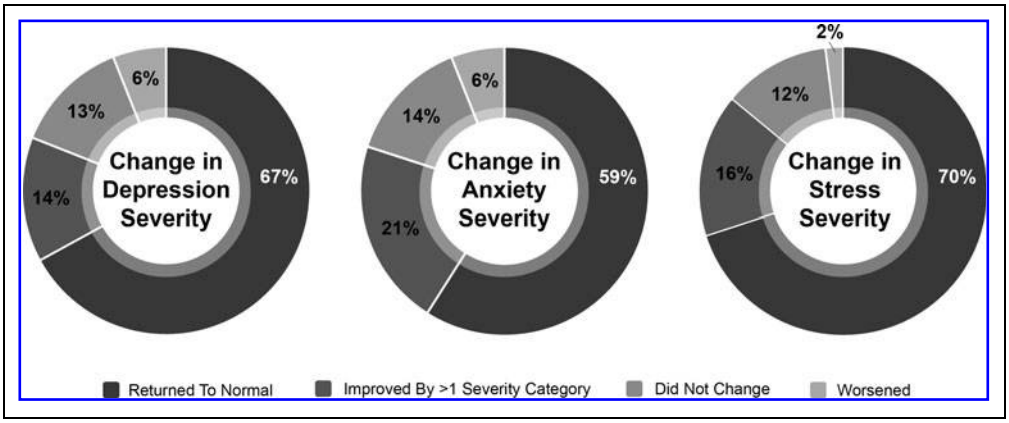

Fig. 1. Change in DASS severity among diabetes program participants with elevated baseline scores. DASS, depression, anxiety, and stress scale.

DASS Depression Score Category at Baseline (%)	DASS Depression Score Category at Graduation (%)				
	Normal	Mild	Moderate	Severe	Extremely Severe
Mild	26%	2%	2%	0%	0%
Moderate	33%	6%	7%	1%	1%
Severe	3%	2%	1%	1%	1%
Extremely Severe	5%	1%	4%	0%	2%

DASS Anxiety Score Category at Baseline (%)	DASS Anxiety Score Category at Graduation (%)				
	Normal	Mild	Moderate	Severe	Extremely Severe
Mild	14%	4%	1%	1%	1%
Moderate	27%	7%	6%	1%	1%
Severe	9%	3%	4%	2%	1%
Extremely Severe	9%	1%	2%	4%	3%

DASS Stress Score Category at Baseline (%)	DASS Stress Score Category at Graduation (%)				
	Normal	Mild	Moderate	Severe	Extremely Severe
Mild	29%	4%	1%	0%	1%
Moderate	29%	8%	6%	0%	1%
Severe	10%	2%	4%	1%	0%
Extremely Severe	3%	0%	1%	1%	1%

[a] Depression N=139 (8 missing), Anxiety N=142 (11 missing), Stress N=136 (9 missing)

Fig. 2. Change in DASS severity categories among diabetes program participants with elevated baseline scores.

−15.8 mg/dL ($p < 0.0001$). Age, sex, or U.S. region was not associated with percent change in morning glucose; higher baseline morning glucose levels were associated with greater mean reductions in glucose over the program period.

Participants with normal depression scores at graduation were more likely to have lower morning glucose levels (<the mean) at graduation versus those with non-normal graduation depression scores (odds ratio [OR] = 2.0; 95% CI = 1.1–3.7); similar associations were observed between normal graduation anxiety (OR = 1.2; 95% CI = 0.7–2.1) and stress (OR = 2.1; 95% CI = 1.1–3.9) scores and odds of having lower glucose levels at graduation.

Discussion

This retrospective analysis of records from over 460 participants in a behavioral telehealth program for patients with diabetes documented significant improvements in mental health and diabetes self-care outcomes. Depression, anxiety, and stress symptom scores each improved by at least 45%; and more than 65% of participants with non-normal baseline depression scores recovered to normal by the end of treatment. Frequency of glucose self-testing increased to almost three of four participants, with significant reductions in mean morning glucose levels observed among participants with elevated baseline glucose values. Normal depression score was associated with lower glucose level at program end.

The specific impact of remotely delivered behavioral therapy interventions on depression, anxiety, and/or stress among patients with diabetes is not well studied. Prior research has examined the impact of educational telehealth interventions on diabetes patient self-management and psychosocial health outcomes and has established feasibility and acceptability.[23] While some of these data have shown that education-based programs can be as effective as in-person interventions to improve emotional well-being,[24] others have yielded no significant differences in mental health improvements,[25] highlighting a need for targeted tele-behavioral health interventions for patients with diabetes.

Our study demonstrated that a standardized behavioral health program, grounded in evidence-based approaches and tailored to diabetes patients, can be successfully delivered through telehealth. Participants experienced significant improvements in depression scale scores associated with clinical improvement and return to normal among two-thirds of participants with non-normal scores at baseline. These results corroborate findings from a small ($N = 83$) 10-week pilot trial recently conducted by Aburizik et al.[26] The intervention was not solely targeted to diabetes, but results supported efficacy of a counselor-delivered tele-behavioral health intervention to significantly reduce depressive symptoms among U.S. veterans with a chronic condition (diabetes, hypertension, and/or chronic pain).[26] Similarly, Piette et al. recently showed that telephone-delivered, nurse-administered, cognitive behavioral therapy decreased depressive symptoms among a sample of diabetes patients recruited from a community healthcare

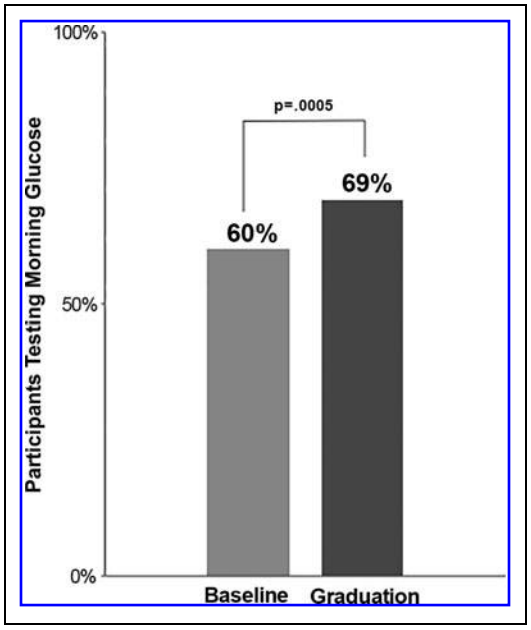

Fig. 3. Proportion of participants performing glucose self-testing at baseline and at graduation.

system.[27] Our program had several distinct characteristics. First, in addition to targeting and improving depressive symptoms, our program targeted and improved anxiety and stress, as well as participants' individual diabetes self-care goals. Second, our program utilized a national network of trained and supervised LCSW therapists, in contrast to site-specific nurses or counselors. Third, our program systematically identified and engaged diabetes patients during a teachable moment such as a recent hospitalization, which may promote behavior change.[28] Fourth, our program enrolled participants from a larger, diverse, nationally drawn sample.

Participants experienced an increase in glucose self-monitoring frequency, with almost three of four testing their morning glucose levels at the time of program completion. Prior data to demonstrate the impact a psychological telehealth intervention has on diabetes self-management behaviors are sparse. However, proof of concept for tele-interventions to increase frequency of glucose self-monitoring and improve glycemic control has been demonstrated through educational and clinically focused interventions.[29–35] In addition, psychotherapy interventions for diabetes patients, not delivered through telehealth, have been shown to be effective to improve glucose self-monitoring frequency.[14] The results provide new evidence that a behavioral health intervention specifically designed for tele-delivery can be associated with improved diabetes self-management.

Strengths of this study include the evaluation of behavioral health and clinical outcomes among participants in an evidence-based diabetes behavioral telehealth program. Consistent with prior research, our results linked depressive symptoms and glucose levels at program completion, supporting external validity of the clinical data.[36–38] An additional strength is the national sampling of participants, which (1) allowed us to evaluate associations between diverse participant characteristics and observed changes in DASS scores and glucose levels and (2) illustrates the potential for generalizability and widespread dissemination.

This research has limitations. The nonrandomized single-arm design limits causal inferences linking the program to outcomes. The study includes program completers and results may not be generalizable to participants who did not complete the program. Glucose measures were documented based on self-reported data, which may be subject to bias.

In conclusion, this study demonstrated the feasibility and potential impact of an evidence-based tele-behavioral health program to improve mental health and self-management among persons with diabetes. Depression, anxiety, and stress symptoms, and mean glucose levels decreased among program graduates, while frequency of glucose self-testing increased. Future aims include reassessment of participant outcomes over the longer term to determine persistence of improvements gained over the course of the program period. The high national prevalence of diabetes and associated comorbid depressive symptoms indicate a need for diabetes-focused behavioral health programs that could possibly be filled by a national, scalable, behavioral telehealth program.

Disclosure Statement

H.M.-G., A.L., and L.V. are employees of AbilTo. A.P. is an employee of and holds an equity interest in AbilTo. She serves as AbilTo's Chief Clinical Officer. R.L.P. is an employee of and holds an equity interest in AbilTo. She serves as AbilTo's Chief Medical Officer.

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Research Talk 11:00 AM - 12:00 PM

PREVALENCE AND CHANGE IN LONELINESS AMONG OLDER U.S. ADULTS ENGAGED IN TELEBEHAVIORAL HEALTHCARE

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[1]AbleTo Behavioral Health, New York, NY

Background: Loneliness affects one in four adults aged 70 and older and is associated with adverse mental and physical health outcomes.

Purpose: We aimed to describe the prevalence and correlates of loneliness, as well as changes in loneliness, among older adults with medical comorbidities engaged in telebehavioral healthcare.

Methods: This retrospective cohort study evaluated de-identified clinical data from 425 participants consecutively enrolled in a standardized, evidence-based 8 week behavioral therapy program delivered over telephone or secure video. Sociodemographic and clinical characteristics including loneliness level (6-item DeJong Gierveld Loneliness Scale), self-rated health, and psychological symptom severity (Depression Anxiety Stress Scales 21) were assessed at baseline by a licensed therapist. Participants with complete loneliness data at baseline (N=405 [95%]) were included in the analytic sample (72% female, 22% non-white race/ethnicity, mean age 76.0 + 8.0 years). Chi-square statistics were used to assess for associations between baseline characteristics and loneliness. Change in loneliness was evaluated by paired t-tests and linear regression models.

Results: Approximately 61% of participants were lonely at baseline (44.4% moderately lonely, 17.0% severely lonely). Odds of being lonely were higher among participants with elevated DASS-21 scores (OR=2.5; 95%=1.6–3.7). Severe loneliness was more common among those who rated their health as fair or poor (vs. good, very good, excellent; OR=2.3; 95% CI=1.4–4.0). Among participants lonely at baseline, mean within-person loneliness score was 35% lower at 8 weeks ($p < .0001$). Percent change in loneliness score was correlated with percent change in DASS-21 depression score during the same timeframe ($r=.43$; $p < .0001$). In the fully adjusted linear regression model, change in loneliness was non differential by age group, sex, or race/ethnic group ($p > .05$).

Conclusion: Loneliness was prevalent among older adults enrolled in a virtual behavioral therapy program. Loneliness levels were reduced after 8 weeks of therapy and associated with reductions in psychiatric symptom severity.

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Research Talk 11:00 AM - 12:00 PM

PREVALENCE AND SOCIODEMOGRAPHIC DIFFERENCES OF HIGH BLOOD PRESSURE IN CHILDREN

Melissa Goulding, MS[1], Stephenie C. Lemon, PhD[1]

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Background: In 2017, the American Academy of Pediatrics' (AAP) clinical practice guidelines for pediatric hypertension were updated with a focus on the role of weight as a risk factor. We provide contemporary, nationally representative, prevalence estimates of pediatric hypertension and examine gender, racial/ethnic, and socioeconomic differences in these prevalence rates while accounting for the influence of weight status.

Methods: This cross-sectional study used 2011–2018 National Health and Nutrition Examination Survey data, for a complete case analysis including children aged 8–17 years (N=5,971, weighted N=36,612,323). Children's blood pressures were categorized as hypertensive, elevated, or normal according to 2017 AAP guidelines. Children with elevated or hypertensive blood pressure were classified as having high blood pressure. Prevalence estimates with 95% confidence intervals (CI) were determined with log binomial regression adjusting for weight status (BMI percentile ≥85). The same methods were used to determine prevalence differences across age, gender, racial/ethnic, parent education and family income subgroups.

Results: About half (52%) of children were aged 13–17 years, 50% were female, 55% were Non-Latino White, and 37% had BMI percentiles in the overweight or obese range (>85%). The unadjusted prevalence estimate of pediatric high blood pressure was 11.1% (95% CI 9.9%-12.4%) In unadjusted analyses, high blood pressure prevalence was higher in Mexican American and Non-Latino Black children, compared to Non-Latino White children. Children ≥13, males, and those of lower socioeconomic status (measured by family education and income) also had higher prevalence estimates. After adjustment for BMI percentile, high blood pressure prevalence remained greater in Non-Latino Blacks compared to Non-Latino Whites (prevalence difference +4.6% 95% CI 2.5%-6.8%), children ≥13 (+2% 95% CI 0.3%-3.6%), and males (+5.9% 95% CI 3.5% to 8.3%).

Conclusion: Approximately 11% of children aged 8 to 17 in the United States have high blood pressure and the burden of this disorder is not evenly distributed. After adjustment for weight status more males, older, and Non-Latino Black children experience high blood pressure. Thus, additional factors beyond disparities in weight status contribute to disparities in high blood pressure in U.S. children. Further work is warranted to understand the causes of these disparities in order to inform targeted public health efforts.

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American Diabetes Association. diabetes

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2383-PUB: Improved Medication Adherence among Diverse Participants in a Virtual Behavioral Therapy Program for Adults with Diabetes

HEIDI M. GREENBERGER EVIE ANDREOPOULOS SOPHIE A. BELL and REENA L. PANDE

Diabetes 2019 Jun; 68(Supplement 1): -. https://doi.org/10.2337/db19-2383-PUB

Abstract

Background: Virtual cognitive behavioral therapy (i.e., delivered by telephone or video) increases access to mental health treatment, but few studies describe the impact of virtual therapy on medication adherence among individuals with diabetes. We aimed to evaluate changes in medication adherence among adults with diabetes and common behavioral health issues such as depression or anxiety participating in a nationally available 8-week treatment program (AbleTo).

Methods: This retrospective cohort study included 524 participants consecutively enrolled between 1/1/2017-12/31/2017 of which 369 had complete adherence data for inclusion in the analytic sample (59% female, 43%non-white race/ethnicity, mean age 54+10 years). Prescription medications were documented at baseline (week 1); polypharmacy was defined as >5 medication types. Adherence was measured at weeks 1 and 8 using the standardized question, “Did you miss any doses this week?”; non-adherence was defined as missing any doses. Associations between adherence and participant characteristics (medication count, sex, race/ethnicity, age) were assessed using logistic regression. Change in medication adherence from weeks 1 to 8 was evaluated by McNemar’s test for paired nominal data.

Results: Baseline medication adherence was 86%. Adherence was lower among participants with polypharmacy (82% vs. 91%; p=.02), but did not differ by sex, race/ethnicity (white vs. non-white) or age group (≥55 vs. <55 years). Non-adherence significantly improved from 14% to 8% at week 8 (-42%; p=.005). Improvements were observed in all subgroups and were statistically significant among participants with polypharmacy, females, and non-whites (p<.05).

Conclusion: Medication adherence was improved among participants in an 8-week virtual behavioral therapy program supporting the positive clinical impact of novel care delivery models for adults with diabetes and behavioral health conditions.

Disclosure H.M. Greenberger: Employee; Self; AbleTo. E. Andreopoulos: None. S.A. Bell: None. R.L. Pande: Employee; Self; AbleTo, Inc. Stock/Shareholder; Self; AbleTo, Inc.

Improved Heart Failure Self-Care In A Medicare Population Receiving Virtual Behavioral Therapy: A Health Plan-Provider Collaboration

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ABSTRACT

Introduction: Behavioral health challenges are associated with suboptimal self-care and adverse clinical outcomes in heart failure (HF). Cognitive behavioral therapy addressing these challenges improves depression symptoms and HF self-care, but stigma and access to care issues contribute to low treatment rates. Virtual delivery of behavioral therapy overcomes these barriers, but few studies have evaluated HF outcomes among virtual care recipients.
Hypothesis: HF self-care and depression symptoms will improve among participants in a virtually delivered behavioral therapy program.
Methods: This retrospective study analyzed clinical data from individuals with a Humana Medicare Advantage health plan with Stage B or C HF who participated in a chronic condition-focused behavioral therapy program (AbleTo) in 2018 (N=194; 63% female, 30% non-white, mean age=70 (standard deviation 8.8y), 28% Stage C, 72% Stage B). The program included standardized, evidence-based cognitive behavioral therapy modules tailored to individual goals and was delivered by licensed therapists over ~8 weeks via telephone or video. Standardized assessments were conducted at baseline and week 8 and included 1) the Self-Care of HF Index (SCHFI) v6 maintenance scale (adequate defined as score >70); 2) Depression Anxiety Stress Scales-21 to assess depression symptoms (above normal >9 points); and 3) assessment of knowledge of physician instructions. Changes in these metrics were evaluated by paired t-tests**.**
Results: At baseline, 28% of participants were not aware of physician instructions, fewer than half (41%) had an adequate SCHFI score, and 47% had depression symptoms. At week 8, knowledge of physician instructions increased to 87% (P<.0001); mean SCHFI score increased from 67.1 to 72.2 (P<.0001), and proportion with adequate score increased to 57% (P<.01). Mean reduction in depression symptoms was 52.4% (P<.0001) among participants symptomatic at baseline. Magnitude of improvements in knowledge, SCHFI, and depression was non-differential by HF stage (P>.05).
Conclusion: Significant improvements in HF self-care, depression symptoms, and awareness of physician recommendations were observed among patients that received HF-focused virtual behavioral therapy.

OBJECTIVE

To evaluate the observed changes in knowledge of physician instructions, psychological symptoms and heart failure (HF) self-care behaviors among a cohort of adults with diagnosed HF who participated in a virtually-delivered behavioral therapy program.

METHODS

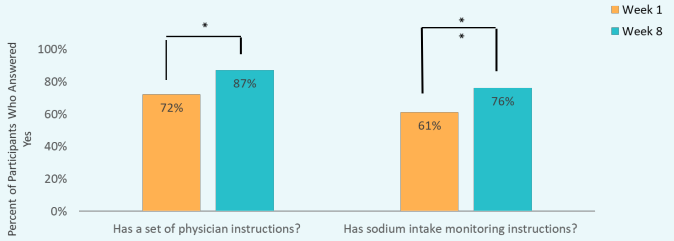
Study Design: A retrospective cohort analysis.
Study Population: The study population comprised of a consecutive sample of adults with Stage B or Stage C HF enrolled in Humana Medicare Advantage health plan in 2018, who completed the intervention (N=194).
Intervention: The AbleTo program consisted of an initial assessment followed by fifteen standardized, evidence-based cognitive behavioral therapy and coaching sessions, delivered by licensed therapists and behavioral coaches, respectively, over ~8 weeks via secure telephone or video. Sessions were tailored to each participants' needs and goals, with a dual focus on improving mental health functioning and cardiac self-management.
Data Collection: Standardized assessments were conducted at baseline and Week 8 and included 1) assessment of knowledge of physician instructions; 2) Depression Anxiety Stress Scales-21 (DASS-21) to assess depression symptoms (above normal >9 points), anxiety symptoms (above normal >7 points), and stress symptoms (above normal >14 points); and 3) the Self-Care of HF Index (SCHFI) v6 maintenance scale and confidence scale (adequate defined as score > 70).[1]
Data Analysis: Descriptive statistics were used to evaluate participant socio-demographic and clinical characteristics. Changes in knowledge, psychometrics, and HF self-care were evaluated using chi-squared statistics, paired t-tests, and Wilcoxon ranked sum test.

RESULTS

Table 1: Characteristics of Consecutive Humana-AbleTo Program Graduates (N=194)

Baseline Characteristics	Distribution	Baseline Characteristics	Distribution
Age, mean (±SD)	69.7 (±8.8)	Heart Failure Stage, n (%)	
		Stage B	154 (72.2)
		Stage C	40 (27.8)
Sex, n (%)		Self-Rated Health, n (%)	
Female	123 (63.4)	Fair/Poor	139 (71.6)
Male	71 (36.6)	Good/Very Good/Excellent	55 (28.4)
Race/Ethnicity, n (%)		Medical History, n (%)	
African American	37 (19.1)	Chronic Kidney Disease	23 (11.9)
Asian	0 (0.0)	Diabetes	116 (60.1)
Hispanic	11 (5.7)	High Blood Pressure	133 (68.9)
White	128 (66.0)	High Cholesterol	76 (39.4)
Other	10 (5.2)	Stroke	15 (7.8)
Declined to Answer	8 (4.1)		
		Psychological History, n (%)	
		Anxiety	60 (31.1)
		Depression	101 (52.3)
		Panic	17 (8.8)

Figure 1: Program Participants Had Improved Knowledge of Physician Instructions



* P= .0001 for within person change from Week 1 to Week 8; N=183
**P= .0002 for within person change from Week 1 to Week 8; N=186

Figure 2: Changes in Depression, Anxiety, and Stress Symptoms Over 8 Weeks Among Humana-AbleTo Program Participants

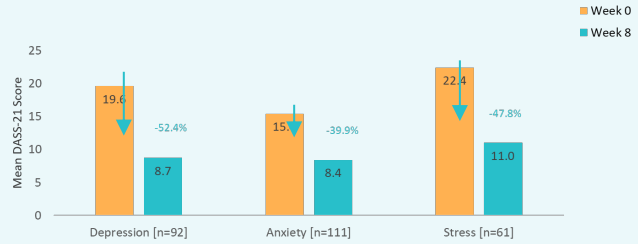
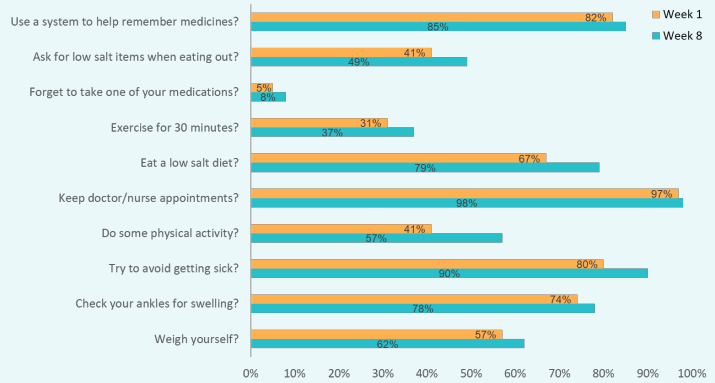
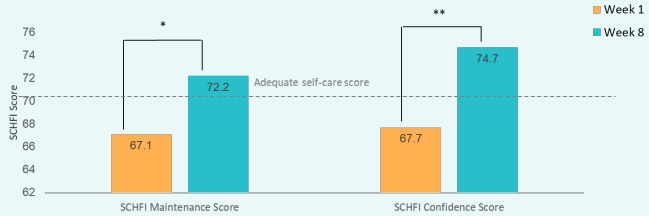


Figure 3: Self-Care of Heart Failure Index (SCHFI)[1] Maintenance Behaviors Observed Among Humana-AbleTo Program Participants



*% indicates proportion of respondents answering always/frequently (vs. sometimes/never); N=183

Figure 4: Mean SCHFI Maintenance and Confidence Scores Observed Among Humana-AbleTo Program Participants



* P < .01 for within person change in SCHFI Maintenance score from Week 1 to Week 8; N=183
** P < .001 for within person change in SCHFI Confidence score from Week 1 to Week 8; N=184

CONCLUSION

Medicare Advantage patients with stage B or stage C HF had improved knowledge of physician instructions, reduced psychological symptoms, and improved HF self-care behaviors after participation in an 8 week virtually delivered cognitive behavioral therapy program. These data spotlight a successful collaboration between a health plan and a virtual behavioral therapy provider to provide access to evidence-based care, resulting in an observed positive impact on HF outcomes.

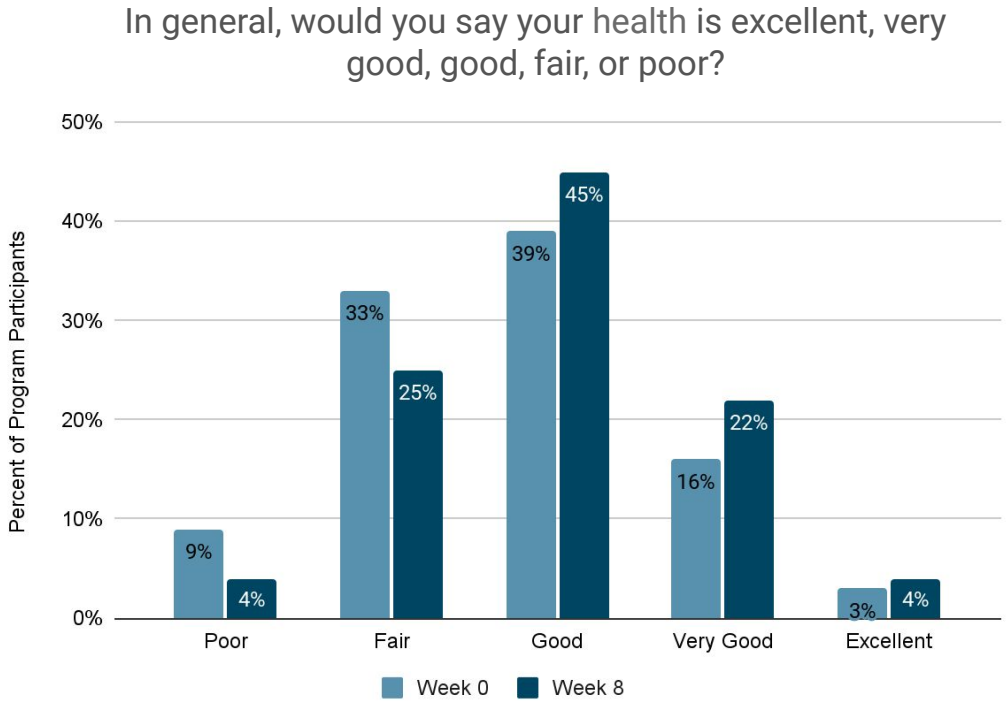
REFERENCE

1. Riegel B, Lee CS, Dickson VV, Carlson B. An Update on the Self-Care of Heart Failure Index. J Cadiovasc Nurs. 2009;24(6):485–497.

American Heart Association. Scientific Sessions

Disclosure: This study was supported by AbleTo, Inc.

Self-Rated Health Significantly Improves among AbleTo Program Participants



Data from a consecutive sample of AbleTo Therapy 360 Program graduates 1/1/21-9/30/21 inclusive (N=17,543); n=112 cohort members (<1%) excluded from analysis due to missing data.

AbleTo

Original Paper

Evaluation of a Commercial Mobile Health App for Depression and Anxiety (AbleTo Digital+): Retrospective Cohort Study

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Abstract

Background: Digital solutions, such as web-based and mobile interventions, have the potential to streamline pathways to mental health services and improve access to mental health care. Although a growing number of randomized trials have established the efficacy of digital interventions for common mental health problems, less is known about the real-world impact of these tools. AbleTo Digital+, a commercially available mental health app for depression and anxiety, offers a unique opportunity to understand the clinical impact of such tools delivered in a real-world context.

Objective: The primary aim of this study is to examine the magnitude of change in depression and anxiety symptoms among individuals who used AbleTo Digital+ programs. The secondary aim is to evaluate Digital+ module completion, including the use of 1:1 coaching.

Methods: In this retrospective cohort study, we analyzed previously collected and permanently deidentified data from a consecutive cohort of 1896 adults who initiated using one of the three Digital+ eight-module programs (depression, generalized anxiety, or social anxiety) between January 1 and June 30, 2020. Depression, generalized anxiety, and social anxiety symptoms were assessed within each program using the Patient Health Questionnaire-9, the Generalized Anxiety Disorder-7, and the Social Phobia Inventory, respectively. Linear mixed effects models were built to assess the association between module completion and symptom change among users who completed at least four modules and had at least mild baseline symptom elevations, controlling for age, gender, and baseline symptom severity. Digital+ use, including module completion, 1:1 coaching calls, and in-app coach messaging, was also evaluated.

Results: Significant effects were observed among depression (Cohen *d*=1.5), generalized anxiety (Cohen *d*=1.2), and social anxiety (Cohen *d*=1.0) program participants who completed at least four modules and had mild baseline elevations (n=470). Associations between module completion and change in depression (β=−1.2; *P*<.001), generalized anxiety (β=−1.1; *P*<.001), and social anxiety (β=−2.4; *P*<.001) symptom scores retained significance with covariate adjustment. Participants completed an average of 2.6 (SD 2.7) modules. The average total length of app use was 52.2 (SD 83.5) days. Approximately two-thirds of the users engaged in at least 1 coaching call (66.82%, 1267/1896) or in-app text messaging (66.09%, 1253/1896). Participants who completed at least four modules participated in significantly more coaching calls per module (mean 1.1, SD 0.7) than users who completed fewer than four modules (mean 1.0, SD 1.2; t_{1407}=−2.1; *P*=.03).

Conclusions: This study demonstrated that AbleTo Digital+ users experienced significant reductions in depression, generalized anxiety, and social anxiety symptoms throughout the program.

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KEYWORDS

digital mental health; mHealth; iCBT; coaching; depression; generalized anxiety; social anxiety; mobile phone

Introduction

Background

Effective mental health interventions exist for depression and anxiety [1,2], yet more than 50% of people in need of these services do not receive them [3]. A number of systemic- and individual-level barriers lead to these service gaps, including mental health workforce shortages, stigma, and financial barriers [4,5]. In addition, even when individuals are able to access traditional face-to-face services, the lag between symptom onset and treatment initiation is, on average, 11 years [6,7]. As the rates of anxiety and depression continue to increase [8], hastened in part by the current COVID-19 pandemic [9,10], access gaps are likely to worsen in an already strained, fragmented, and underresourced mental health care system [11]. These gaps in service have large societal, familial, and individual costs [12]. For example, in the United States, the estimated annual economic burden of depression alone is US $210 billion [13,14].

Digital solutions, including web-based and mobile behavioral health care interventions, have great potential to streamline pathways to mental health services and improve access to quality mental health care [15]. Stand-alone and adjunctive digital tools can provide timely mental health support that fits individuals' daily lives from the comfort of their own homes. As such, these interventions have the potential to mitigate some of the most common barriers to mental health care, including transportation, time constraints, and stigma. In addition, digital interventions offer a cost-effective and scalable alternative to traditional treatment modalities.

A growing body of research supports the efficacy of digital interventions (ie, mobile interventions and web-based interventions), particularly for common mental health problems such as depression and anxiety [15-19]. Indeed, between 2009 and 2015, the National Institute of Mental Health awarded 404 grants to technology-enabled interventions, and more than 100 randomized trials have been conducted [20]. However, questions remain about the effectiveness of these tools, particularly in real-world settings [21], and their reach is often limited. Few mental health apps developed in the context of university-based research are being widely used, limiting their potential [22,23].

On the other hand, more than 10,000 commercially developed mobile apps focused on mental health are now widely available and easily accessible [24]. However, the vast majority of these tools lack rigorous testing or evaluation. A systematic review suggests that as few as 3% of the commercially available mobile mental health apps have any peer-reviewed evidence [25], and the apps most commonly downloaded and used contain minimal evidence-based content [23]. For example, Wasil et al [23] examined the proportion of evidence-based content based on monthly use data of common apps. They found that common treatment elements, such as exposure, reached only 2% of users. As a result, numerous efforts have been made to evaluate commercially available apps and create app repositories with standard reporting, and at least 45 frameworks have been developed to assist consumers in identifying the most effective and appropriate apps [24-26]. However, these efforts have fallen short. To date, personal searches on commercial app stores remain the most common method for finding mental health apps [27], and consumers are looking for new approaches to find these tools [28].

Partnering with health plans and employers to help disseminate these tools has the potential to help guide consumers to evidence-based apps that have the greatest potential for impact. There have been calls for health plans to incorporate digital solutions into their behavioral health resources and help their members navigate and discover apps that best meet their needs [29]. This approach may improve behavioral health care use by directing users to additional mental health services. In addition, employers are uniquely situated to link their employees to behavioral health resources. Adults in the United States spend most of their time at work, and mental health problems are often costly to employers because of lost workdays and decreased productivity. Preliminary research suggests a US $2-$4 return on investment for every dollar that employers spend on mental health resources [30]. However, little is known about the effects of these approaches.

Objectives

There is a need to better understand the impact of digital interventions disseminated to real-world users in these new ways. AbleTo's Digital+ program (AbleTo Digital+ has previously been reported on as Joyable [31]. Joyable, Inc, was acquired by AbleTo, Inc, in March 2019) provides a unique opportunity to understand the impact of such tools. Digital+ is a web- and mobile-based platform with personalized coaching for anxiety and depression made available to users through health plans and employer partners. Users are directed to one of three different programs based on their symptom presentation and goals. All Digital+ programs are based on cognitive behavioral principles and include psychoeducation, brief activities (<10 minute), weekly symptom tracking, and 1:1 coaching via phone and in-app messaging. Programs include (1) depression, an eight-module program focused on behavioral activation; (2) generalized anxiety, an eight-module program focused on worry exposures and distress tolerance; and (3) social anxiety, an eight-module program focused on exposure to feared social situations [31]. A critical next step is to better understand the impact of this tool on real-world users. The primary objective of this study is to examine the magnitude of changes in depression and anxiety symptoms among individuals who used the Digital+ programs. The secondary aim is to evaluate Digital+ use across the eight modules of each program and the use of 1:1 coaching.

Methods

Participants

In this retrospective cohort study, we analyzed previously collected and permanently deidentified data from a consecutive cohort of 1896 adults enrolled in an AbleTo Digital+ program between January 1 and June 30, 2020. Participants were aged ≥18 years and were required to have access to their own devices. Participants were excluded if they reported active suicidal ideation or psychosis. All study procedures were submitted to the Sterling institutional review board, Atlanta, Georgia, United States, and deemed exempt.

Procedure

AbleTo, a technology-enabled virtual behavioral health care organization, partners with employers and health plans to make Digital+ accessible to employees and covered members in their networks. Employees and covered members are made aware of Digital+ through marketing campaigns and employer communications that explain the potential benefits of engaging in evidence-based, time-bound digital programs. A variety of engagement strategies were used to make individuals aware of the program and facilitate enrollment. These methods included divulging information about Digital+ on an employer's benefits webpage, via posters, flyers, and table tents in office settings, and through email and text campaigns. Interested participants were then directed to access Digital+ via the web or a mobile app to complete a brief survey (approximately 2 minutes) to determine program appropriateness and create an account.

Description and Structure of the Program

During enrollment, users completed a series of questions designed to assess their appropriateness for Digital+ and generate initial program recommendations. Screening questions to assess participant goals and primary presenting problems were used to determine which of Digital+'s three programs—(1) depression, (2) generalized anxiety, or (3) social anxiety—would best fit the users' needs. Users had the opportunity to review the recommendation and select a different program if they felt that it was not the correct fit. Users then completed one of three standard assessments to establish baseline symptom severity and screening questions about suicidality and psychosis designed to assess safety and risk. Users were also asked to report any current or prior history of common, high-risk, comorbid psychiatric challenges (ie, substance use, eating disorders, bipolar disorder, and posttraumatic stress disorder) to further evaluate the clinical complexity.

Those deemed inappropriate for Digital+ (eg, active suicidal ideation and psychosis) were routed to various resources depending on their employer or health plan. These resources included, but were not limited to, the National Suicide Hotline, a Digital+ in-network provider matching service, or linkage to their health plan to assist in connecting individuals with a higher level of care. In addition, for some partners, individuals were offered the opportunity to enroll in a purely self-guided, five-module skills-based program if they did not wish to engage with a coach or in any of the primary Digital+ programs. Individuals who endorsed active suicidal ideation or psychosis and those in the five-module skills-based program were excluded from this analysis.

Digital+ programs included eight content modules, a 1:1 coaching option, and mood and symptom assessment. All psychoeducational materials and activities were based on core components of cognitive behavioral therapy (CBT), including cognitive restructuring, gradual exposure, and behavioral activation. Each module consisted of 4 to 6, approximately 10-minute activities, including deep breathing, progressive muscle relaxation, cognitive restructuring, and behavioral activation. The activities were organized to help users learn about CBT, depression, or anxiety; develop skills to challenge maladaptive thoughts; and practice newly acquired skills in real-life settings. Each module was designed to be completed within approximately 1 week, but users were not required to complete them in that amount of time. New activities become available once the previous activity is completed. Once the content was made available to users, they were able to revisit previous modules and activities and complete them as many times as desired. At the end of each module, users completed a standard assessment (refer to the *Measures* section for more information) before proceeding to a new module. Users were presented with feedback on their scores, and these scores were accessible to their coaches (see Table 1 for a description of the content of each program).

Table 1. Description of AbleTo Digital+ programs.

Module	Programs					
	Depression		Generalized anxiety		Social anxiety	
	Number of Activities	Content	Number of Activities	Content	Number of Activities	Content
1	6	• Psychoeducation about depression • Introduction to distress tolerance skills (eg, deep breathing)	6	• Psychoeducation about stress and anxiety • Introduction to distress tolerance skills (eg, deep breathing)	4	• Psychoeducation about social anxiety • Introduction to distress tolerance (eg, deep breathing)
2	4	• Introduction to behavioral activation and planning for first activity	5	• Introduction to automatic thoughts and cognitive distortions	4	• Introduction to automatic thoughts and cognitive distortions
3	4	• Introduction to automatic thoughts and cognitive distortions	4	• Psychoeducation about avoidance and exposure • Completion and review of first exposure activity	5	• Psychoeducation about avoidance and exposure • Completion and review of first exposure activity
4	3	• Introduction to values-based behavioral activation, planning and completion of an activation exercise	5	• Practicing cognitive skills, planning, and completing a worry-based exposure	4	• Creating a fear hierarchy and planning and completing an exposure activity
5	4	• Plan and complete an additional values-based activation	5	• Plan and complete an additional exposure and mindfulness activity	4	• Pick a new exposure from the fear hierarchy, plan, and complete the exposure.
6	4	• Plan and complete an additional values-based activation	5	• Plan and complete an additional worry-based exposure	4	• Pick a new exposure from the fear hierarchy, plan, and complete the exposure
7	4	• Plan and complete an additional values-based activation	5	• Plan and complete an additional exposure and mindfulness activity	4	• Pick a new exposure from the fear hierarchy, plan, and complete the exposure
8	6	• Plan and complete an additional final activation • Introduction to core beliefs and preparation for maintaining gains	5	• Plan and complete final exposure • Introduction to core beliefs and preparation for maintaining gains	4	• Plan and complete final exposure • Introduction to core beliefs and preparation for maintaining gains

Coaching

All users were assigned a coach during program enrollment. Coaches are nonlicensed professionals with bachelor's degrees and relevant work experience, course work, or certification in coaching. They receive intensive training in the principles of behavior change, motivational interviewing, Digital+ program content, and crisis intervention. Coaches are trained to focus on motivation and engagement by using motivational interviewing and validating the participants' experiences with depression or anxiety. They also help users understand how program content and activities align with their individual goals, reinforce activity completion and skill use, and provide additional accountability through reminders and encouragement. Coaches are trained in crisis intervention and use the question, persuade, and refer method of crisis intervention. If a user needs a higher level of care, coaches will refer to external resources to better meet the user's needs. Coaches receive ongoing supervision from a motivational interviewing certified trainer and one-on-one supervision to monitor competence in program knowledge and client service. A subset of coaching calls is reviewed to assess adherence to motivational interviewing protocols and monitor quality.

Users have the option to engage in coaching by scheduling an initial kickoff call with their coach during program enrollment, and a welcome message is sent to all users. Kickoff calls are 30 minutes and are used to orient users to the program, establish goals, and set expectations. If a user does not schedule a kickoff call during enrollment, coaches make three attempts to engage

users. After three attempts with no contact, the proactive reach out from the coaches is suspended. Users, however, continue to have access to coaches and can schedule calls or message coaches throughout the program, regardless of their initial preference for coaching, and coaches respond within one business day. Subsequent weekly 15-minute coaching calls are available to users throughout the eight-module program and focus on reviewing activities, clarifying goals, and encouraging ongoing use. Users also have access to in-app text messaging.

Measures

Participant Characteristics

Consistent with the standard program experience, users provided basic demographic information (ie, age and gender) and indicated any current or recent serious behavioral health concerns by selecting all that applied from a list of common comorbid mental health problems, including substance use, bipolar disorder, eating disorder, and posttraumatic stress disorder.

Outcome Measures

Participants in the depression program completed the Patient Health Questionnaire-9 (PHQ-9) [32] during enrollment and after completion of each module. The PHQ-9 is a 9-item self-report measure designed to evaluate the presence of depressive symptoms during the past two weeks. Items are rated on a scale ranging from 0 (*not at all*) to 3 (*nearly every day*). Total scores range from 0 to 27, and cut-off scores for mild, moderate, moderately severe, and severe depressive symptoms are 5, 10, 15, and 20, respectively.

Participants in the generalized anxiety program completed the Generalized Anxiety Disorder-7 (GAD-7) scale [33] during enrollment and after completion of each module. The GAD-7 is a 7-item self-report measure of anxiety. Items are rated on a scale ranging from 0 (*not at all*) to 3 (*nearly every day*). Total scores range from 0 to 21, and the cut-off scores for mild, moderate, and severe anxiety symptoms are 5, 10, and 15, respectively.

Participants in the social anxiety program completed the Social Phobia Inventory (SPIN) [34] during the enrollment and after completion of each module. The SPIN is a 17-item self-report questionnaire that assesses social anxiety symptoms during the past week. Items are rated on a scale ranging from 0 (*not at all*) to 4 (*extremely*). Total scores range from 0 to 68, and the cut-off scores for mild, moderate, severe, and very severe are 20, 31, 41, and 51, respectively [35,36].

Digital+ Use

Patterns of Digital+ activity and module completion were explored using passive data collected through a digital platform. These data included whether the modules were started and/or completed. Time spent using Digital+ was assessed by examining the dates of the first and last activity use. In addition, patterns of coaching use were evaluated using the number of coaching calls completed per module and the number of incoming messages per module.

Statistical Analysis

Baseline demographic and clinical characteristics were reported as frequencies and percentages for categorical variables and means and SDs for continuous variables. Outcome measures throughout time were reported as means and SDs. Baseline characteristics were compared between those who completed all eight modules and those who discontinued use before completion using a two-sample, two-tailed *t* test for continuous variables and chi-square tests for categorical variables. Linear mixed models with a random intercept and slope were constructed using restricted maximum likelihood estimation procedures to examine the association between module completion and depression, anxiety, and social anxiety symptom change throughout the Digital+ programs.

First, models were estimated separately for each outcome measure, and the covariance structure that provided the best model fit was identified. On the basis of model fit indices, the best-fitting model was carried forward into the covariate models to examine the associations between baseline participant characteristics (ie, baseline symptom severity, age, and gender) and changes in symptom severity throughout time. Participants with at least mild symptom severity at baseline (ie, PHQ-9 ≥5, GAD-7 ≥5, or SPIN ≥20) who completed at least four modules were included in these analyses. Consistent with established standards for internet-based interventions [37], users who had completed four modules were included because they were exposed to all primary program content at this point (ie, psychoeducation, cognitive restructuring, and practice activities). In addition, we examined within-subject effect sizes and the association between module completion and symptom reduction using linear mixed models among users who enrolled with at least mild baseline symptom elevations, regardless of intervention exposure (n=1694). Digital+ module completion, completed coaching calls, and incoming and outgoing messages were reported using frequencies and means. The association between module completion and baseline scores was assessed using unadjusted linear regression. Program retention or time spent using Digital+ was defined as the number of days between completing the first and last recorded activities. All analyses were conducted using SAS 9.4.

Results

Participants

A total of 1896 participants were enrolled and initiated the use of Digital+ between January 1, 2020, and June 30, 2020. The baseline characteristics of the users are shown in Table 2.

Table 2. Baseline sample characteristics (N=1896)[a].

Variables	Total (N=1896)	Depression (n=560)	Generalized anxiety (n=974)	Social anxiety (n=362)
Age (years), mean (SD)	37.4 (11.8)	37.1 (12.2)	38.2 (11.7)	35.9 (11.6)
Gender, n (%)				
Female	1196 (63.1)	356 (63.6)	636 (65.4)	204 (56.4)
Male	470 (24.8)	147 (26.3)	231 (23.7)	92 (25.4)
Nonbinary	14 (0.7)	7 (1.3)	2 (0.2)	5 (1.4)
Not disclosed	215 (11.3)	50 (8.9)	104 (10.7)	61 (16.9)
Missing	1 (0.1)	0 (0)	1 (0.1)	0 (0)
Source, n (%)				
Employer	1359 (71.7)	399 (71.3)	667 (68.5)	293 (80.9)
Health plan	537 (28.3)	161 (28.8)	307 (31.5)	69 (19.1)
Patient-reported psychiatric history[a], n (%)				
Substance use	29 (1.5)	15 (2.7)	4 (0.4)	10 (2.8)
Eating disorder	145 (7.6)	61 (10.9)	56 (5.8)	28 (7.7)
Bipolar disorder	83 (4.4)	36 (6.4)	31 (3.2)	16 (4.4)
Passive suicidal ideation	95 (5)	44 (7.9)	31 (3.2)	20 (5.5)
Posttraumatic stress disorder	117 (6.2)	39 (7)	57 (5.9)	21 (5.8)

[a]Individuals could endorse more than one psychiatric difficulty. In total, 17.51% (332/1896) of users reported at least one current or recent psychiatric challenge.

Of those enrolled, 29.54% (560/1896) enrolled in the depression program, 51.37% (974/1896) enrolled in the generalized anxiety program, and 19.09% (362/1896) enrolled in the social anxiety program. At baseline, 95.2% (533/560) of users met the criteria for at least mild depression on the PHQ-9 (ie, total score ≥5). The criteria for at least mild anxiety on the GAD-7 scale (ie, total score ≥5) were met by 90.3% (879/974) of users in the generalized anxiety program. The criterion for social anxiety (ie, total score ≥20) was met by 77.9% (282/362) of users in the social anxiety program.

Users were asked to select any current or recent psychiatric concerns from a list of common comorbidities during program enrollment. At least one current or recent psychiatric disorder was endorsed by 17.51% (332/1896) of users. Users who endorsed at least one recent or current psychiatric concern had significantly higher baseline PHQ-9 (14.8 vs 11.8; $P<.001$), GAD-7 (14.2 vs 11.0; $P<.001$), and SPIN (35.7 vs 30.0; $P=.002$) scores than users who did not endorse any recent or current psychiatric concerns.

Clinical Outcomes

Descriptive statistics for the outcome measures throughout time are summarized in Table 3 for all the users.

Among users who completed at least half of the program content and had mild baseline symptom elevations (n=470), there were significant reductions in PHQ-9, GAD-7, and SPIN scores. These reductions corresponded to large within-group effect sizes across all three programs among those who completed at least four modules. The effect sizes for depression, generalized anxiety, and social anxiety symptoms were 1.5, 1.2, and 1.5, respectively. Similarly, the within-group effect sizes among those participants who completed all eight modules were large across all three programs. The effect sizes for depression, generalized anxiety, and social anxiety symptoms were 1.7, 1.7, and 1.4, respectively.

Of those who completed at least four modules in the depression program and had at least moderate depressive symptoms at baseline (PHQ-9 ≥10; mean 15.0, SD 3.6), 75.7% (87/115) of participants met the criteria for treatment response (PHQ-9 <10; mean 6.6, SD 4.8). In addition, 73.9% (122/165) of participants in the generalized anxiety program who completed four modules and had at least moderate symptoms (GAD-7 ≥10) at baseline (mean 15.0, SD 3.1) met the criteria for response (GAD-7 <10) at their last assessment (mean 7.0, SD 4.6). For the social anxiety program, among users who completed at least four modules and had SPIN scores of 20 and higher at baseline (mean 37.0, SD 11.0), 42% (31/74) of participants achieved a response (SPIN<20) by their last assessment (mean 24.9, SD 14.5).

Table 3. Symptom severity by module completed (N=1896).

Outcome	Module 1 (N=1896)	Module 2 (n=976)	Module 3 (n=700)	Module 4 (n=525)	Module 5 (n=430)	Module 6 (n=343)	Module 7 (n=305)	Module 8 (n=267)	Users who completed ≥4 modules		Users who completed all 8 modules	
									Effect size (Cohen *d*)	*P* value	Effect size (Cohen *d*)	*P* value
Depression, n (%)	560 (29.5)	273 (48.8)	230 (41.1)	181 (32.4)	157 (28)	135 (24.1)	119 (21.3)	102 (18.2)	N/A[a]	N/A	N/A	N/A
PHQ-9[b], mean (SD)	12.5 (5.6)	9.9 (5.3)	8.4 (4.9)	7.20 (4.8)	6.3 (4.9)	5.5 (4.7)	5.0 (5.0)	4.8 (4.8)	1.5	<.001	1.7	<.001
PHQ-9 >4, n (%)	533 (95.2)	231 (84.6)	177 (77)	122 (67.4)	94 (58.9)	64 (47.4)	49 (41.2)	33 (32.3)	N/A	N/A	N/A	N/A
PHQ-9 >9, n (%)	368 (65.7)	130 (47.6)	77 (33.5)	46 (25.4)	29 (18.5)	22 (16.3)	18 (15.1)	13 (12.8)	N/A	N/A	N/A	N/A
Generalized anxiety, n (%)	974 (51.4)	500 (51.3)	342 (35.1)	248 (25.5)	206 (21.2)	159 (16.3)	136 (14)	126 (12.9)	N/A	N/A	N/A	N/A
GAD-7[c], mean (SD)	11.4 (5.2)	10.13 (4.9)	8.14 (4.2)	7.4 (4.3)	6.87 (4.3)	6.59 (4.5)	5.1 (3.8)	4.7 (3.6)	1.2	<.001	1.7	<.001
GAD-7 >4, n (%)	879 (90.3)	432 (86.4)	270 (79)	180 (72.6)	141 (68.5)	101 (63.5)	76 (52.8)	61 (48.4)	N/A	N/A	N/A	N/A
GAD-7 >9, n (%)	589 (60.5)	262 (52.4)	116 (33.9)	67 (27)	44 (21.4)	32 (20.1)	16 (11.1)	13 (10.3)	N/A	N/A	N/A	N/A
Social anxiety, n (%)	362 (19.1)	203 (56.1)	128 (35.3)	96 (26.5)	67 (18.5)	51 (14.1)	40 (11.1)	39 (10.8)	N/A	N/A	N/A	N/A
SPIN[d], mean (SD)	31.1 (13.8)	31.2 (13.9)	26.1 (14.9)	24.8 (14.3)	21.5 (13.4)	18.9 (11.8)	16.7 (11.8)	14.7 (11.6)	1.0	<.001	1.7	<.001
SPIN >19, n (%)	282 (77.9)	155 (76.4)	77 (60.2)	58 (60.4)	34 (50.8)	22 (43.1)	15 (37.5)	11 (28.2)	N/A	N/A	N/A	N/A

[a]N/A: not applicable.

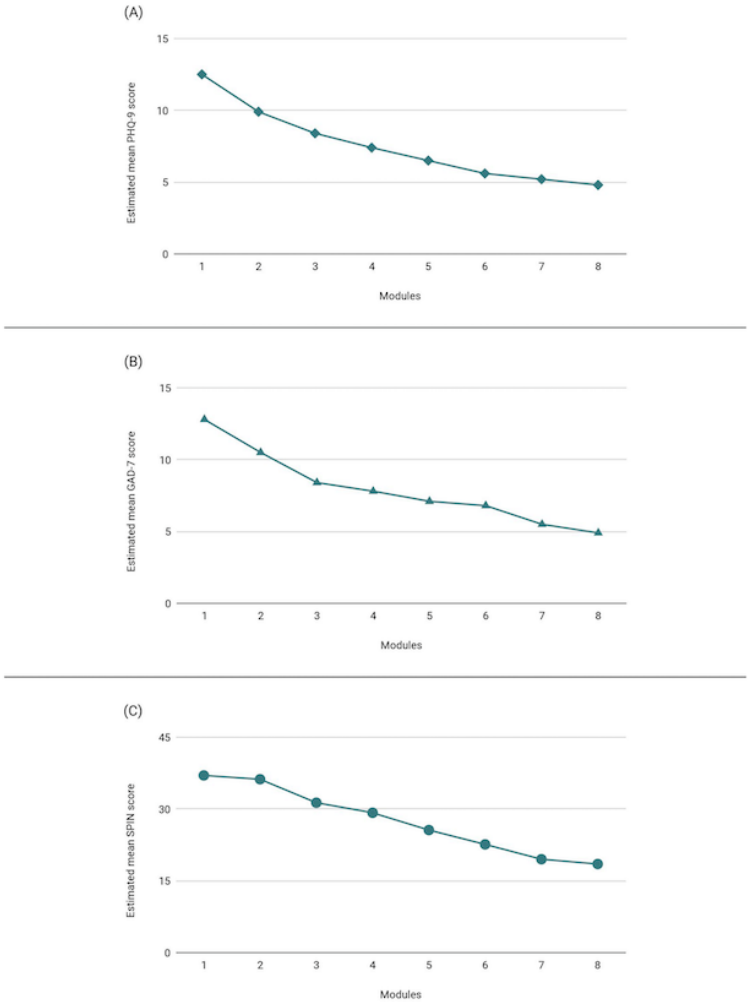
[b]PHQ-9: Patient Health Questionnaire-9.

[c]GAD-7: Generalized Anxiety Disorder-7.

[d]SPIN: Social Phobia Inventory.

Model-implied estimates for PHQ-9, GAD-7, and SPIN scores by program module are presented in Figure 1. In the linear mixed model to evaluate associations between depression program module completion and symptom reduction among users with at least mild baseline symptom severity (PHQ-9 ≥5) and exposure to at least four modules (n=169), significant fixed effects of module completion (F_{1972}=319.4; P<.001) and baseline PHQ-9 scores (F_{1164}=454.9; P<.001) but not age (F_{1164}=1.2; P=.19) or gender (F_{2164}=0.82; P=.44) were observed. There was also significant variability around the mean intercept (P=.001) and slope (P<.001) and significant residual variance (P<.001).

Figure 1. Estimated mean outcome scores by module for users who completed at least four modules. (A) depression program; (B) generalized anxiety program; and (C) social anxiety program. GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9; SPIN: Social Phobia Inventory.



Similarly, there were significant fixed effects of anxiety program module completion ($F_{11,258}$=332.5; P<.001) and baseline GAD-7 scores (F_{1222}=492.2; P<.001) but not age (F_{1222}=0.17; P=.68) or gender (F_{2222}=0.40; P=.67) on changes in symptom severity throughout time among users who had at least mild baseline generalized anxiety disorder symptoms (GAD-7 >5) and completed at least four modules of content (n=227). There was also significant variability around the mean intercept (P=.02) and slope (P<.001) and significant residual variance (P<.001).

In the linear mixed effects model among social anxiety program users with elevated baseline symptoms (SPIN >20) exposed to four or more digital modules (n=74), there were significant fixed effects of module completion (F_{1366}=114.9; P<.001), baseline SPIN scores (F_{169}=326.3; P<.001), and age (F_{169}=9.2; P=.004), but not gender (F_{269}=1.3; P=.27). There was also significant variability around the mean intercept (P=.02) and slope (P<.001), and there remained significant residual variance (P<.001).

To understand the impact of the intervention as delivered, we examined primary outcomes among all users who enrolled with at least mild baseline symptom elevations, regardless of intervention exposure (n=1694). The within-person effect sizes were 0.58, 0.50, and 0.44 for depression, generalized anxiety, and social anxiety symptom scores, respectively. There was a significant association between the number of modules completed and symptom reduction on the PHQ-9 (P<.001), GAD-7 (P<.001), and SPIN (P<.001) scores. Across all three programs, higher baseline symptom severity was significantly associated with slower symptom reduction (P<.001). There were no significant relationships among age, gender, and symptom reduction.

Digital+ Use

Of those who enrolled, 27.9% (529/1896) completed at least half of the program content (ie, four modules), and 13.08% (248/1896) completed all eight modules in their respective programs. Among users who completed all eight modules in one program and those who did not, there were no significant differences in mean age (38.5 vs 37.3 years; P=.13), gender (26.21% female (313/1196) vs 24.59% (116/470) male; P=.14), or mean baseline scores on the GAD-7 (12.1 vs 11.3; P=.14) or SPIN (30.1 vs 31.2; P=.66). However, there were significant differences in baseline PHQ-9 scores (P=.01) between individuals who completed all program content (mean 11.2, SD 5.1) and those who discontinued (mean 12.8, SD 5.7).

Digital+ users completed 2.6 (SD 2.7) modules on average. Participants in the depression program (mean 2.9, SD 3.0) completed significantly (F_2=4.2; P=.01) more modules than those in the generalized (mean 2.5, SD 2.7) and social anxiety (mean 2.5, SD 2.4) programs. On average, the length of time from first to last activity was 52.2 (SD 83.5) days, and of the 1896 participants who initiated the use of Digital+, 45.09% (855/1896) were retained at 30 days and 26.85% (509/1896) were retained at 60 days.

Higher baseline depressive symptomatology was associated with fewer modules completed (β=−.1; P=.02). However, higher baseline generalized anxiety symptomatology was associated with more modules completed (β=.1; P=.01). Gender was also significantly associated with the number of modules completed (F_3=4.3; P=.01), with women completing 2.7 modules (SD 2.7) and men completing 2.6 modules (SD 2.7) on average. However, there was no significant relationship between the number of modules completed and baseline SPIN scores, age, or endorsing at least one recent or current psychiatric concern.

Coaching

Overall, 66.82% (1267/1896) of participants engaged in at least one coaching call. On average, users scheduled 3.8 (SD 4.4) calls and completed 3.1 (SD 4.2) calls throughout their programs. Those who completed at least four modules (mean 1.1, SD 0.7) completed significantly more calls per module than those who completed fewer than four modules (mean 1.0, SD 1.2; t_{1407}=−2.1; P=.03). In addition, users who completed at least one coaching call (mean 3.4, SD 2.8) completed significantly more modules than users who never engaged in coaching calls (mean 1.0, SD 1.5; t_{1894}=−20.3; P<.001).

There was a significant relationship between age and the number of calls completed, such that older participants completed more calls than younger participants (β=.02; P=.01). In addition, baseline depression (β=−.1; P=.03) and generalized anxiety (β=.1; P=.01) symptom severity scores were associated with the number of calls completed. In the depression program, users with higher baseline levels of depressive symptomatology completed fewer calls than those with lower baseline symptomatology. In contrast, in the generalized anxiety program, users with higher baseline levels of anxiety symptoms completed more calls than those with lower baseline symptom severity. There were no significant associations among program (P=.21), gender (P=.16), or current or recent psychiatric difficulties (P=.89); baseline social anxiety symptom severity (P=.92); and the number of calls completed.

In-app messaging was used by most participants, with 66.09% (1253/1896) of users sending at least one in-app coach text message and an average of 4.5 (SD 11.1) messages sent to coaches. Users who completed fewer than four modules sent approximately one message to every seven messages coaches sent, whereas users who completed at least four modules sent approximately one message to every four messages from coaches (14.28% vs 25.75%; P<.001). There were no significant associations between program (P=.13), gender (P=.51), baseline depression (P=.68), or social anxiety (P=.76) symptom severity and the number of messages sent to coaches. However, there was a significant relationship between baseline generalized anxiety symptom severity and the number of messages users sent to coaches, such that higher baseline anxiety was associated with more sent messages (β=.2; P<.001). Age was also significantly related to the number of messages sent, such that older users sent coaches significantly fewer messages than younger users (β=−0.1; P=.03). Finally, there was also a significant relationship between user-endorsed recent or current psychiatric concerns and the number of incoming messages from users (F_1=4.24; P=.04), such that those who endorsed at least one concurrent psychiatric challenge sent coaches significantly more messages (mean 5.6, SD 10.4) than those who did not report any recent or current psychiatric concerns (mean 4.2, SD 11.3).

Discussion

Principal Findings

This study adds to a small yet growing body of literature examining the magnitude of symptom reduction among users of commercially available digital mental health apps in a real-world context. Overall, Digital+ programs demonstrated significant reductions in depressive, generalized anxiety, and social anxiety symptoms throughout the program. The magnitude of these effects appeared to grow as more modules were completed; however, users who completed at least half of the program content also experienced significant and large reductions in symptomatology. These improvements were largely consistent across participant characteristics (ie, age and gender). In all three programs, those with more severe baseline symptomatology experienced smaller symptom reductions than those with lower baseline symptom severity. Of the 1896 AbleTo Digital+ users who initiated use between January 1, 2020, and June 30, 2020, 27.90% (529/1896) completed half of the program content, and 13.08% (248/1896) completed all the program content, with a 30-day retention rate of 45.09% (855/1896). Completion rates were consistent across age, gender, and baseline generalized and social anxiety symptom severity. Users with more severe baseline depressive symptomatology completed fewer modules than those with lower baseline scores. Almost all Digital+ users endorsed interest in 1:1 coaching, and approximately two-thirds of users engaged in at least one coaching call (66.2%, 1267/1896) and/or in-app text messaging (66.09%, 1253/1896). Users who completed at least four modules completed significantly more coaching calls per module than users who completed fewer than four modules.

Comparison With Previous Work

Regarding clinical outcomes, the magnitude of symptom reduction among participants in Digital+ programs was comparable with or larger than those seen in the broader literature for internet-based CBT [38-40] and similar digital products for anxiety and depression [41,42]. For example, a recent meta-analysis suggests that in randomized trials, smartphone apps had moderate positive effects on depression [18] and anxiety symptomatology [17]. Also consistent with broader literature, these findings suggest comparable outcomes across several key demographic variables, including age and gender. Thus, this study adds to the growing body of literature

supporting the efficacy of these interventions for a broad range of users [18]. Notably, the magnitude of symptom improvement is similar to effect sizes seen in studies of face-to-face CBT [43,44], although it is important to note that individuals engaging in Digital+ may differ from those presenting to face-to-face treatment.

AbleTo Digital+'s completion rate was comparable with or higher than that reported in a previous meta-analysis of similar digital interventions (ie, 0.5%-28.6%) [45], and the 45% 30-day retention rate was approximately 15 times higher than the 3.3% 30-day retention rate previously reported for other commercial mental health apps without human support, which is known to be key for improving engagement [46]. Although the use and retention rates were relatively high compared with other commercially available apps, there was still a substantial drop off, particularly earlier in the programs. For digital interventions to reach their full potential, optimizing engagement is necessary and remains a top research priority [47,48]. We hypothesized several reasons for premature dropouts. First, Digital+ may not be the appropriate intervention for some individuals, and they prematurely drop out because the intervention did not meet their needs. A key priority should be to link individuals to the appropriate level of care, and strategies are needed to link users to appropriate services. Digital+ coaches were trained to assist users in finding a more appropriate level of care if needed by linking them to their health plan resources or a Digital+ in-network provider matching service, which helped users locate and schedule appropriate care. Alternatively, it is possible that some individuals left the program owing to feeling better or what has been termed *happy abandonment* [49]. Although some Digital+ users experienced significant symptom reduction when completing only half of the program content, the long-term impact of premature dropout among these individuals remains unknown. Finally, given the finding that individuals with more severe baseline depression were more likely to discontinue using Digital+, motivation may be a primary target for sustained engagement. Future research is required to explore the reasons for and predictors of premature dropout, including both user- and program-related factors and the clinical implications of premature dropout.

Human support has consistently been shown to improve engagement in and sustained use of digital interventions [50-52]; however, much remains unknown about the aspects of coaching most closely linked to improved engagement [53]. Research has demonstrated that coaching focuses on reminding users to engage, and providing personalized feedback on completed content can boost engagement [53-55]. However, questions remain about the timing, intensity, and structure of coaching associated with higher engagement. More intensive coaching earlier in Digital+ programs may be needed to decrease premature dropout, particularly among groups of users who are more prone to drop out. In addition, one-third of the users did not engage in 1:1 coaching. Given the relationship between coaching and engagement, strategies are needed to promote coaching initiation among those most likely to benefit from additional support. Future research is also necessary to better understand the impact of coaching interactions on engagement and outcomes and develop and test tailored coaching strategies, including testing different coaching techniques, methods, and doses.

Although users with a broad range of symptom presentations benefited from Digital+, there was a consistent finding across programs that those with more severe baseline symptomatology experienced less improvement throughout the programs. In the case of depression, these individuals were also more likely to discontinue use prematurely. These findings are consistent with and add to the randomized controlled trial literature suggesting that digital interventions have the most consistent benefit for those experiencing mild to moderate symptoms at the time of initiation [18,56]. As digital mental health interventions continue to evolve, it is critical that we better understand who is most likely to benefit from these interventions to direct patients to the appropriate level of care and optimize outcomes.

Several stepped and staged care models that incorporate digital interventions into the broader behavioral health care system are emerging. For example, the United Kingdom's National Health System's Improving Access to Psychological Treatments [57] and Australia's Mindspot Clinics [58] have integrated computerized and digital interventions into their suite of treatment options to improve efficiency and access to care. In both of these systems, digital interventions are considered first-line interventions that can be effective for those with mild to moderate symptoms and serve as a gateway to additional or more intensive interventions, if needed. Incorporating interventions such as Digital+ into the behavioral health care system offerings has the potential to reserve more intensive interventions for those who need them the most, decrease wait times, and mitigate worsening workforce shortages. As we learn more about who is likely to engage and benefit, we can use data-driven approaches combined with personal preferences to direct people to timely and appropriate services.

Finally, despite a growing body of literature supporting the efficacy of these interventions and consumer interest, consumers continue to struggle to identify high-quality, evidence-based products [27,28]. Novel approaches to disseminating tools such as Digital+ are needed to help people identify the tools best supported by research evidence that are most likely to help them. Research suggests that the interest in digital mental health interventions outpaces uptake and that individuals desire easier access to information on effective tools and look to trusted providers for information on which tools to use [28]. Health plans and employers may be uniquely situated to help streamline the dissemination of these tools and direct users to the best possible services by adding them to their suite of behavioral health care offerings. This approach can boost awareness and enhance credibility. This study demonstrates the potential of this approach; however, future research is needed to continue to evaluate the impact of these dissemination methods, particularly concerning improving access and decreasing health care and workplace costs.

Limitations

The results of this study must be interpreted in light of some limitations. First, the lack of a control group means that we were unable to account for the natural remission of symptoms, the effect of missing data, or fully understand the impact of 1:1

coaching on engagement and outcomes. This limitation, however, was mitigated to some extent by the weekly collection of symptom severity scores and conservative statistical modeling that incorporated those who did not complete all intervention content [59]. In addition, the real-world context of this study is seen as a primary strength in that it establishes proof of concept for a health plan and employer rollout of mental health apps while establishing clinical impact.

Second, only a small number of baseline characteristics were collected to minimize user burden. However, this limited our ability to evaluate a broader set of factors that might be related to engagement and treatment response. The results suggest that above and beyond the known participant characteristics (eg, age, gender, and baseline symptom severity), there was significant variability unaccounted for in both engagement and treatment response. Although age and gender were not associated with treatment response, indicating the potential broad applicability of Digital+, additional information on participant demographics, including race or ethnicity and socioeconomic status, may help us better understand who is most likely to benefit. In addition, other data such as treatment history, concurrent treatment, and psychiatric medication use were not available. Collecting these data in the future would allow us to better understand how psychiatric treatment history affects program retention and response and potentially inform the integration of Digital+ into staged or stepped care models.

Third, these analyses precluded examining the impact of suicidal ideation and/or psychosis on outcomes, app use, or 1:1 coaching. Future research is needed to better understand the impact of these risk factors. Fourth, all users needed access to a device (eg, smartphone, tablet, or computer) and internet access to participate in Digital+. Although 81% of adults in the United States own a smartphone [60], this may limit the generalizability of these results to individuals who do not have access to a device or the internet. Finally, participants were not followed beyond the program period, making it difficult to draw conclusions about the sustained impact of Digital+ programs. This may be particularly important for users who discontinued use before full program completion yet showed symptom improvement. Future research is needed to understand the long-term clinical impact of tools such as Digital+.

Conclusions

This study demonstrated that Digital+ users experienced significant reductions in depression, generalized anxiety, and social anxiety symptoms throughout the programs, independent of user age, gender, and baseline symptom severity. Overall, 30-day retention rates were significantly higher than previously reported rates for other commercially available mental health apps, particularly self-guided ones. In addition, users who completed at least half of the program content completed more 1:1 coaching calls than users who completed fewer than half of the program content. Participants who enrolled in Digital+ through their employees and health plan benefits experienced clinically significant symptom reductions. Digital+ may offer a scalable, low-cost additional service that may help mitigate workforce shortages and other common barriers to treatment. Future research is needed to continue to identify those who are most likely to benefit from these apps and examine how best to integrate digital interventions such as Digital+ into the broader behavioral health care system.

Conflicts of Interest

MTA is an employee of AbleTo. HMG is an employee of and holds an equity interest in AbleTo. EA is an employee of AbleTo. RLP is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Medical Officer.

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Abbreviations

CBT: cognitive behavioral therapy
GAD-7: Generalized Anxiety Disorder-7
PHQ-9: Patient Health Questionnaire-9
SPIN: Social Phobia Inventory

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Evaluation of an Open-Access CBT-Based Internet Program for Social Anxiety: Patterns of Use, Retention, and Outcomes

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Summary

A retrospective study was conducted to evaluate utilization and clinical outcomes among a cohort of adults who participated in Joyable, an internet-based open access cognitive behavioral therapy (CBT) program for social anxiety. Results from the evaluation documented high participant retention (>11 weeks on average) and significant reductions in social anxiety symptoms measured by the validated Social Phobia Inventory. The study results suggest Joyable is an effective internet-based mental health services option for individuals seeking an evidence-based program for social anxiety.

Demographics

- 3,384 Participants
- Average age 29.8 years
- 54% male/ 46% female

Key Outcomes

Significant program retention

- Average of 81 days (>11 weeks) in program

Significantly reduced social anxiety symptoms

- Observed among users with a wide range of baseline symptom severity
- Included clinically meaningful responses in almost three of four (72%) adherent users
- Associated with behavior coach contact

The positive outcomes and easy accessibility of Internet-delivered cognitive-behavioral therapy-based interventions, such as Joyable, could play a key role in disseminating effective evidence-based treatments to a broader population of individuals experiencing social anxiety.

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Evaluation of an Open-Access CBT-Based Internet Program for Social Anxiety: Patterns of Use, Retention, and Outcomes

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Objective: Internet-delivered cognitive–behavioral therapy (ICBT) has been established as both efficacious and effective in reducing symptoms of social anxiety. However, most research has been conducted in controlled settings, and little is known regarding the utility of such programs in an open-access format. The present study examined the use, adherence, and effectiveness of Joyable, an open-access, Internet-delivered, coach-supported CBT-based intervention for social anxiety. ***Method:*** Participants were 3,384 registered users (M_{age} [*SD*] = 29.82 [7.89]; 54% male) that created an account between 2014 and 2016. Characteristics of use, factors related to attrition and adherence, and within-group outcomes were examined. The primary outcome measure was the Social Phobia Inventory. ***Results:*** On average, participants remained in the program for 81.02 days (*SD* = 60.50), during which they completed 12.14 activities (*SD* = 11.09) and 1.53 exposures (*SD* = 3.18). About half (57%) had contact with a coach. Full adherence to the program was achieved by 16% of participants, a rate higher than previously published open-access studies of ICBT. Social anxiety symptoms were significantly reduced for participants that engaged in the program, with medium within-group effects from baseline through the cognitive restructuring module (*d* = 0.63–0.76) and large effects from baseline through the exposure module (*d* = 1.40–1.83). Response rates were high (72%). Exposures and coach contact were significant predictors of retention and outcome. ***Conclusions:*** This open-access online CBT-based program is effective in reducing social anxiety symptoms and has the potential to extend Internet-based mental health services to socially anxious individuals unwilling or unable to seek face-to-face evidence-based therapy.

What is the public health significance of this article?
This study suggests that the positive outcomes and easy accessibility of Internet-delivered cognitive–behavioral therapy-based interventions, such as Joyable, could play a key role in disseminating effective evidence-based treatments to a broader population of individuals experiencing social anxiety.

Keywords: social anxiety, cognitive–behavioral treatment, Internet treatment, effectiveness

Individuals with social anxiety experience intense fear and avoidance of social situations, resulting in significant functional impairment in social, occupational, and personal domains (Ruscio et al., 2008). Fortunately, effective interventions for social anxiety exist. Meta-analytic reviews have identified cognitive–behavioral therapy (CBT) as the most effective therapeutic intervention, with controlled effect sizes ranging from *d* = 0.70–1.19 (Acarturk, Cuijpers, van Straten, & de Graaf, 2009; Mayo-Wilson et al., 2014). However, the number of socially anxious individuals that actually seek treatment is low, with only about one third receiving treatment that specifically targets social anxiety (Ruscio et al., 2008), and those with more severe levels of social anxiety may not seek treatment at all. For example, socially anxious individuals who responded to an Internet survey reported significantly higher

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levels of social anxiety than did a treatment-seeking sample (Erwin, Turk, Heimberg, Fresco, & Hantula, 2004). Thus, individuals with social anxiety may be less likely to seek face-to-face treatment, possibly due to fear of being judged and avoidance of the social interaction inherent in therapy. The development of an effective form of CBT that can be made accessible to individuals with social anxiety outside of a research center or health clinic will be especially important for reaching this population.

To this aim, researchers have developed and evaluated Internet-based CBT (ICBT) for social anxiety (Hedman, Botella, & Berger, 2016). Randomized controlled trials (RCTs) have shown ICBT to yield symptom reduction equivalent to or greater than face-to-face CBT for social anxiety, with pre-to-posttreatment effect sizes ranging from $d = 0.82–1.50$ and controlled effect sizes ranging from $d = 0.74–1.38$ (e.g., Boettcher, Carlbring, Renneberg, & Berger, 2013; Hedman et al., 2011; Tulbure et al., 2015). ICBT also yields positive long-term outcomes, with participants maintaining gains up to 5 years (Andersson et al., 2006; Carlbring, Nordgren, Furmark, & Andersson, 2009; Hedman et al., 2011).

ICBT has several potential advantages over face-to-face CBT. It avoids logistical barriers to in-person treatment, such as travel time and work and child care arrangements, thereby making treatment more accessible. ICBT is also more cost-effective than face-to-face CBT, with lower direct costs (e.g., health care visits, medication costs) and indirect costs (e.g., work days lost, reduced productivity; Hedman et al., 2014; Nordgren et al., 2014). ICBT may be especially advantageous for social anxiety because it allows individuals to participate in therapy at their own pace and from the convenience of their own home. Without the social-evaluative concerns that can be triggered by face-to-face therapy, individuals with social anxiety may be more likely to seek treatment and less likely to drop out early. Thus, ICBT represents a potentially important advance in treatment for individuals with social anxiety.

ICBT programs for social anxiety have been developed and empirically evaluated on an international scale. Programs in Sweden (Andersson et al., 2006; also evaluated in Romania, Tulbure et al., 2015), Switzerland (Berger, Hohl, & Caspar, 2009), Australia (Titov, Andrews, Choi, Schwencke, & Mahoney, 2008), Spain (Botella et al., 2010), and England (Stott et al., 2013)[1] have all been found to be efficacious for social anxiety. Given the success of these programs in non-American populations, the high prevalence of social anxiety disorder (SAD) in the United States (12.1% lifetime prevalence; Kessler et al., 2005), and the high rates of Internet use among U.S. adults (87% in 2014; Pew Research Center, 2014), investigating the utility of Internet-delivered CBT for social anxiety in a predominantly American population is an important step. Only one research group has developed and evaluated an ICBT program for social anxiety with an American sample. Gershkovich, Herbert, Forman, and Glassman (2016) created an acceptance-based guided ICBT program and evaluated the 8-week protocol with 13 participants from across the United States. Results of this pilot study indicated significant reductions in social anxiety symptoms at posttreatment and 3-month follow-up ($d = 0.90–1.47$). However, no research has yet evaluated the effects of a more traditional ICBT program in the United States.

In addition to efficacy trials, some evidence exists for the effectiveness of ICBT for social anxiety in clinical settings. Aydos, Titov, and Andrews (2009) examined the effectiveness of ICBT as part of outpatient treatment at an anxiety disorders clinic in Australia. Of the 17 participants, 82% completed all lessons over an 8-week period. Large effect sizes were found for completer ($d = 1.51$) and intent-to-treat ($d = 1.05$) samples. Two controlled effectiveness trials have also been published, in which participants were self-referred or referred by their physician to a psychiatric clinic. ICBT for social anxiety was as effective as individual face-to-face CBT (Andrews, Davies, & Titov, 2011) and more effective than group face-to-face CBT (Hedman et al., 2011). Most recently, a large ($N = 654$) longitudinal cohort study examined the effectiveness of ICBT in an outpatient clinic (El Alaoui et al., 2015). ICBT yielded significant reductions in social anxiety symptoms at posttreatment ($d = 0.86$) and 6-month follow-up ($d = 1.15$).

Good evidence exists for the efficacy and effectiveness of ICBT for social anxiety, but additional research is needed to examine the utility of ICBT outside of controlled settings. The large majority of ICBT research has used an RCT design (Hedman et al., 2016), which is essential for determining efficacy (i.e., the effects of treatment under controlled experimental conditions). However, it is difficult to generalize RCT results to a larger population outside of the research context because such trials (necessarily) involve strict exclusion criteria. Published RCTs of ICBT for social anxiety only include participants that meet diagnostic criteria for primary SAD and often exclude individuals that have received CBT in the past, are currently receiving any other psychological treatments, have not been taking a stable medication dosage for at least 1 month, and are diagnosed with substance use disorders, bipolar disorder, or psychosis (e.g., Andersson et al., 2006; Berger et al., 2009; Hedman et al., 2011; Tulbure et al., 2015). Moreover, recruitment for an RCT typically involves contact with a clinician or research coordinator, either over the phone or in person, to assess diagnostic status and confirm eligibility. The intensive in-person contact required at the beginning of a research study may discourage individuals with more severe social anxiety and/or various logistical barriers from participation, meaning that current research may not encompass the full range of individuals experiencing impairment related to social anxiety. Even in the four published effectiveness studies, participants actively sought outpatient treatment for social anxiety and were required to participate in an in-person or phone-administered diagnostic evaluation and meet specific inclusion/exclusion criteria. Thus far, research on ICBT for social anxiety has not fully used the advantages of an Internet-based intervention, which has the potential to be accessible even to individuals with impairing levels of social anxiety that will not present for in-person treatment.

The purpose of the present study was to examine the use, retention, and outcomes of a newly developed online CBT-based intervention for social anxiety called *Joyable*. Joyable is the first ICBT-based program for social anxiety to be developed and widely disseminated in the United States. Like other ICBT programs, Joyable incorporates the core components of face-to-face CBT, including psychoeducation, cognitive restructuring, and graduated exposure to feared situations. However, unlike programs examined in previous ICBT trials, Joyable is made accessible directly to users via the Internet with few exclusionary criteria or

[1] See Hedman et al. (2016) for a detailed description of each of these programs.

diagnostic restrictions. Joyable users proceed through the protocol at their own pace and pay a monthly fee. Joyable also provides guidance and support from coaches via phone, text, and email. Coaches are not mental health professionals but receive initial and ongoing training as part of their work with Joyable. The majority of published ICBT programs for social anxiety provide guidance from licensed clinicians (Hedman et al., 2016). However, nonclinician coaching has yielded positive effects when compared to clinician coaching ($d = 1.47$ vs. $d = 1.51$, respectively; Titov et al., 2009). Thus, the Joyable program provides a unique opportunity to examine the user characteristics, patterns of use, and effectiveness of an ICBT-based program for individuals with social anxiety.

No published research has yet evaluated an open-access Internet-delivered CBT-based program for social anxiety. Previously studied open-access ICBT programs for depression/anxiety (Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004) and panic disorder (Farvolden, Denisoff, Selby, Bagby, & Rudy, 2005) have yielded positive treatment outcomes, although attrition rates have been high, with only 1–4% of registered users completing the programs. Our aims were to (a) examine the usage and user characteristics of a new ICBT-based program developed in the United States, (b) investigate rates and predictors of program participation and attrition, and (c) evaluate the effectiveness of the program in reducing social anxiety symptoms.

Method

Participants

The current study was conducted with data from consecutively registered users ($N = 3{,}439$) of Joyable, Inc., an ICBT-based program for social anxiety. The program is hosted on a single dedicated website (www.joyable.com) and can be accessed from any Internet-capable device. Users are recruited through a variety of unpaid and paid sources, including advertisements on Facebook, Google, and Reddit, as well as word of mouth, media and press coverage, and therapist referral. To create a profile and account, interested individuals are asked to provide basic demographic information (i.e., first name, age, and gender) and are invited to review Joyable's coach notice and terms of use. Users are offered a 7-day free trial, after which the program costs $99 per month. Only users that agreed to the Joyable terms of use and continued past the 7-day free trial were included in the present analyses.

Description and Structure of Program

The Joyable program is similar in structure to traditional cbt protocols for social anxiety that have received strong empirical support in either individual or group formats (Heimberg & Becker, 2002; Heimberg & Magee, 2014). the program comprises five modules: psychoeducation ("learning"), cognitive restructuring ("core skills"), two exposure modules ("practice" and "your goals"), and a graduation module ("maintaining gains"). Table 1 describes the number and progression of activities and assessments through these five modules. It should be noted that participants complete four exposures during the first exposure module ("practice"), whereas the second exposure module ("your goals") allows for the continuation of exposures in collaboration with a coach and includes no preset number of activities. Typically, a Joyable coach provides access to the graduation module ("maintaining gains") after the coach and user have collaboratively decided that the user has achieved individualized program goals; for those users that choose not to interact regularly with a coach, coaches can still monitor user progress and advance a user to the second exposure module and/or graduation module as needed.

The Joyable program uses stepwise access to activities and modules. After users have signed up for an account, they are given access to the first activity of the first module. Each subsequent activity is only accessible after the previous activity has been completed, and each module is only accessible after all activities of the previous module have been completed. Once an activity has been completed, it can be repeated as often as desired. Completion of activities is self-paced. The program is designed to last approximately 12 weeks. Users can discontinue the program and close their account at any time.

Coaches and Notifications

Use of a coach is recommended but not required for participation. Coaches communicate with users via email, text, instant message, or phone. Coaches undergo extensive training in CBT

Table 1
Progression of Activities and Assessments in the Joyable Program

Module	Activities	Assessment	Content
0. Baseline	1	Baseline SPIN	Initial SPIN administration, prior to beginning the program.
1. Learning	5	(As needed)	Introduction to social anxiety, developing a fear hierarchy, and identifying treatment goals; no systematically administered SPIN.
2. Core skills	8	CR SPIN	Introduction to automatic thoughts and thinking errors, practicing cognitive restructuring, and introduction to exposures.
3. Practice	11	EX SPIN[a]	Completion of four exposures to feared social situations and introduction to the concept of core beliefs.
4. Your goals	(As needed)	(As needed)[a]	Continuation of exposures as desired by the participant; no systematically administered SPIN.
5. Maintaining gains	2	Graduation SPIN[a]	Final SPIN and presentation of information about maintaining gains outside of the program.

Note. CR = cognitive restructuring; EX = exposure; SPIN = Social Phobia Inventory. Each exposure comprises three activities: (a) cognitive restructuring, (b) planning, and (c) debriefing. The exposure itself is conducted between the planning and debriefing activities and occurs outside of the program.
[a] The SPIN completed immediately prior to account termination at any point in these three modules (and after two exposures) was identified as the Endpoint SPIN.

and motivational techniques but are not licensed mental health professionals. Coaches also receive training in recognizing and addressing signs of suicidal ideation and intent and follow specific protocols for referring users for whom the program may not be appropriate.

The coach provides guidance, support, and motivation to encourage users to follow and complete the program. A user is paired with a coach as soon as the user signs up for an account. After account initiation, the user has the option to schedule an initial "kick-off call" with the coach. The kick-off call serves to introduce the user to the program and the role of the coach and provides opportunities for the user to discuss their personal experiences with social anxiety, ask questions about the program, and discuss the pace of movement through the program. Following the kick-off call, coaches continue to provide encouragement and support to the user through weekly check-in calls. Coaches are also notified when a user completes an activity, after which they provide feedback and suggestions over email. Finally, coach-initiated and automated reminders encourage program participation and progress. Coaches are available by text, email, or phone to address questions or concerns for the duration of the user's participation in the program.

Measures

Outcome measure. The primary outcome measure was the Social Phobia Inventory (SPIN; Connor et al., 2000). The SPIN is a 17-item measure that assesses social anxiety symptoms over the past week and includes items assessing fear, avoidance, and physiological arousal. Participants are asked to respond to each item using a Likert-type scale ranging from 0 (*not at all*) to 4 (*extremely*). The SPIN demonstrated good to excellent reliability in clinical (α = .87–.94) and nonclinical samples (α = .82–.90; Connor et al., 2000) and also has been used in previous ICBT research (Stott et al., 2013). Connor and colleagues (2000) found that a cutoff score of 19 distinguished between those with and without SAD, with good sensitivity (72.5%), specificity (84.3%), and diagnostic accuracy (79%). No minimum SPIN score was required to start the Joyable program.

Assessment points.

Baseline SPIN. Table 1 provides information about each of the SPIN assessment points and related terminology. Participants complete their first SPIN immediately prior to or upon activating their Joyable account. For the purposes of the present study, we refer to this very first SPIN administration as the baseline SPIN. At this time point, participants have not completed any activities in the Joyable program; thus, it represents the participant's level of social anxiety prior to starting the program.

Postcognitive restructuring SPIN. After activating an account, the SPIN is readministered in subsequent modules as a "measuring progress" activity. The second SPIN is typically completed after the cognitive restructuring activities. A small proportion of participants (n = 13) took the SPIN after completing some, but not all, of the cognitive restructuring activities; their SPIN was included at this time point as well. We refer to this second SPIN administration as the CR SPIN.

Postexposure SPIN. The third assessment of social anxiety is typically completed during the exposure module, after users have completed their first four exposures. Some participants (n = 88) took the SPIN after completing at least one but less than four exposures, and of these participants, we included only those that had completed at least two exposures (n = 32). We refer to this third SPIN administration as the EX SPIN.

Endpoint and graduation SPIN. After the first exposure module, participants may continue completing activities and exposures until they reach their program goals. At this point in the program, the SPIN is available to take as often as desired. Consequently, participants may complete different numbers of SPINs over the course of the program; in the present study, the maximum number of SPINs completed was 10. Participants that officially graduate from the program complete a final SPIN as part of the "maintaining gains" module. We refer to this final SPIN administration as the graduation SPIN and those that completed it as graduators. However, the graduation SPIN is not administered to all participants because access to the graduation module must be granted by a coach. For the purposes of measuring social anxiety change across the duration of program participation, regardless of graduation status, we defined the endpoint SPIN as the last SPIN that a participant completed before closing his or her Joyable account (which may or may not be the EX SPIN or Graduation SPIN).

Additional information collected. Users provided their age and gender when signing up for a Joyable account. Start date was recorded at account activation. We also calculated the number of days active in the program (i.e., the number of days between account activation and the endpoint SPIN). Data were extracted for number of activities completed and number of exposures completed at each SPIN administration. Total number of activities completed and total number of exposures completed at account termination were also recorded. A dichotomous variable was created to indicate whether or not a participant had completed the maintaining gains activity, indicating that their coach had initiated program termination and that their endpoint SPIN was also their graduation SPIN.

A psychoeducation quiz was administered during each of the first three modules to assess user knowledge and engagement with the material. The first quiz was administered after the psychoeducation activity on social anxiety, the second quiz after the psychoeducation activity on cognitive restructuring, and the third quiz after the psychoeducation activity on exposures. Score and percent correct were extracted for the present data analyses.

Number of phone calls with a coach was extracted, and a dichotomous variable was also created to represent whether or not a participant had phone contact with a coach. Data on email and text exchanges were not available for the present analyses.

Data Collection and Privacy

Data were collected by Joyable, Inc., and stored on a secure Structured Query Language (SQL) server. Users were informed via the Terms & Conditions and Privacy Policy that Joyable "may use information we collect about you to conduct research and measurement activities." Data for the present study were extracted by Joyable, Inc., directly from the SQL database, and a fully deidentified dataset was provided to the authors for the conduct of data analyses.

Data Analytic Plan

Usage and users of the program. Statistical analyses were conducted using SPSS 21.0. Group differences in user characteristics (e.g., age, gender) and program usage (e.g., contact with coach) were tested with independent-samples *t* tests for continuous data and chi-square tests for categorical data. For comparisons where the assumption of homogeneity of variance was violated, degrees of freedom and *t*-values are presented with equal variances not assumed. Less than 5% of data were missing for age ($n = 125$, 3.6%), gender ($n = 137$, 4.0%), and coach contact ($n = 43$, 1.3%). Thus, we were able to treat the missing data as though it were missing completely at random and no further analyses of missingness were conducted.

Attrition analyses. Discontinuation points were established to examine predictors of program attrition. We examined differences among participants that discontinued between baseline and CR SPIN assessments (i.e., did not complete the cognitive restructuring activities), participants that discontinued between the CR and EX SPIN assessments (i.e., did not complete two or more exposures), and participants that reached the EX SPIN assessment (i.e., completed two or more exposures). Participants that reached the EX SPIN assessment were considered fully adherent to the online program (see description below). Group differences across discontinuation points were tested using one-way analyses of variance (ANOVAs) and followed up with independent-sample *t* tests. Chi-square analyses were used to examine group differences in categorical variables.

Outcome analyses. Outcome analyses were conducted using linear mixed modeling. Mixed models are advantageous for repeated-measures data because they incorporate both fixed and random effects to account for nonindependence of repeated observations. Maximum likelihood estimations were used to address missingness, thereby allowing for the use of all available data without excluding cases with missing observations. The random effect covariance structure was declared using a scaled identity matrix (i.e., the random intercept and slope had individually estimated variance estimates and the covariance between the random intercept and slope were restricted to zero). The repeated measures covariance type was specified as diagonal, which freely estimated residual variances across all assessments.

We conducted two sets of outcome analyses using linear mixed modeling. First, we examined whether participants that engaged in the Joyable program experienced a significant reduction in their social anxiety over the course of the program. Only participants with at least two SPIN assessments (i.e., baseline SPIN and either CR or EX SPIN) were included. The effects of the intervention on SPIN score were examined from baseline to CR SPIN, CR to EX SPIN, and baseline to EX SPIN.

Second, we examined whether participants that were fully adherent to the program experienced a significant reduction in their social anxiety. Using the standard proposed in a review of Internet interventions for anxiety and depression (Christensen, Griffiths, & Farrer, 2009) and adopted by a recent effectiveness trial of ICBT for social anxiety (El Alaoui et al., 2015), adherence was defined as the extent to which participants experienced the content of the Internet intervention. Thus, participants that engaged in all three primary program modules (i.e., psychoeducation, cognitive restructuring, and exposures) and completed at least two exposures were considered fully adherent. Linear mixed modeling was used to examine the effects of the intervention from baseline to CR SPIN, CR to endpoint SPIN, and baseline to endpoint SPIN. Linear mixed models were also used to examine predictors of program outcome between baseline and CR SPIN and between CR and endpoint SPIN.

For fully adherent participants, we were further interested in determining whether the trajectory of change differed between participants that graduated from the program (graduators) and those that discontinued without graduating (nongraduators). Linear mixed models tested the interaction of time (i.e., change in SPIN score) with group (i.e., graduator or nongraduator). Results were followed up by conducting separate linear mixed models for graduators and nongraduators. All calculations of within-group effect sizes (Cohen's *d*) were based on estimated marginal mean differences and used the pooled within-group standard deviation (Dunlap, Cortina, Vaslow, & Burke, 1996). Hierarchical linear regressions tested predictors of endpoint SPIN scores.

Lastly, responder status was determined based on the criteria for clinically significant and reliable change outlined by Jacobson and Truax (1991). Reliable change is meant to reflect a meaningful change in symptoms over the course of the intervention and was determined using the Reliable Change Index (Jacobson & Truax, 1991). Clinically significant change is meant to reflect that the individual's symptoms are no longer at a dysfunctional level following the intervention. We used the third definition of clinically significant change provided by Jacobson and Truax (1991), that "the level of functioning subsequent to therapy places that client closer to the mean of the functional population than it does to the mean of the dysfunctional population" (p. 13). Mean SPIN scores for a clinical and a control population were extracted from the SPIN development and validation paper (Connor et al., 2000). Based on these definitions, a SPIN score decrease (i.e., change from baseline to endpoint) of more than 8.77 points indicated reliable change, and an endpoint SPIN score lower than 26.6 indicated clinically significant change. Rates of response to the program were estimated using these criteria.

Results

Usage and Users of the Program

Only users that agreed to the terms of use, continued past the 7-day free trial, and had closed their account at the time of data extraction were included in the present analyses. Over a 17-month period between 2014 and 2016, 3,439 users registered for a Joyable account and met the above criteria. Users under age 18 ($n = 31$) or that did not complete at least one SPIN assessment ($n = 23$) were excluded from analyses. One additional user was excluded as a multivariate outlier. The final study sample consisted of 3,384 participants. The slight majority of participants were male (54.2%) with ages ranging from 18 to 79 ($M_{age} = 29.82$, $SD = 7.89$).

Participants remained in the program for an average of 81.02 days ($SD = 60.50$), during which they completed an average of 12.14 activities ($SD = 11.09$) and 1.53 exposures ($SD = 3.18$). Average baseline SPIN for the full sample was 37.76 ($SD = 10.48$). Because the program has no SPIN score requirements for program participation, baseline SPIN ranged from 3 to 68, although only 3.3% of participants ($n = 112$) had a baseline SPIN at

or below the clinical cutoff of 19 (Connor et al., 2000). Slightly less than half of the sample (49.7%, n = 1,683) completed a CR SPIN, 16.0% (n = 540) completed an EX SPIN (i.e., after they completed at least two exposures) and were considered fully adherent to the program, and 9.6% (n = 326) completed a graduation SPIN and were considered graduators from the program. See Figure 1.

Approximately half of participants (56.9%) had at least one phone call with a coach, completing an average of 3.37 calls (SD = 3.05) during their program participation. Participants that had phone contact with a coach did not differ in age, $t(3077.51) = -6.31$, $p = .54$, gender, $\chi^2(1, N = 3{,}190) = 3.28$, $p = .07$, or baseline SPIN, $t(3339) = 0.59$, $p = .55$, but they did start the program later, on average, than did participants with no coach contact, $t(3145.52) = -7.49$, $p < .001$.

Attrition Analyses

One-way ANOVAs examined differences in age, start date, and baseline SPIN by discontinuation time point (i.e., between baseline and CR SPIN, between CR and EX SPIN, or after EX SPIN). See Table 2. No significant differences emerged in either age, $F(2, 3256) = 0.07$, $p = .93$, or baseline SPIN, $F(2, 3381) = 0.87$, $p = .42$. However, there were significant differences in start date across the three discontinuation points, $F(2, 3381) = 7.06$, $p = .001$. Follow-up independent-samples t tests were conducted to examine group differences in start date, using a Bonferroni-corrected $p = .0167$. Participants that dropped between baseline and CR SPIN started the program at an earlier date relative to those that dropped between CR and EX, $t(2842) = -3.61$, $p < .001$. No other group differences were significant.

A chi-square test revealed no differences in gender across discontinuation time points, $\chi^2(2, N = 3{,}230) = 4.39$, $p = .11$. However, there were differences in coach support, $\chi^2(2, N = 3{,}341) = 654.00$, $p < .001$. Participants that dropped between baseline and CR SPIN were less likely to have had phone contact with a coach than participants that dropped between CR SPIN and EX SPIN and those that completed an EX SPIN (see Table 2).

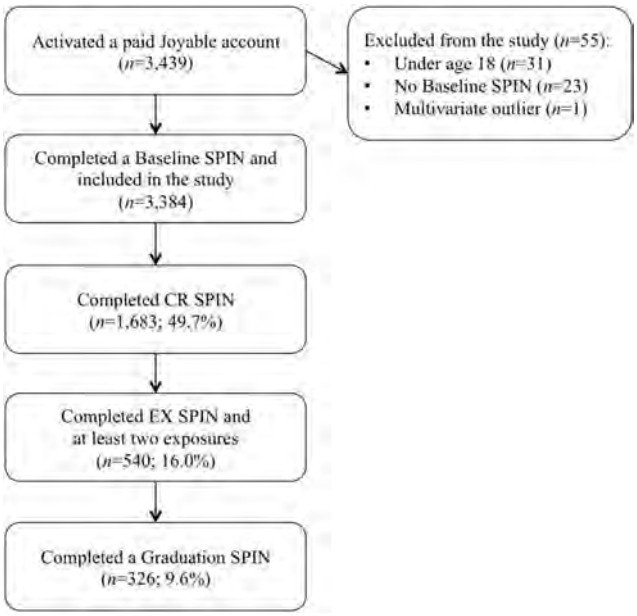

Figure 1. Participant flow through the program. CR = cognitive restructuring; EX = exposure; SPIN = Social Phobia Inventory.

Outcome Analyses

Outcome based on program engagement. Engagement outcome analyses were conducted for participants (n = 1,768) that completed at least two SPIN assessments (baseline SPIN and either CR SPIN or EX SPIN).[2] Time (assessment point) was entered as a fixed effect of SPIN score in a linear mixed model. SPIN score significantly decreased over time between baseline and CR SPIN ($b = -6.51$, $SE = 0.21$, $t(1747.84) = -30.62$, $p < .001$), CR and EX SPIN ($b = -8.02$, $SE = 0.35$, $t(652.47) = -23.15$, $p < .001$), and baseline and EX SPIN ($b = -14.53$, $SE = 0.35$, $t(681.21) = -42.08$, $p < .001$). See Figure 2. The within-subject effect size was medium between baseline and CR SPIN (d = 0.63), medium-to-large between CR and EX SPIN (d = 0.77), and large between baseline and EX SPIN (d = 1.40).

Outcome based on program adherence. Analyses were conducted for participants (n = 540) that were fully adherent to the program, meaning they had engaged in all three primary program modules (i.e., psychoeducation, cognitive restructuring, and at least two exposures), using baseline SPIN, CR SPIN, and endpoint SPIN. Mean scores were 37.35 (SD = 10.27) at baseline SPIN, 30.49 (SD = 10.02) at CR SPIN, and 18.80 (SD = 9.87) at endpoint SPIN. On average, participants had completed 29.04 (SD = 9.98) activities and 6.59 (SD = 4.31) exposures by their endpoint SPIN (see Table 2).

Time (assessment point) was entered as a fixed effect of SPIN score in a set of mixed models using fully adherent participants. SPIN score significantly decreased over time between baseline and CR SPIN ($b = -6.76$, $SE = 0.37$, $t(489.78) = -18.28$, $p < .001$), CR and endpoint SPIN ($b = -11.78$, $SE = 0.39$, $t(598.65) = -30.08$, $p < .001$), and baseline and endpoint SPIN ($b = -18.55$, $SE = 0.42$, $t(724.71) = -44.69$, $p < .001$). Within-subject effect sizes were medium between baseline and CR SPIN (d = 0.66), large between CR and endpoint SPIN (d = 1.16), and large between baseline and endpoint SPIN (d = 1.83).

To test the effect of graduation status, a dichotomous group variable (graduated vs. not graduated) was added to the model as a time-invariant covariate to explore group differences in SPIN score change over time (i.e., the interaction of group with time). The Group × Time interaction was not significant at CR SPIN ($b = -0.97$, $SE = 0.78$, $t[477.28] = -1.25$, $p = .21$), demonstrating that graduators and nongraduators experienced equivalent decreases in SPIN score between baseline and CR SPIN. The Group × Time interaction was significant at endpoint SPIN ($b = -8.04$, $SE = 0.78$, $t[714.26] = -10.28$, $p < .001$), demonstrating that graduators experienced a significantly greater de-

[2] All participants were included in these analyses, regardless of baseline SPIN score. We ran the same outcome analyses using only participants with baseline SPIN scores above the clinical cutoff (19; Connor et al., 2000), and the results were nearly identical. Detailed results can be provided upon request.

Table 2
Characteristics of Users and Usage by Point of Discontinuation

Variable	Early attritors (n = 1,616; 47.8%)		Post-CR attritors (n = 1,228; 36.3%)		Fully adherent users (n = 540; 16.0%)		Total (n = 3,384)	
	M (SD)	% (n)	M (SD)	% (n)	M (SD)	% (n)	M (SD)	% (n)
Age (years)	29.88 (7.93)		29.76 (7.77)		29.82 (7.99)		29.82 (7.88)	
Day in program	68.84 (58.92)		80.88 (57.68)		117.75 (56.62)		81.06 (60.50)	
Activities completed	4.15 (2.84)		13.63 (3.64)		32.68 (9.96)		12.14 (11.09)	
Baseline SPIN	37.70 (10.71)		38.03 (10.28)		37.35 (10.27)		37.76 (10.48)	
CR SPIN	—		31.59 (10.62)		30.49 (10.62)		—	
EX SPIN	—		—		22.84 (10.02)		—	
Endpoint SPIN	—		—		18.80 (9.87)		—	
Gender (male)		50.4 (814)		57.1 (701)		58.9 (318)		54.2 (1,833)
Coach contact (yes)		34.7 (551)		71.3 (875)		89.8 (474)		56.1 (1,900)
Graduated (yes)		.1 (1)		.5 (6)		60.4 (326)		9.8 (333)

Note. CR = cognitive restructuring; EX = exposure; SPIN = Social Phobia Inventory. Early attritors = participants that discontinued the program between baseline SPIN and CR SPIN; Post-CR = participants that discontinued the program between CR SPIN and EX SPIN; Fully adherent users = participants that completed EX SPIN (and may have continued beyond that point).

crease in SPIN score between baseline and endpoint SPIN than did nongraduators. See Figure 3.

Linear mixed models were used to examine change in SPIN score for graduators and nongraduators separately. For graduators, there was a significant decrease between baseline and CR SPIN ($b = -7.15$, $SE = 0.52$, $t[262.31] = -13.78$, $p < .001$, $d = 0.76$), CR and endpoint SPIN ($b = -14.58$, $SE = 0.46$, $t[372.58] = -32.06$, $p < .001$, $d = 1.56$), and baseline and endpoint SPIN ($b = -21.73$, $SE = 0.50$, $t[434.32] = -43.73$, $p < .001$, $d = 2.32$). Nongraduators also exhibited a significant decrease between baseline and CR SPIN ($b = -6.17$, $SE = 0.56$, $t[213.68] = -10.98$, $p < .001$, $d = 0.61$), CR and endpoint SPIN ($b = -7.52$, $SE = 0.59$, $t[223.74] = -12.86$, $p < .001$, $d = 0.74$), and between baseline and endpoint SPIN ($b = -13.69$, $SE = 0.60$, $t[266.24] = -22.85$, $p < .001$, $d = 1.35$).

Prediction of symptom change. A hierarchical linear regression examined predictors of endpoint SPIN. Age, gender, number of coach calls, scores on the psychoeducation quizzes, and number of exposures completed were entered as predictors, with baseline SPIN and number of days in the program entered as covariates. Activities completed was highly collinear with exposures completed (variance inflation factor = 24.18) and thus was not included as a predictor. After controlling for baseline SPIN and days in the program, only number of exposures significantly predicted endpoint SPIN ($\beta = -.10$, $t(511) = -2.68$, $p = .008$), such that completing more exposures was associated with a lower endpoint SPIN. The final model accounted for 30.7% of the variance in endpoint SPIN.

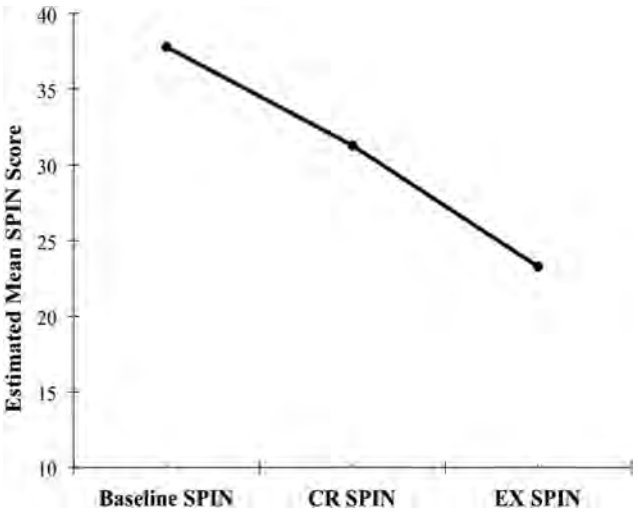

Figure 2. Estimated mean Social Phobia Inventory (SPIN) scores for participants that completed at least two SPIN assessments during the Joyable program (n = 1,768). CR = cognitive restructuring; EX = exposure.

Rates and predictors of response. Responder status was determined using Jacobson and Truax's (1991) criteria for clinically significant and reliable change, described above. Participants with both clinically significant and reliable change between baseline and endpoint SPIN were classified as responders. According to these criteria, 72.3% (n = 391) of fully adherent participants were classified as responders.[3] Rate of response was significantly higher for graduators (87%) than nongraduators (49.5%), $\chi^2(1, N = 540) = 90.96$, $p < .001$.

Independent-samples t tests compared responders and nonresponders on age, baseline SPIN, CR SPIN, and days active in the program. Compared to nonresponders, responders had a lower baseline SPIN, $t(208.35) = 2.24$, $p = .03$, $d = 0.23$, had a lower CR SPIN, $t(211.44) = 5.55$, $p < .001$, $d = 0.54$, and spent more days active in the program, $t(539) = -6.07$, $p < .001$, $d = 0.54$. Responders and nonresponders did not differ on age. Analyses of covariance were conducted to compare responders and nonre-

[3] Note that the SPIN clinical cutoff score recommended by Connor and colleagues (2000) is 19, as determined by "efficiency, sensitivity, specificity, and predictive value" (p. 382). This cutoff score roughly aligns with Jacobson and Truax's (1991) first definition of clinically significant change, in which they specify that "level of functioning subsequent to therapy should fall outside the range of the dysfunctional population, where range is defined as extending to two standard deviations beyond (in the direction of functionality) the mean for that population" (p. 13), which would be a score of 20.7 based on the mean SPIN score for individuals with SAD as determined by Connor and colleagues (2000), M (SD) = 41.1 (10.2). Using the more conservative cutoff score of 19 to represent clinically significant change, 55.2% (n = 298) of the sample would be classified as responders.

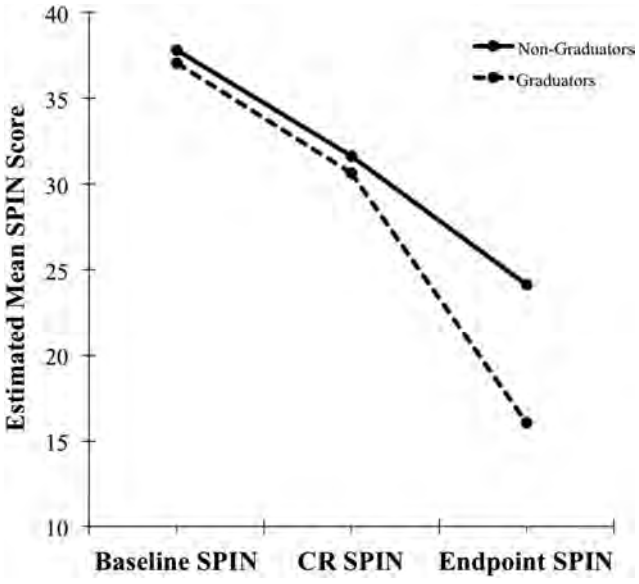

Figure 3. Estimated mean Social Phobia Inventory (SPIN) scores for fully adherent participants (n = 540). CR = cognitive restructuring.

sponders on coach calls, psychoeducation quiz scores, and number of exposures after controlling for days active in the program. Responders had more calls with their coach, $F(1, 526) = 4.93$, $p = .03$, and completed more exposures, $F(1, 538) = 6.33$, $p = .01$, than did nonresponders. Responders and nonresponders did not differ on scores on their psychoeducation quizzes, nor did they differ in gender, $\chi^2(1, N = 530) = 0.11$, $p = .74$.

Discussion

Our study is the first to examine an Internet-delivered CBT-based program for social anxiety on a large scale and in an open-access format. Of the 3,384 users that registered for an account, approximately 16% experienced the full content of the program (i.e., psychoeducation, cognitive restructuring, and exposures), an adherence rate higher than previously published studies of open-access Internet interventions for anxiety and depression (Christensen et al., 2004; Farvolden et al., 2005). Adherent participants experienced considerable symptom reduction, with large pre-to-post effect sizes (d = 1.35–2.32) that matched or exceeded those for completers of face-to-face CBT (e.g., d = 0.72–1.95; Hofmann, 2004; Herbert, Rheingold, Gaudiano, & Myers, 2004) and other ICBT programs for social anxiety (e.g., d = 0.52–1.51; Aydos et al., 2009; Titov et al., 2008). Response rates were estimated at 72% for these participants (or 55% using more conservative criteria), higher than the posttreatment rates reported in previously published studies of ICBT (e.g., 44.7%; Tulbure et al., 2015) and face-to-face CBT (e.g., 43.8% for group CBT; Kocovski, Fleming, Hawley, Huta, & Antony, 2013). These results provide strong evidence that the Joyable program is an effective intervention for individuals with social anxiety and adds to the growing evidence that internet CBT programs have great utility in reducing social anxiety symptoms (Hedman et al., 2016).

Usage and Users of the Program

Descriptive analyses revealed that the average age and gender composition of our sample was comparable to that of individuals seeking face-to-face treatment for social anxiety (e.g., Dryman, Gardner, Weeks, & Heimberg, 2016; Fracalanza, McCabe, Taylor, & Antony, 2014). The average baseline SPIN score was slightly lower than previously published trials of face-to-face CBT (Connor et al., 2000; Fracalanza et al., 2014) and ICBT for social anxiety (Stott et al., 2013; Tulbure et al., 2015), which is likely a reflection of our broad inclusion criteria. Even so, over 96% of users recorded a baseline SPIN score that met or exceeded the clinical cutoff (Connor et al., 2000), suggesting that the Joyable user base is predominantly comprised of individuals experiencing clinical levels of social anxiety.

Retention and Adherence

Neither age nor baseline SPIN scores were predictors of discontinuation, suggesting that the online program is acceptable for individuals of varying ages and with a broad range of social anxiety severity. Interestingly, individuals that started the program earlier in the program's existence were likely to drop out sooner. One of the strengths of the Joyable program is that developers are continually evaluating usage data to make improvements to the user interface and module content to enhance the user experience.[4] The effect of program start time on attrition suggests that these adjustments, although minor, may have had cumulative positive effects on user retention and adherence. In a similar vein, El Alaoui and colleagues (2015) found a gradual increase in treatment effect over four years at their ICBT-focused clinic and concluded that "local quality improvement initiatives" (p. 911) were likely contributors.

Although low relative to other open-access ICBT protocols, attrition rates were higher than RCTs on ICBT for social anxiety, which have reported rates between 1% and 41% (Boettcher et al., 2013). A similar discrepancy in attrition rates has been evident in previous research (Christensen et al., 2004, 2009), which found that public users of ICBT completed fewer online assessments than did their research counterparts. Specifically, 15.6% of public users compared to 66.5% of research subjects completed at least two of five modules of an online CBT program for anxiety and depression, although the two groups of users benefited equally.

Although our data included a limited number of possible predictors, a review of self-reported reasons for dropout in prior ICBT studies described multiple factors that may have affected attrition in our sample. Specifically, participants reported reasons for dropout that included "time constraints, lack of motivation, technical or computer access problems, depressive episode or physical illness, lack of face-to-face contact, preference for taking medication, perceived lack of treatment effectiveness, improvement in condition, and burden of the program" (Christensen et al., 2009, p. 11). We might expect similar reasons for attrition in our sample. Differences in individual characteristics, such as preferred method

[4] Examples of such improvements include adding illustrations to reinforce concepts, associating thinking error labels with specific iconography, and modifying the user interface to remove distraction and facilitate better focus on the content.

of learning, social support, education level, and socioeconomic status may also have influenced program discontinuation in our sample (Al-Asadi, Klein, & Meyer, 2014).

In addition, a notable proportion of participants (36.3%) closed their accounts after completing the cognitive restructuring module but before completing two exposures. Attrition at this later time point in the program may be indicative of avoidance of or difficulty completing exposures for some participants. Given that exposure completion was an important predictor of positive outcome for completers, future research should attempt to understand why some users stopped at this point in the program and what can be done to encourage their continued participation during the exposure modules (e.g., additional coaching during the exposure module, incorporating exposures in earlier modules).

We can also speculate about factors that may have enhanced the Joyable program's retention relative to other open-access programs. For one, participants that made contact with a coach over the phone stayed in the program longer than participants that did not make phone contact with a coach, suggesting that coaching had a positive impact on retention. The software design and user experience of Joyable may also have positively influenced retention rates. In contrast to previous open-access programs, Joyable was developed within the technology industry (rather than a research laboratory or mental health clinic) and has committed extensive resources to designing a user interface that is interactive, engaging, and intuitive. The program incorporates software designed to promote habit formation, and all program components are extensively tested prior to implementation. The finding that attrition decreased over the course of time supports the possibility that enhanced user experience played a positive role in retention.

The pay-for-service nature of the program may also have influenced our retention rate. The Joyable program differs from other open-access programs in that users pay monthly to maintain their account, which may have increased motivation for program continuation. Furthermore, our sample included users that remained in the program past the 7-day free trial and did not include users that initiated but never paid for an account. This decision was intended to reduce bias by not including users who had little intention of engaging in the program. However, to the extent that previous open-access studies calculated their full study sample from Day 1, rather than Day 7, our retention percentage may have been inflated. Additional research will be necessary to examine each of these potential influences on program attrition and retention.

Outcome Analyses

Our outcome analyses yielded positive results for participants that engaged in the program (n = 1,786) and those that were fully adherent to the program (n = 540). In both sets of analyses, SPIN scores decreased across assessment points, with social anxiety improving between baseline and cognitive restructuring and between cognitive restructuring and exposures. That the addition of exposures more than doubled the average reduction in SPIN scores for adherent participants is especially notable given that the number of exposures completed was also a significant predictor of outcome in the program. These findings highlight the importance of exposures (in conjunction with cognitive restructuring) in ICBT for social anxiety. They also provide encouraging evidence that individuals with clinical levels of social anxiety are willing to attempt exposures on their own, without the support and structure of the face-to-face therapy environment. Thus, exposures remain an important component of social anxiety treatment and can be used effectively through an Internet-delivered intervention.

Coach contact also emerged as an important component of the program. Participants that remained in the program past the psychoeducation module were more likely to have made contact with a coach, and the number of phone calls with a coach differentiated responders from nonresponders. Although prior research on guided versus unguided ICBT for social anxiety has been mixed (Berger et al., 2011; Furmark et al., 2009; Titov et al., 2008), our findings align with broader meta-analytic evidence that guided ICBT yields superior outcomes and adherence relative to unguided ICBT (Richards & Richardson, 2012; Spek et al., 2007). One unique aspect of the present study is that users could make their own choice regarding coaching (rather than being randomly assigned to a guided or unguided condition). Given that choice, only about half of participants chose to use a coach, and coach contact was associated with longer program retention and positive program outcome. Although there were no differences in baseline social anxiety levels, it is possible that participants that made contact with their coach were more motivated in general, contributing to their choice regarding coaching, their retention in the program, and their ultimate symptom improvement. Future research should evaluate both participant and coach factors that may contribute to the preference for (or avoidance of) coach support and its relation to outcome.

Clinical Implications

The Joyable program represents an important next step in the "bench-to-bedside" progression of ICBT for social anxiety. Previous studies have established the efficacy and effectiveness of ICBT within a structured setting, but our study is the first to examine the utility of an Internet-based intervention for individuals with social anxiety without requiring diagnostic evaluation or strict inclusion/exclusion criteria. Users that engaged in the program, especially those that were exposed to all three primary components, experienced a meaningful decrease in symptoms, suggesting that an online CBT-based protocol can be an effective intervention for social anxiety in a real-world setting.

Although it is the hallmark of SAD, interpersonal apprehension and avoidance is elevated in a range of psychiatric disorders, including most anxiety and mood disorders (Gros, McCabe, & Antony, 2013), autism (e.g., Kuusikko et al., 2008), and psychosis (e.g., Michail & Birchwood, 2009), as well as numerous physical health conditions (e.g., Altintas, Yerdelen, & Taskintuna, 2015). Participants in our sample were not interviewed to determine whether SPIN elevations were primarily due to disorder-level social anxiety or better accounted for by another disorder. This necessarily limits conclusions regarding the specificity of the current findings to threshold SAD. Importantly, however, it underscores the likely robust transdiagnostic effectiveness of Joyable—and more broadly CBT for social anxiety—to address social concerns secondary to a range of difficulties. Furthermore, ICBT specifically targeted to social anxiety has therapeutic effects that extend to comorbid disorders such as depression, panic, and generalized anxiety as well as nonspecific dimensional distress and functional disability (Dear et al., 2015). As such, in addition to remediating principal social anxiety as well as social concerns sec-

ondary to other conditions, there is likely the added benefit of nonspecific symptom reduction. In the future, broader assessment of symptom constellations and disorder-level comorbidity could help disentangle the relative contributions of these processes to overall therapeutic change and skill generalization related to ICBT for social anxiety.

Taken together, ICBT has the potential to extend Internet-based mental health services to those with social anxiety that may otherwise be unwilling or unable to seek out face-to-face treatment. This includes very severe and/or highly avoidant individuals who may be less likely to pursue face-to-face intervention (Erwin et al., 2004), individuals whose schedules do not permit the time commitment for weekly in-person visits, and individuals that live in rural areas with limited access to providers trained in CBT (Cavanagh, 2014). ICBT has the potential to provide immediate access (i.e., no waitlist) to an empirically supported treatment with "sessions" that can be completed at any time and from any location. Online platforms also now play an integral role in socio-occupational functioning for many individuals, and ICBT is keeping pace with the trend to seek out health care in this manner.

Strengths and Limitations

A principal strength of the present study was its application of ICBT in a real-world context, thereby allowing us to examine a large cohort of socially anxious individuals without the constraints of a laboratory-based research clinic. However, limitations must also be acknowledged. First, we had limited data on the demographic characteristics of our participants. Information regarding race, ethnicity, socioeconomic status (SES), education, employment, and marital status will be essential to better understand the characteristics of program users, and importantly, program responders. For instance, individuals with higher SES and more education may be more computer literate, making them more likely to stay in the program longer and thus more likely to respond positively. Nonetheless, age and gender did not predict response, suggesting that the program can be effective for a broad range of users.

Second, important other data, such as treatment history, concurrent treatment, medication usage, diagnostic status, and the presence of comorbid disorders, were not available. Because many prior ICBT studies had exclusion criteria specifically based on these categories, our understanding of these factors and their contributions to treatment response are especially limited. Gathering such data in the future will allow an examination of whether program users are more typically treatment naïve, whether the program is helpful as an adjunct to treatment-as-usual, and whether comorbidity affects program retention and response.

Third, because of the online nature of the program, certain clinical variables were more difficult to track than they are during face-to-face interventions. For instance, Joyable coaches have anecdotally noted that their clients reported completing exposures on their own that they did not log in the program. It is therefore possible that our data underestimate the number of exposures completed by some participants. Likewise, our data may have underrepresented the amount of coach contact during the program, as we were unable to systematically track contact via text, email, or instant messages. Many individuals with social anxiety are highly anxious about talking over the phone, and as such, alternative forms of communication may be especially important for this population. More systematic tracking of these important details is needed to understand their effects on outcome and adherence.

Fourth, the pay-for-service nature of the program may have introduced additional bias into our sample. The present study only included users that remained active in the program past the 7-day free trial, meaning all participants in the current study paid $99 per month. Users willing to pay for the service may be more motivated to engage in the program, may try harder and be more active in the program, and may stay in the program longer than would nonpaying users. Furthermore, the cost of the program may have been prohibitive for lower SES individuals, skewing the sample toward a higher SES (and likely more educated and computer literate) sample. Nonetheless, individuals with a broad range of social anxiety severity were willing to pay for the program.

Finally, because of the open-access nature of the program, we could not include a control condition or longitudinal follow-ups in the current study. The inclusion of a control condition can provide more certainty regarding the causal nature of the intervention outcome. Follow-up assessments would also have increased confidence in the sustainability of the positive effects of the program. Prior studies of ICBT for social anxiety have demonstrated large controlled effect sizes and treatment gains that are maintained up to five years (Boettcher et al., 2013; Hedman et al., 2011), suggesting that ICBT for social anxiety performs well when compared to control conditions and appears to have enduring effects. Subsequent examinations of the Joyable program would do well to include a waitlist or nonactive control condition, conduct diagnostic assessments including commonly comorbid symptoms presentations at intake as well as follow-up, and offer the program free-of-charge to participating users to reduce selection bias and increase confidence regarding causality.

Future Directions

Future directions of Internet-based interventions are especially important to consider, given the rapid pace of technological developments and advances in Internet applications. In particular, personal media devices are becoming increasingly prevalent, with 64% of Americans owning a smartphone and nearly 20% of Americans relying exclusively on their smartphone for Internet access (Pew Research Center, 2015). Smartphone technology has the potential to make psychological interventions more accessible, efficient, and interactive for patients (Boschen & Casey, 2008), in part by providing Internet access while also being more portable and more frequently used. Only one published study has empirically examined the efficacy of CBT delivered through a smartphone. An RCT found that a "mobile CBT" protocol based on the ICBT program developed by Andersson and colleagues (2006) resulted in greater improvement in social anxiety symptoms than did mobile interpersonal psychotherapy for social anxiety (Dagoo et al., 2014). Additional research is needed to evaluate characteristics of mobile CBT users, predictors of response, and the effectiveness of ICBT in a smartphone (or tablet) format.

Future research should also target other components of the Joyable program. In addition to the CBT-based modules, the program also offers access to an online community where users can share their activities and progress with other users. Given the social isolation that often accompanies severe social anxiety, the online community may act as a source of support for users with limited social networks and

may also enhance motivation and treatment adherence (Berger et al., 2011; Furmark et al., 2009). Many published ICBT programs include a discussion forum as part of their program (Hedman et al., 2016), but only one study has systematically investigated its influence. Specifically, Titov and colleagues (2008) found that adding a clinician-moderated discussion forum yielded small improvements in within-group effect sizes for ICBT. Gaining an understanding of who uses the online community forum and whether or not the forum influences outcome will be important next steps in evaluating the Joyable program.

Conclusions

This study demonstrated that an online CBT-based intervention for social anxiety delivered in a real-world setting yielded reductions in social anxiety for users with a wide range of symptom severity. Rates of adherence were higher than previously published open-access trials of ICBT for anxiety and depression, and outcomes were comparable to or exceeded controlled trials of ICBT as well as face-to-face CBT for SAD. Exposures and guidance from a coach emerged as important predictors of positive outcomes. Taken together, the Joyable program represents an easy-to-access and effective intervention that extends Internet-based mental health services to individuals that may otherwise experience barriers to receiving evidence-based treatment for social anxiety.

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Prevalence and Change in Work Productivity and Activity Impairment among Employed U.S. Adults Completing a Cognitive Behavioral Telehealth Treatment for Depression and Anxiety

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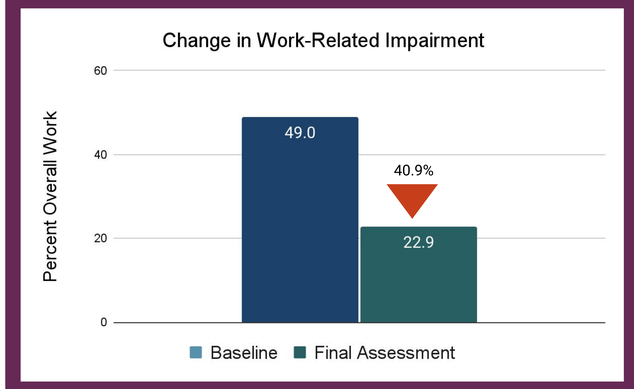
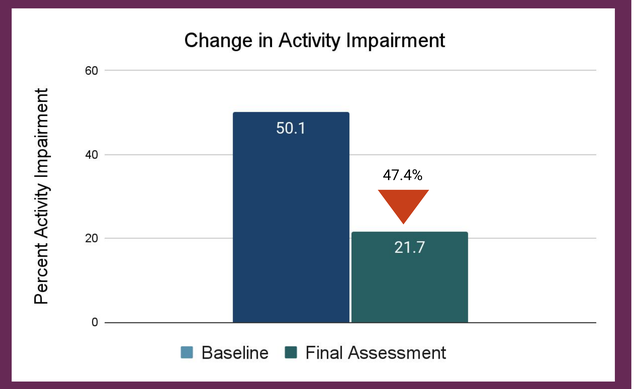
BACKGROUND

- Depression and anxiety are leading causes of disability and associated with $1 trillion of lost productivity in the global economy annually[1-2]
- There is a need for accessible and effective mental health care to help combat adverse workplace outcomes associated with depression and anxiety
- Time limited, evidence-based, telebehavioral health care options may help meet these needs
- We aimed to evaluate 1) baseline prevalence of work impairment and non-work activity impairment and 2) the association between change in depression and anxiety symptoms and work and activity impairment at the final session among employed U.S. adults who completed an ~8-week protocolized cognitive behavioral telehealth treatment for depression and anxiety

METHODS

- Therapy+ is an ~8 week protocolized, cognitive behavioral treatment for anxiety and depression that is delivered via telephone or video by a licensed therapist
- We analyzed previously collected de-identified data from a consecutive cohort of 532 program participants
- Total work impairment (absenteeism [% work time missed] plus presenteeism [% impairment experienced at work]) and activity impairment (impairment in regular activities outside of work) due to behavioral health problems were assessed using the W*ork Productivity and Activity Impairment* (WPAI) scale
- Depression and anxiety symptom severity were measured by the *Depression Anxiety Stress Scales 21* (DASS-21) at baseline and final session
- Multivariate linear regression was used to examine the association between change in depression and anxiety symptom severity and work and activity impairment at the final session among individuals with workplace or activity impairment and elevated depression or anxiety symptoms at baseline
- All models were adjusted for age, gender, race/ethnicity, and baseline impairment





Work and activity impairment were prevalent among a cohort of employed U.S. adults engaged in a cognitive behavioral telehealth treatment. Significant improvements in impairment were observed, and were associated with concurrent improvements in depression and anxiety symptoms.

Take a picture to download additional information.

RESULTS

- Participants were 75.0% female, 46.1% non-White race/ethnicity, and the mean age was 39.5 years
- At baseline, 73.0% of participants endorsed work impairment with 15.6% reporting absenteeism and 68.5% experiencing presenteeism
- Additionally, 76.0% of participants reported impairment in non-work activities
- Among participants with baseline impairment, a 40.9% mean reduction in total work impairment and 47.4% mean reduction in non-work activity impairment was observed from baseline to final assessment
- There was a significant direct association between change in depression (β=1.1, p<.001) and change in anxiety (β=1.0, p<.001) symptom severity and total work impairment at the final session among participants with elevated depression (n=235) and/or anxiety (n=182) symptoms and work impairment at baseline
- There was also a significant direct association between change in depression (β=1.0, p<.001) and change in anxiety (β=0.8, p<.001) symptom severity and activity impairment at the final session among participants with elevated depression (n=279) and/or anxiety (n=209) symptoms and activity impairment at baseline

CONCLUSIONS

- Work and activity impairment were prevalent among a cohort of employed U.S. adults engaged in a cognitive behavioral telehealth treatment for depression and anxiety
- There were significant improvements in work and activity impairment over the course of the program, and these changes were associated with concurrent improvements in depression and anxiety symptoms
- Time limited, cognitive behavioral telehealth treatments for depression and anxiety have the potential to improve workplace outcomes

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Prevalence and Change in Work-Related Impairment Among Users of a Guided Digital Intervention for Depression and Anxiety

A Retrospective Cohort Analysis

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Although there is a growing body of evidence to demonstrate the efficacy and effectiveness of digital interventions for reducing psychological symptom severity, relatively few studies have examined the impact of these tools on functional impairment, including work-related impairment. Work-related impairment is a primary driver of individual and societal costs associated with depression and anxiety and is a key treatment outcome of interest. This study aimed to describe the impact of a guided digital intervention for depression, generalized anxiety, and social anxiety on user-reported work-related impairment by examining 1) the prevalence of work-related impairment, 2) the magnitude of change in work-related impairment over the course of the program, and 3) the association between symptom severity and work-related impairment. Results suggest that 25.1% of users reported that their work was very much or extremely impaired by their depression or anxiety symptoms. There was a significant association between module completion and improved work-related impairment for the Depression (β=-0.1; p<.0001), Generalized Anxiety (β=-0.1; p<.0001), and Social Anxiety (β=-0.1; p<.0001) programs. Associations between module completion and change in work-related impairment retained significance with covariate adjustment. Of the users reporting the most severe baseline impairment, 78% endorsed improved functioning at their final assessment. There was also a moderate correlation (r= 0.2-0.5, p<.05) between baseline symptom severity and work-related impairment. Digital interventions have potential to improve work-related impairment and measuring impairment in addition to symptom severity may add important clinical information allowing for a more thorough evaluation of the effectiveness of these tools.

Keywords: digital mental health, mHealth, iCBT, depression, anxiety, work-related impairment

Depression and anxiety are two of the most common mental health problems. Over 17 million adults in the United States have had at least one major depressive episode and over 18 million have an anxiety disorder (NIMH, 2017). Additionally, the rates of depression and anxiety continue to grow, exacerbated in part by the COVID-19 pandemic (Vahratian et al., 2021).

Although effective interventions have existed for decades (Cuijpers et al., 2008; Hofmann & Smits, 2008), over 50% of those in need of services do not receive them (NIMH, 2019). Over the past decade, there has been increased focus on the potential of technology to help improve access to mental health services, particularly for common mental health problems like anxiety and depression (Ebert et al., 2017). There is a growing body of literature to support the efficacy and effectiveness of digital interventions for depression and anxiety (Firth et al., 2017a; Firth et al., 2017b).

Similar to the treatment literature more broadly (McKnight & Kashdan, 2009), however, the vast majority of these studies only focus on symptom reduction. Although symptom reduction is an important treatment outcome, functional impairment, or limitations in functioning due to mental health symptoms (Üstün & Kennedy, 2009), is another key treatment outcome. In fact, research suggests that for patients, improved functioning is as important as symptom reduction (Langlieb & Guico-Pabia, 2010; Zimmerman et al., 2006).

Although moderately correlated, symptom severity and functional impairment do not always respond to intervention the same way. Functional impairment is often less responsive to intervention and improvements in functional impairment tend to lag behind symptom reduction (Hammer-Helmich et al., 2018; McKnight & Kashdan, 2009). Additionally, research suggests that functional impairment can persist after symptom remission and increase risk for relapse (Hardeveld et al., 2010).

This is particularly important given that the functional impairment associated with anxiety and depression is associated with high individual and societal costs and is a leading cause of disability (Woo et al., 2011). Many of these costs are associated with hindered functioning at work, including lost productivity, absenteeism, and unemployment. For example, worldwide lost productivity associated with depression and anxiety alone account for an estimated $1 trillion of lost productivity (Health, TLG, 2020).

As such, there has been increased interest among health plans and employers in improving access to mental health services and many are incorporating self-management digital tools to help expand their benefits offerings. There is a need to better understand the impact of these tools on work- related impairment. Digital+, a guided internet-based Cognitive Behavioral Therapy (iCBT) program for anxiety and depression, provides a unique opportunity to begin to understand the impact of such tools.

Digital+ is made available to users through health plan and employer partners. Digital+ consists of three, cognitive behavioral therapy-based programs for depression, generalized, and social anxiety. Previous analyses have demonstrated a significant association between program module completion and depressive and anxiety symptom reduction with large effect sizes (Anton et al., 2021; Dryman et al, 2017). A critical next step is to understand the impact of Digital+ on work-related impairment. As such, this study aimed to examine: 1) the prevalence of work-related impairment; 2) the magnitude of change in work-related impairment over the course of the program; and 3) the association between psychological symptom severity and work-related impairment.

Method

Procedure. AbleTo, Inc., a virtual behavioral health company, partners with employers and health plans to make Digital+ available to covered members and employees. These individuals learn about Digital+ through various marketing campaigns, including information provided on an employer's benefits webpage, via posters and flyers in office settings, and through email and text campaigns. Interested individuals may access Digital+ via the web or a mobile app and are asked to complete a brief survey to determine program appropriateness (e.g., safety) and program focus (e.g., depression, generalized anxiety, or social anxiety).

Participants. We analyzed previously collected and permanently de-identified data from a consecutive cohort of 1,896 adult (>=18 years) Digital+ users enrolled between January 1, 2020 and June 30, 2020 Of those, 1,702 (89.8%) had the work-related impairment question embedded in their program, and 478 (28.1%) users completed at least half of the program modules and were included in the final analyses. All study procedures were submitted to the Sterling Institutional Review Board (IRB), Atlanta, GA, USA, and deemed exempt.

Design. This was retrospective cohort analysis.

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Description of the Program. Digital+ is a web- and mobile-based application with personalized coaching for anxiety and depression. Users are directed to one of three programs based on their presenting problem and identified goals. All programs are based on cognitive behavioral principles and include 8 modules that consist of psychoeducation, brief activities (<10 min), mood and symptom tracking, and 1:1 coaching. Programs include: 1) Depression; 2) Generalized Anxiety; and 3) Social Anxiety.

Materials. *Participant Characteristics.* As part of the standard enrollment process, users provided basic demographic information (i.e., age and gender).

Baseline Symptom Severity. Participants in the Depression program completed the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, Williams, 2001) during enrollment. The PHQ-9 is a 9-item self-report measure designed to evaluate the presence of depressive symptoms over the past two weeks. Items are rated on a 0 (*Not At All*) to 3 (*Nearly Every Day*) scale. Total scores range from 0 to 27 and cut-off scores for mild, moderate, moderately severe, and severe depressive symptoms are 5, 10, 15, and 20 respectively.

Participants in the Generalized Anxiety program completed the Generalized Anxiety Disorder-7 (GAD-7; Spritzer et al., 2006) during enrollment. The GAD-7 is a 7-item anxiety self-report measure. Items are rated on a 0 (*Not at All*) to 3 (*Nearly Every Day*) scale. Total scores range from 0 to 21 and cut-off scores for mild, moderate, and severe anxiety symptoms are 5, 10, and 15 respectively.

Participants in the Social Anxiety program completed the Social Phobia Inventory (SPIN; Connor et al., 2000) during enrollment. The SPIN is a 17-item self-report questionnaire that assesses social anxiety symptoms over the past week. Items are rated on a 0 (*Not At All*) to 4 (*Extremely*) scale. Total scores range from 0 to 68 and scores 20 and greater are considered clinically significant (Chukwujekwu & Olose, 2018; Lauria-Horner, 2016)

Work-Related Impairment. Work-related impairment was assessed with a single item adapted from the functional impairment item on the PHQ-9. The item asked users to rate: "*How much has depression [persistent anxiety or stress; or fear of judgement in social situations] interfered with your ability to do your work"* on a 1 (*Not At All*) to 4 (*Extremely*) scale. Total scores range from 1 to 4.

Statistical Analysis. Baseline demographic and clinical characteristics were reported as frequencies and percentages for categorical variables and means and standard deviations for continuous variables. Outcome measures over time were also reported as means and standard deviations, as well as frequencies. Linear mixed models with a random intercept and slope were constructed using restricted maximum likelihood estimation procedures in the PROC MIXED function of SAS 9.4 to examine the association between Digital+ program completion and change in work-related impairment. First, models were estimated separately for each program and the covariance structure that provided the best model fit was identified. Based on model fit indices, the best fitting model was carried forward into the covariate models to examine the associations between baseline participant characteristics (i.e., baseline symptom severity and work-related impairment, age, and gender) and change in work-related impairment over time. Participants who completed at least four modules were included in these analyses. In order to examine the association between baseline symptom severity and work-related impairment, Pearson's correlation coefficients were estimated. Additionally, the correlation between change in symptoms and change in work-related impairment were estimated.

Results

Participants

A total of 1,896 participants enrolled in and initiated use of Digital+ between January 1, 2020 and June 30, 2020. Of those 1,702 (89.8%) had the work-related impairment item embedded in their program. Among those 1,702 users, 478 (28.1%) completed at least four modules and were retained for the final analyses. Baseline characteristics for these users can be found in Table 1. There were no significant differences in age, baseline depressive, generalized, or social anxiety symptom severity among those who completed fewer than four modules and those who completed at least four modules. There was, however, a significant difference in gender, such that those who did not disclose their gender were less likely to complete four or more modules (p=.04).

Prevalence of Work-Related Impairment

At baseline, 17.2% (n=82/478) of users reported no work-related impairment, 57.7% (n=276/478) of users reported some work-related impairment, 18.4% (n=88/478) of users reported that their work was very much impaired, and 6.7% (n=32/478) reported that their work was extremely impaired because of their depression or anxiety. There were no significant differences in the distribution of baseline work-related impairment across the three different programs (p=.07). Descriptive statistics for the work-related impairment item at baseline, module 4, and module 8 are summarized in Table 2 for all users who completed at least half the program content.

Change in Work-Related Impairment

Among the 478 users who completed at least half the program content, 204 (42.7%) reported improvements in their work impairment, 238 (49.8%) rated the same level of work impairment, and 36 (7.5%) individuals reported more severe work impairment at their final assessment. On average, there was a 0.4-point reduction in impairment between the first and last assessment. Of the 120 (25.1%) individuals who reported that their work was very much or extremely impaired at baseline, 93 (77.5%) reported improved functioning at their final assessment. Among these individuals there was an average reduction of 1.0 in impairment between the first and last assessment.

Model-implied estimates for work-related impairment by program are presented in Figure 1. In the linear mixed model to evaluate associations between Depression program completion and reductions in work-related impairment among users with exposure to at least four modules (n=164), significant fixed effects of module completion (F(1, 809)=70.1, p< .0001) and baseline work-related impairment (F(1,158)=389.1, p<.0001), but not age (F(1,158)=1.8, p=.18), gender (F(2, 158)=0.4, p=.69), or baseline depressive symptomatology (F(1, 158)=0.1, p=.74) were observed. There was also significant variability around the mean slope (p=.0001) and significant residual variance (p<.0001).

Similarly, there were significant fixed effects of Generalized Anxiety program completion (F(1, 1,050)=52.7, p<.0001), baseline work-related impairment scores (F(1,213)=580.8, p<.0001), and baseline generalized anxiety symptoms (F(1,213)=4.1, p=.045), but not age (F(1,213)=0.2, p=.64), or gender (F(2, 213)=0.7, p=.51) on change in work-related impairment among users who completed at least four modules (n=219). There was also significant variability around the mean slope (p<.0001) and significant residual variance (p< .0001).

In the linear mixed effects model among Social Anxiety program users exposed to four or more digital modules (n=95), there were significant fixed effects of module completion (F(1, 393)=30.5, p<.0001), baseline work-related impairment scores (F(1,89)=283.0, p<.0001), and baseline social anxiety symptomatology (F(1, 89) =7.4, p=.008) on reductions in work-related impairment, but not age (F(1,89)=0.5, p=.47) or gender (F(2, 89)=1.1, p=.34). There was also significant variability around the mean slope (P=.009) and there remained significant residual variance (p<.0001).

Work-related Impairment and Baseline Symptom Severity

Among the 164 users in the Depression program, there was a large correlation between baseline depressive symptoms and work-related impairment (r=0.5, p<.0001). In the Generalized Anxiety Program (n=219), there was a moderate correlation between baseline symptom severity and work-related impairment (r=0.4, p<.001). Similarly, among the 95 users in the Social Anxiety program, there was a moderate correlation between baseline social anxiety symptoms and work-related impairment (r=0.2, p=.02). See Table 3 for a summary of these results and Figure 2 depicts the association between baseline psychological symptom severity and work-related impairment.

Additionally, we examined the correlation between change in psychological symptom severity and change in work-related reduction among users who completed at least half the program content. There was a moderate correlation between change in depressive symptoms and change in work-related impairment (r=0.2, p=.001), as well as between changes in generalized anxiety symptoms and work-related impairment (r=0.3, p<.0001). There, however, was not a significant correlation between changes in social anxiety symptoms and change in work-related impairment (r=0.1, p=.26).

Figure 1. ***Estimated mean work-related impairment by modules completed for users who completed at least four modules.***

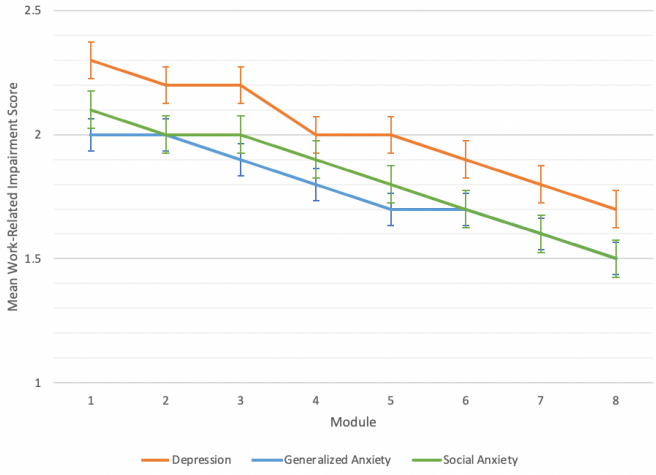

Figure 2. ***Associations between mean baseline psychological symptom severity total scores and work-related impairment total scores.***

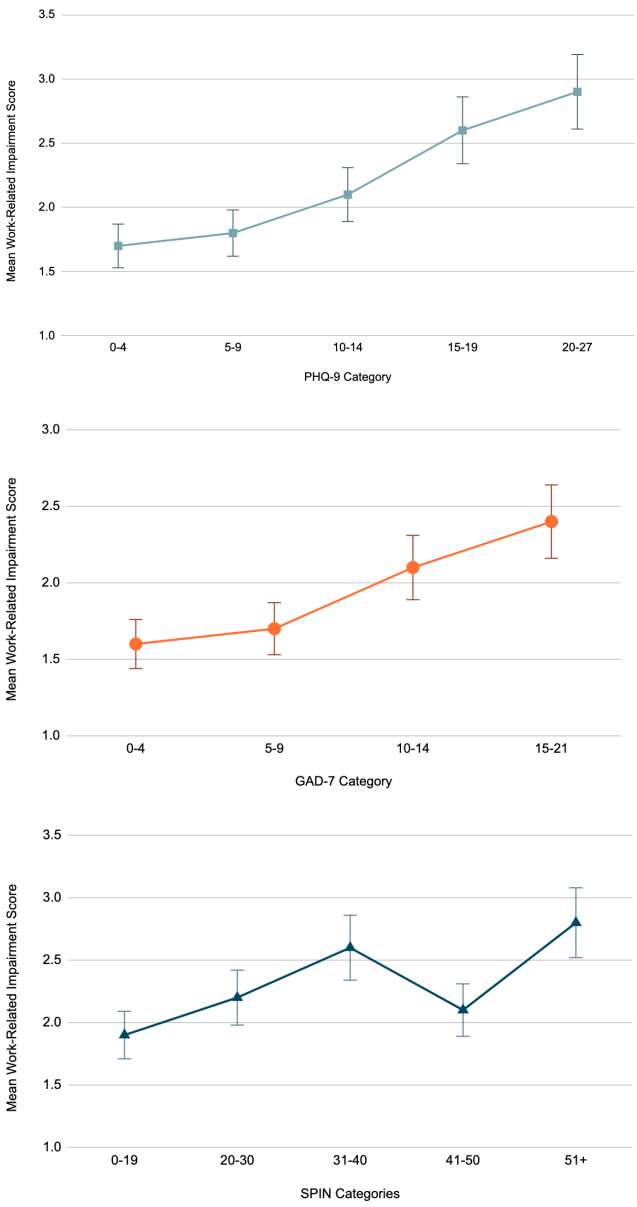

Table 1. ***Baseline sample characteristics among users who completed at least four modules (N=478).***

Variables		Depression (*n*=164)	Generalized Anxiety (*n*=219)	Social Anxiety (*n*=95)
Age (years) *M* (*SD*)	38.2 (12.7)	37.2 (12.9)	40.6 (12.7)	34.5 (11.3)
Gender *n* (%)				
Female	306 (64.0)	109 (66.5)	142 (64.8)	55 (57.9)
Male	131 (27.4)	43 (26.2)	63 (28.8)	25 (26.3)
Non-binary	5 (1.1)	3 (1.8)	0 (0.0)	2 (2.1)
Not Disclosed	36 (7.5)	9 (5.5)	14 (6.4)	13 (13.7)
Source				
Employer	327 (68.4)	118 (72.0)	137 (62.6)	72 (75.8)
Health Plan	151 (31.6)	46 (28.0)	82 (34.4)	23 (24.2)
Program				
Depression	164 (34.3)	--	--	--
Generalized Anxiety	219 (45.8)	--	--	--
Social Anxiety	95 (19.9)	--	--	--

Table 2. ***Distribution of work-related impairment by modules (N=478).***

Outcome	Baseline	Module 4	Module 8
Overall	*N*=478*	*n*=472**	*n*=226
Work-Related Impairment (mean, SD)	2.1 (0.8)	1.9 (0.7)	1.7 (0.7)
(1) Not At All (n, %)	82 (17.2)	143 (30.3)	107 (43.5)
(2) Somewhat (n, %)	276 (57.7)	271 (57.4)	115 (46.8)
(3) Very Much (n, %)	88 (18.4)	43 (9.1)	17 (6.9)
(4) Extremely (n, %)	32 (6.7)	15 (3.2)	7 (2.9)
Depression	*n*=164	*n*=163	*n*=95
Work-Related Impairment (mean, SD)	2.2 (0.8)	1.9 (0.7)	1.7 (0.9)
(1) Not At All (n, %)	26 (15.9)	42 (25.8)	44 (46.3)
(2) Somewhat (n, %)	92 (56.1)	95 (58.3)	38 (40.0)
(3) Very Much (n, %)	32 (20.1)	20 (12.3)	7 (7.4)
(4) Extremely (n, %)	13 (7.9)	6 (3.7)	6 (6.3)
Generalized Anxiety	*n*=219	*n*=215	*n*=112
Work-Related Impairment (mean, SD)	2.1 (0.7)	1.7 (0.6)	1.7 (0.7)
(1) Not At All (n, %)	45 (20.6)	76 (35.4)	45 (40.2)
(2) Somewhat (n, %)	126 (57.5)	121 (56.3)	57 (50.9)
(3) Very Much (n, %)	38 (17.4)	15 (7.0)	9 (8.0)
(4) Extremely (n, %)	10 (4.6)	3 (1.4)	1 (0.9)
Social Anxiety	*n*=95	*n*=94	*n*=39
Work-Related Impairment (mean, SD)	2.3 (0.8)	1.9 (0.8)	1.6 (0.6)
(1) Not At All (n, %)	11 (11.6)	25 (26.6)	18 (46.2)
(2) Somewhat (n, %)	58 (61.1)	55 (58.5)	20 (51.3)
(3) Very Much (n, %)	17 (17.9)	8 (8.5)	1 (2.6)
(4) Extremely (n, %)	9 (9.5)	6 (6.4)	0 (0.0)

Note. *Baseline scores represent responses provided at Modules 1 unless missing then the first available assessment was used. *N*=87 (18.2%) had data at Module 1. *N*=391 (81.8%) had data at Module 2. **N*=6 (1.2%) were work-related impairment data missing data at Module 4

Table 3. ***Means, standard deviation, and Pearson correlation for work-related impairment and baseline psychological symptom severity.***

	Variable	Mean	SD	Work-Related Impairment
1.	Work-Related Impairment	2.1	0.8	--
2.	PHQ-9	12.0	5.1	0.5**
3.	GAD-7	11.7	5.3	0.4**
4.	SPIN	31.4	13.8	0.2*

Note. PHQ-9: Patient Health Questionnaire-9; GAD-7: Generalized Anxiety Disorder-7; SPIN: Social Phobia Inventory.
*p<.05 **p<.01

Discussion

This study adds to the literature on digital interventions at reducing symptoms of depression and anxiety by examining the change in user-reported work-related impairment among users of a guided digital intervention. At the beginning of the program, work-related impairment was prevalent with more than a quarter of users endorsing that their work was very much or extremely impaired by their depression or anxiety symptoms. There were significant improvements in work-related impairment among participants in all three Digital+ programs, with 43% of users endorsing a lower level of impairment at their final assessment relative to their first assessment and 78% of the users reporting the most severe baseline impairment endorsing improved functioning at their final assessment. Additionally, across all three programs there was a significant association between module completion and improved work-related functioning, controlling for both baseline symptom severity and work-related impairment, as well as age and gender. Higher baseline work-related impairment was associated with a slower reduction in impairment overtime. In the Generalized and Social Anxiety programs, but not the Depression program, higher baseline symptom severity was also associated with a slower reduction in work-related impairment. There was a moderate correlation between baseline symptom severity and work-related impairment across all three programs. Similarly, there was a moderate relationship between change in depressive and generalized anxiety symptoms and changes in work-related impairment, but not changes in social anxiety symptoms.

The rate of work-related impairment among this cohort of Digital+ users was lower than that seen among those experiencing depression and anxiety more broadly. For example, 63.8% of United States adults who have a major depression episode experience severe impairment, including work-related impairment (NIMH, 2019). This might suggest that users who are self-selecting into digital interventions experience lower levels of impairment than those who self-select into more intensive interventions, such as more traditional one-on-one treatment.

Relatedly, although users with higher baseline work-related impairment also benefited from Digital+ programs, they experienced a slower reduction in impairment relative to those with lower baseline impairment. There is increased interest in identifying individuals who are most likely to benefit from these tools, in order to help direct individuals to appropriate care. Randomized trial research consistently demonstrates that those who are experiencing higher levels of symptomatology are less likely to adequately engage in and benefit from digital interventions (Arean et al., 2016; Firth et al., 2017a). Similarly, in the broader treatment literature higher functional impairment is associated with lower treatment response (Delgadillo, Moreea, & Lutz, 2016). It is possible that those experiencing higher levels of work-related impairment may be better served by a higher level of care. As such, it may be important for digital tools to assess functional impairment in order to direct individuals to appropriate care.

Finally, consistent with the broader literature (McKnight & Kashdan, 2009; McKnight et al., 2016), this study demonstrated that although baseline symptom severity and work-related impairment were moderately associated, the relationship between module completion and changes in functional impairment were independent of baseline symptom reduction. Additionally, the changes in work-related impairment and symptom change were only modestly correlated, and for the Social Anxiety program not correlated. Therefore, the inclusion of both measures of functional impairment and symptom scores may not only provide the most thorough and useful clinical information, but also more adequately assess treatment response in the context of digital interventions.

Limitations and Future Directions

The results of this study must be interpreted considering its limitations. First, the lack of a control group means that we were unable to account for natural changes in work-related impairment or the effect of missing data. The real-world context of this study, however, is seen as a primary strength. Second, analyses focused on only a subset of users who completed at least half the program content. This approach, however, may have overestimated the impact of Digital+ on work-related impairment for users who completed fewer than four modules. This limitation was mitigated to some extent by a relatively conservative analytic approach that included those who did not complete all program content. Third, work-related impairment was measured using a single item, in order to enhance usability and reduce user burden. Other well-validated measures of functional impairment, including work-related impairment exist, and may offer a more comprehensive assessment of impairment. Relatedly, we did not collect information on current employment status. This information could help further contextualize user's ratings of work-related impairment. Additionally, although individuals' perceptions of impairment are critical to their lived experience and overall functioning, more objective assessments of functioning at work, including absenteeism and presenteeism may add additional pertinent information. Future research should include these measures to assess not only the association between user-reported impairment and these more objective metrics, but also the impact of these interventions on work productivity. Finally, future research should examine the enduring impact of digital interventions on functioning at work beyond the intervention period.

Conclusions

Work-related impairment was prevalent among users, and there were significant improvements in function at work over the course of a guided digital intervention for depression and anxiety. Given the high societal and individual burden associated with depression and anxiety, it is critical to evaluate the impact of digital interventions on functioning, particularly at work. Digital

interventions for depression and anxiety, like Digital+, have potential to improve work-related impairment. Assessing impairment in combination with symptom severity throughout the program may add important clinical information allowing for a more thorough evaluation of the effectiveness of these tools.

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An Innovative Technology-Enabled Behavioral Health Solution to Improve Employee Productivity: Outcomes from a National Real-World Population

Behavioral Therapy for U.S. Workers with Comorbid Medical and Mental Health Conditions

Introduction

There is a pressing need for behavioral health solutions to meet the significant economic and health burden of comorbid mental and medical illness among adults in the United States (U.S.) workforce. Depression and other mental health issues affect nearly 1 in 5 adults in U.S., commonly co-occur with chronic medical conditions, and together increase the likelihood of absenteeism, presenteeism, and overall reduced work productivity (1-5). The incremental cost burden attributable to depression among U.S. employees amounts to nearly $210 billion annually owing equally both to avoidable medical expenditures and to the cost of lost work productivity (2). Moreover, as with the broader U.S. population, many employees with depression go undiagnosed and untreated (6). These data underscore the tremendous opportunity and need for innovative solutions to identify, engage, and treat individuals with depression and medical conditions in the workforce in order to reduce the personal impact on employees and reduce the cost burden for individuals, employers and the health care system.

Innovative Solutions: Proactive Tele-Behavioral Therapy

For individuals with medical conditions, behavioral therapy is an effective treatment option for depression and is associated with improved adherence to prescribed medical and lifestyle therapies (7). However, numerous barriers limit psychotherapy treatment initiation in working populations; structural barriers (e.g. lack of time) and attitudinal barriers (e.g. stigma), as well as lack of awareness treatment is needed, are part of a long list of reasons why individuals who may benefit do not access behavioral healthcare (8, 9).

The incremental cost burden to US employers attributed to depression

$210 BILLION

High quality, proactive behavioral therapy delivered remotely by telephone or video may dramatically increase access to therapy for employees experiencing these obstacles. Behavioral therapy delivered by telephone or video has been demonstrated to be effective and face-to-face therapy for the treatment of depression (10-13) and has also been shown effective to improve work productivity in employed populations (14, 15).

AbleTo: Reaching Employees with Medical and Behavioral Health Issues

AbleTo is a national tech-enabled behavioral health care provider that offers condition-specific behavioral health services via telephone or secure video to patients across the United States. AbleTo programs are tailored to meet the behavioral health needs of patients with specific common medical conditions such as cardiac disease, diabetes, and chronic pain (16-18).

In collaboration with employers and health plan partners, AbleTo identifies individuals with pre-existing medical conditions who may be at risk for behavioral health issues. AbleTo engagement specialists proactively outreach to eligible individuals to offer enrollment into the program. Examples of eligible individuals include those:

- living with a complex medical condition (e.g. heart disease, diabetes, chronic pain, etc.), or
- experiencing a recent life event (e.g. birth of a child, bereavement, serving as caregiver for an adult or child, etc.).

Participants can also be directly referred by a medical provider in the community or at a health plan, behavioral health specialists, or employee assistance programs.

AbleTo Programs

AbleTo's technology-enabled behavioral health programs are designed to address depression, anxiety, and/or stress symptoms through behavioral strategies and positive lifestyle changes, enabling participants to better manage their medical conditions. The programs use a common set of evidence-based approaches including cognitive behavioral therapy; acceptance and commitment therapy; distress tolerance; mindfulness; and motivational interviewing. Programs are developed by the AbleTo clinical team, in collaboration with an interdisciplinary advisory group of physicians, psychologists and clinical social workers. The protocols for each program are standardized, but each program experience is tailored to each participant's personal and clinical needs and goals.

The programs include an initial consultation followed by 15 sessions completed within an approximately eight-week period, all delivered remotely by telephone or video. The initial consultation includes a mental health and psychosocial interview with psychiatric and medical history completed by a LCSW. This initial consultation is followed by eight therapy sessions with an LCSW and seven coaching sessions with a behavioral coach. All sessions are approximately 45 minutes long. During the program period, the LCSW and coach participate in case conferences under the guidance of the clinical supervisor to review participant progress. The clinical supervisor performs weekly review of session notes to ensure high quality standards and adherence to the treatment protocol.

Baseline Psychological Symptoms and Association with Work Productivity

Program participants complete standardized assessments at the initial consultation and at the graduation session. Psychological symptoms including depression, anxiety and stress symptoms are measured by the LCSW using the Depression Anxiety Stress Scales 21 (DASS-21), which has been validated and utilized in diverse clinical and community samples (19-23). Work productivity and activity impairment are assessed using the Work Productivity and Activity Impairment General Health Questionnaire (WPAI; 24, 25).

In a de-identified aggregated program evaluation sample of 737 consecutive employed participants with medical conditions who participated in AbleTo's cardiac, diabetes, chronic pain, or major depression program, the prevalence of work productivity impairment among participants entering the program was substantial (Table 1). At the time of enrollment, over 22% of the sample presented with absenteeism (work time missed due to one's health problem; n=168), and 53% presented with presenteeism (impairment while working due to one's health problem; n=393); more than 58% of participants had some form of work impairment (a combination of absenteeism and presenteeism; n=429) and 62% of participants were experiencing activity impairment (impairment in usual daily activities due to one's health problem; n=458).

Table 1. Baseline Characteristics among Employed AbleTo Program Graduates Overall and by Program Type

Demographics	All (N = 737)	Diabetes (N = 344)	General Depression (N = 141)	Cardiac (N = 131)	Chronic Pain (N = 121)	p
Age, years [mean (SD); range]	52.9 (8.9); [22-81]	54.6 (6.7); [23-66]	48.4 (10.5); [22-65]	56.4 (6.4); [28-77]	49.5 (11.5); [22-81]	<.0001
Male [n (%)]	318 (43%)	156 (45%)	47 (33%)	84 (64%)	31 (26%)	<.0001
Region						
Mid America [n (%)]	86 (12%)	51 (15%)	10 (7%)	13 (10%)	12 (10%)	.0739
North East [n (%)]	226 (31%)	91 (27%)	35 (25%)	63 (48%)	37 (31%)	<.0001
South East [n (%)]	160 (22%)	81 (24%)	36 (26%)	20 (15%)	23 (19%)	.1320
West [n (%)]	265 (36%)	121 (35%)	60 (43%)	35 (27%)	49 (41%)	.0336
Past Medical History						
Diabetes	438 (59%)	325 (94%)[3]	57 (40%)	41 (31%)	15 (12%)	<.0001
Cardiac	189 (26%)	58 (17%)	18 (13%)	107 (82%)[4]	6 (5%)	<.0001
Past Psychiatric History						
Depression	348 (47%)	141 (41%)	102 (72%)	47 (36%)	58 (48%)	<.0001
Anxiety	270 (37%)	101 (30%)	69 (49%)	49 (37%)	51 (42%)	.0003
Baseline DASS-21 Scores[1]						
Elevated Depression [n (%)]	255 (35%)	87 (25%)	87 (62%)	41 (31%)	40 (33%)	<.0001
Elevated Anxiety [n (%)]	274 (37%)	98 (28%)	71 (50%)	61 (47%)	44 (36%)	<.0001
Elevated Stress [n (%)]	275 (37%)	102 (30%)	83 (59%)	44 (34%)	46 (38%)	<.0001
Baseline Work Productivity[2]						
Absenteeism	168 (23%)	49 (14%)	34 (24%)	53 (40%)	32 (26%)	<.0001
Presentiment	393 (53%)	141 (41%)	95 (67%)	79 (60%)	78 (64%)	<.0001
Overall Work Impairment	429 (58%)	152 (44%)	105 (74%)	89 (68%)	83 (69%)	<.0001
Activity Impairment	458 (62%)	162 (47%)	110 (78%)	85 (65%)	101 (83%)	<.0001

[1] Elevated depression score is defined as >9; elevated anxiety is defined as >7; elevated stress score is defined as >14.
[2] Work productivity impairment is defined as absenteeism, presenteeism, overall work impairment or activity impairment score >0%.
[3] N=19 participants in the diabetes program with self-reported 'pre-diabetes.'
[4] N=24 participants in the cardiac program with non-cardiac cardiovascular disease.

And, work productivity and activity impairment was significantly associated with elevated depression, anxiety and/or stress symptoms at the time of program entry (Table 2).

Table 2. Odds of Work Productivity and Activity Impairment Among Participants with Elevated Depression, Anxiety, or Stress Symptoms at Baseline

	Work Productivity and Activity Impairment[1]			
	Absenteeism OR (95% CI)	Presenteeism OR (95% CI)	Overall Work Impairment OR (95% CI)	Activity Impairment OR (95% CI)
Psychological Symptoms[2]				
Elevated Depression Score	1.7 (1.2-2.5)	2.6 (1.9-3.6)	3.3 (2.4-4.7)	3.2 (2.3-4.5)
Elevated Anxiety Score	1.6 (1.1-2.3)	3.1 (2.2-4.2)	3.2 (2.3-4.4)	2.6 (1.9-3.6)
Elevated Stress Score	1.3 (0.9-1.8)	2.3 (1.7-3.2)	2.3 (1.6-3.1)	2.2 (1.6-3.0)

[1] As assessed by Work Productivity and Activity Impairment (WPAI) survey. Absenteeism: work time missed > 0%; presenteeism: percent impairment while working >0; any work impairment: percent work impairment overall > 0%; activity impairment: percent activity impairment > 0%.
[2] Elevated depression is defined as DASS-21 score >9; elevated anxiety is defined as DASS-21 score >7; elevated stress is defined as DASS-21 score >14.

Participants with elevated depression symptom scores were significantly more likely to present with absenteeism (OR=1.7; 95%CI =1.2-2.5), presenteeism (OR=2.6; 95%CI = 1.9-3.6), and/or activity impairment (OR=3.2; 95%CI =2.2-4.5) versus those without elevated scores. Similar associations were observed between elevated anxiety and stress scores and work/activity impairment at baseline. These associations between elevated depression symptoms and work impairment are consistent with prior research in other employee samples (26-28).

Changes in Work Impairment and Psychological Symptoms During Treatment

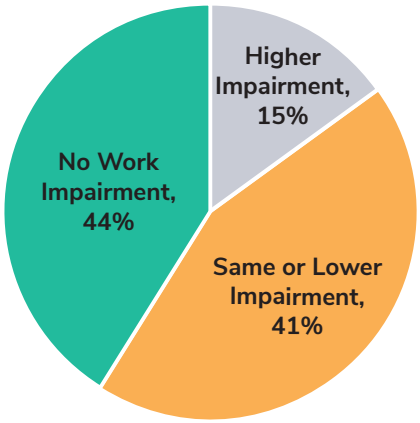
AbleTo program participants in the evaluation sample experienced significant improvements in work and activity impairment and psychological symptoms during the 8-week program period (Table 3).

Table 3. Change in Work Productivity and Activity Impairment among Participants with Baseline Impairment

	Baseline	Graduation	Individual Change	
Work Productivity and Activity Impairment[1]	Mean (SD)	Mean (SD)	Absolute Mean (SD)	Percent
Absenteeism (%)	55.8 (40.2)	19.4 (36.1)	-36.4 (43.5)	-55.0%
Presenteeism (%)	48.0 (29.9)	22.1 (29.4)	-25.8 (33.5)	-43.2%
Overall Work Impairment (%)	50.7 (31.2)	23.9 (30.7)	-26.8 (35.6)	-35.4%
Activity Impairment (%)	51.4 (25.3)	22.8 (25.1)	-28.6 (30.2)	-46.9%

[1] Absenteeism n=168; Presenteeism n=393; Overall Work Impairment N=429; Activity Impairment N=458.

Figure 1



More than 85% of participants with baseline impairment experienced improved work productivity at 8-weeks.

Absolute reduction in absenteeism, presenteeism, and activity impairment scores across all programs was greater than 25%; this represented a -55%, -43%, and -47% mean within-person percent reduction for each metric respectively. More than 85% of participants with work productivity impairment at baseline, experienced reduced overall impairment during the program period, with almost half (44%) returning to zero overall work impairment at program end (Figure 1).

Participants who entered the program with elevated psychological symptoms experienced significant reductions in depression, anxiety, and stress scores during the program period (Table 4).

Table 4. Mean Individual Change in DASS-21 Scores among Participants with Elevated Baseline Scores

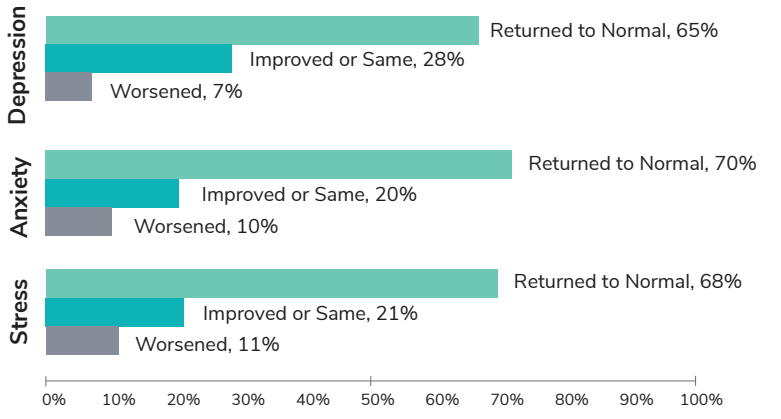
DASS-21 Domain Symptoms[1]	Baseline Score Mean (SD)	Graduation Score Mean (SD)	Individual Change Absolute Mean (SD)	Individual Change Percent
Depression	18.7 (7.7)	7.8 (7.3)	-10.9 (8.3)	-57.4%
Anxiety	14.4 (6.1)	7.1 (6.7)	-7.3 (7.0)	-49.6%
Stress	22.7 (6.0)	12.8 (8.0)	-10.0 (8.9)	-42.2%

[1] Elevated depression score at baseline n=255; elevated anxiety score at baseline n=274; elevated stress score at baseline n=275.

Mean individual improvement in depression symptom severity was 57%; anxiety and stress scores improved by 50% and 42% respectively. More than 90% of participants with elevated symptom scores improved or returned to normal in one or more DASS-21 domain during the program (Figure 2).

More than 90% of symptomatic participants improved or returned to normal by the end of the program.

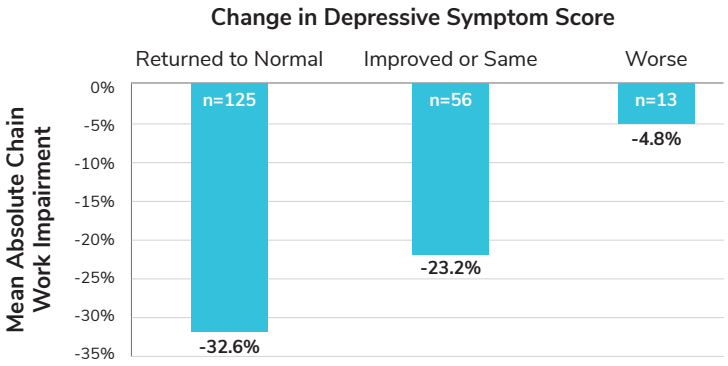
Figure 2



Participants with larger improvements in depression symptoms experienced larger improvements in overall work productivity (p=.01; Figure 3).

Improvements in depression symptoms were associated with improvements in work productivity.

Figure 3



Evaluation Summary and Insights

- This real world example illustrates the potential for a tech-enabled behavioral therapy program to improve psychological and productivity outcomes among employees living and working with chronic medical conditions.
- Participants with depression, anxiety and stress symptoms were two-fold more likely than their asymptomatic counterparts have work productivity impairment at baseline.
- Significant improvements in work productivity and depression, anxiety, and stress symptoms were observed among the majority of program participants who entered the program with impairment.
- Improvements in depression symptoms during the program period were associated with concurrent improvements in work impairment.

AbleTo programs improved depression, anxiety and stress symptoms by 57%, 50% and 42% respectively.

Summary

The past twenty-five years has seen a dramatic increase in recognition of the relation among behavioral health, medical outcomes, and work productivity (2-7, 29-31). Despite the increase in awareness, challenges persist regarding access to high-quality and evidence-based behavioral health care. This is especially true for individuals living and working with medical conditions who may come up against time, logistical, or physical barriers to behavioral health care. Although studies have demonstrated effectiveness of telephone interventions to improve depression and work productivity outcomes (15), few solutions have been developed to address the issue at scale and among the millions of employees with comorbid mental health and medical conditions.

AbleTo has a unique opportunity to help employers and health plans who seek innovative solutions to tackle barriers behavioral health among their employees. Almost one in five adults experience mental health condition in a given year, and the rate is even higher among those living with chronic health conditions (1). It is well recognized that both depression and work productivity impairment impact costs for both employees and employers (4). Conversely, the employer return on investment for treating depression among employees stands to be significant (32). Proactive identification and engagement of employees to offer evidence-based programs is an innovative mechanism whereby many living with medical and mental health issues may be given an opportunity to overcome barriers to behavioral health not previously available to them.

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About AbleTo

AbleTo was founded in 2008 to improve patient outcomes and lower costs by providing treatment that integrates behavioral and medical health care. Our structured therapy programs strengthen medical recovery and self-care among members with complex clinical needs. AbleTo analytics, coupled with our highly-trained engagement team, identify members with unmet, often undiagnosed, behavioral health needs. Our proprietary telehealth platform then connects our members and care teams with our licensed providers who deliver weekly therapy sessions by phone or video. AbleTo programs have been shown to clinically improve both behavioral health and medical outcomes while lowering overall spending for high-cost, high-risk members.

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Work-related burnout was more prevalent among Digital+ users during COVID-19 versus prior

Distribution of work-related burnout among healthcare system employees using Digital+ pre COVID-19 cohort versus COVID-19 cohort

	Pre COVID-19*	COVID-19**
Copenhagen Burnout Inventory Score Categories		
No/Low Burnout (<=49 Points)	**49%**	**37%**
Moderate Burnout (50-74 Points)	**36%**	**39%**
High Burnout (≥75 Points)	**15%**	**24%**

*Pre COVID-19 Cohort: Digital+ M1A1 completers from 1/01/2019-03/15/2020
**COVID-19 Cohort: Digital+ M1A1 completers from 3/16/2020-12/31/2020

Key Takeaways

2 in 3

Digital+ users reported work-related burnout during COVID-19

For **1 in 4,** user burnout was **HIGH**

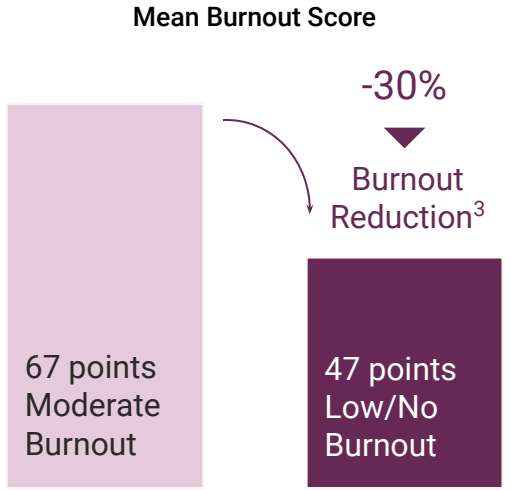
AbleTo

Case study on workplace burnout

AbleTo partnered with a large health system to measure impact on employee burnout

Burnout results from unsuccessfully managed chronic workplace stress[1], driving adverse health and workplace outcomes:

- Feelings of energy depletion or exhaustion
- Increased work-related mental distance or negativism
- Depression
- Absenteeism
- Reduced Productivity
- Employee Turnover
- Lost investment in recruiting, training and expertise



AbleTo added a standardized, validated survey (The Copenhagen Burnout Inventory[2]) to measure work-related burnout among health system employees who utilized Digital+, AbleTo's 8-week coached digital program

1. World Health Organization. Burnout as an occupational phenomenon; International Classification of Diseases. Website: https://www.who.int/mental_health/evidence/burn-out/en/. Accessed 3/12/20
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3. The CBI score is calculated by taking the average of the individual item scores. Data represent observed changes in symptom scores among utilizers enrolled 1/1/19 - 12/31/20 who completed >= 3 Digital+ modules and had an elevated baseline CBI score (>=50 pts).

BARRIERS TO BEHAVIORAL HEALTH CARE

Consumer Insights Reveal Low Engagement and Unmet Needs Persist

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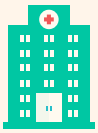
The health care system has witnessed a dramatic shift in the appreciation of the integral role that behavioral health plays in driving overall health outcomes and cost. Common mental health conditions such as depression and anxiety are prevalent among working-age adults and associated with worse physical health and impaired work productivity.[1, 2] Patients and providers alike are recognizing the tight interplay between emotional and physical health which for far too long been have been addressed using a siloed approach. As a result, tackling behavioral health is increasingly seen as a top strategic priority for health plans, hospital systems, and employers. The health care industry is now being called on to develop systems that incentivize evidence-based, integrated, and cost-effective behavioral health treatment.[3]

THE COST OF BEHAVIORAL HEALTH CONDITIONS[1]

From higher medical resource utilization to lost working days, the costs associated with major depressive disorder alone are significant



DIRECT HEALTH CARE COSTS

$293 billion

WORKPLACE COSTS

$193.2 billion

Despite these advances, significant gaps remain. National data indicate only modest increases in the use of mental health services in the past decade.[4] Half of adults in the United States (U.S.) who are diagnosed with common mental health conditions still do not receive treatment, and many never get diagnosed at all.[5, 6] As might be expected, individuals with health insurance coverage are more likely to utilize mental health services than those with no insurance, though cost remains a notable barrier, especially for those with private insurance.[7] Ten years after the Mental Health Parity and Addiction Equity Act was signed into law, the health care industry continues to struggle to meet modern day challenges of access and barriers to mental health care.

To better understand contemporary behavioral health treatment patterns and barriers to care among working-age adults, AbleTo, Inc. conducted a survey of a nationally drawn sample of U.S. adults with employer-sponsored health insurance and clinically significant behavioral health symptoms. The survey insights mapped to three key themes: 1) having employer-sponsored health insurance may not be sufficient to guarantee treatment for behavioral health conditions, 2) individuals with medical conditions frequently go undiagnosed and untreated for behavioral health comorbidities, and 3) concerns about cost and stigma remain the major barriers to seeking mental health treatment. These findings indicate that there is substantially more work to be done to open up pathways into mental health assessment and care.

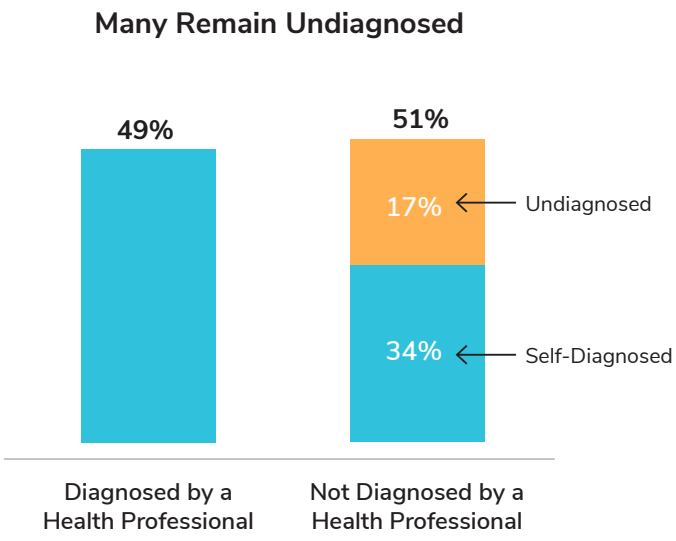
INSURANCE COVERAGE ALONE IS NOT ENOUGH

Having access to employer-sponsored health insurance does not ensure diagnosis or treatment of behavioral health conditions. By design, all survey respondents included in the analysis had elevated DASS-

ABOUT THE SURVEY

- Online survey conducted between December 1, 2016 and January 30, 2017
- A sample population of men and women aged 25 and older
- All respondents were members of an employer-sponsored health insurance plan
- Standardized survey questions were utilized to ascertain participant characteristics, psychiatric and medical history, current behavioral health symptoms, and current behavioral health care utilization and barriers to care
- Screening for behavioral health conditions comprised assessment for clinically elevated depression, anxiety, and/or stress symptoms as measured by the Depression Anxiety Stress Scales 21[8]
- 665 (23%) had elevated symptom scores and were included in the sample
- Almost two-thirds of respondents were under age 50, and more than half were living with one or more chronic medical condition

21 scores indicating active behavioral health symptoms at the time of the survey. Overall, only about half (49%) of respondents in this symptomatic sample reported that they had been previously told by a doctor or other health professional that they had anxiety, depression, or stress. Among those who had not formally been diagnosed, more than two out of three indicated that they considered themselves as having one or more behavioral health condition. Interestingly, a meaningful portion (17%) had neither been diagnosed by a professional nor considered themselves to have depression, anxiety, or stress. Taken together, these findings indicate that a substantial proportion of symptomatic adults remain undiagnosed, even as many recognize themselves that they have a behavioral health issue. A reasonable proportion of symptomatic patients remained undiagnosed and had no recognition of an underlying behavioral health issue.



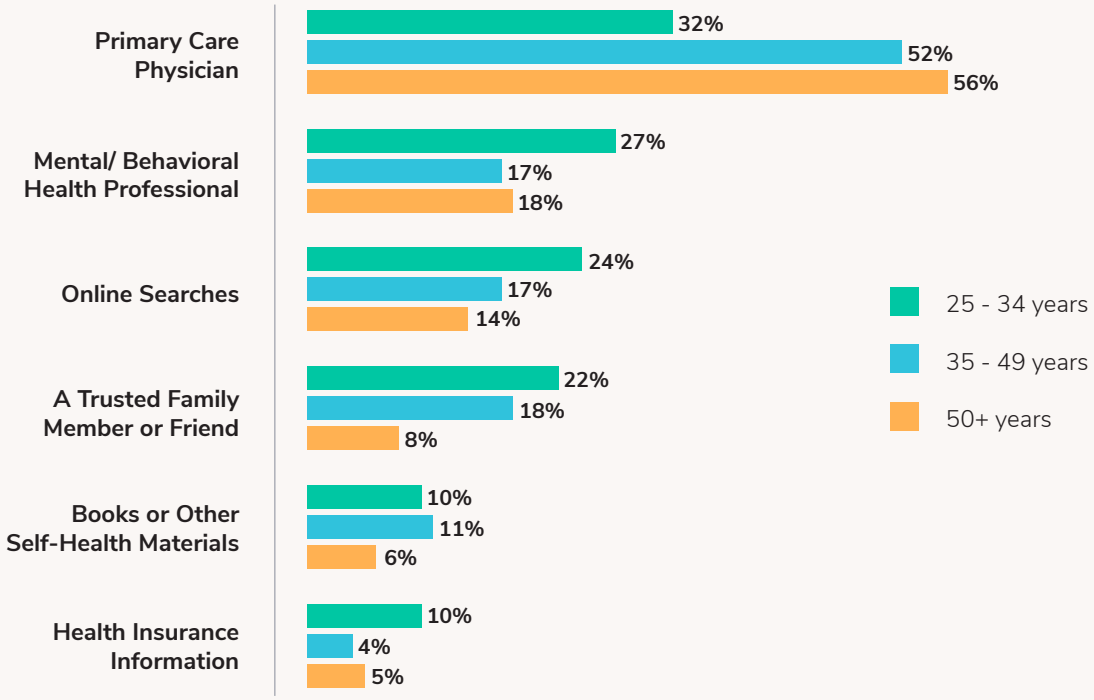
Even fewer individuals in this symptomatic sample reported that they were currently receiving treatment for a behavioral health condition (26%); those who were previously diagnosed with a behavioral health condition were far more likely to report treatment than those not previously diagnosed, but close to half reported no current treatment at all (52% vs. 2%; p<.001).

This low treatment rate is consistent with national data showing approximately 43.1% of adults with any mental illness received treatment in the past year, and that this number may be lower when the sample is limited to adults with private health insurance.[9, 10] The relatively higher treatment rate among diagnosed individuals seen in this sample compared to national statistics could be because the survey specifically queried about anxiety, depression, or stress diagnosis (versus any mental health diagnosis), or the fact that the sample was actively symptomatic. Among those who were diagnosed, the strikingly low treatment rate indicates a tremendous opportunity to improve identification of individuals at risk. Taken together, these findings suggest that there remains a significant gap in diagnosis and treatment of behavioral health issues in an at-risk population despite having employer-sponsored health insurance.

PHYSICAL HEALTH AND BEHAVIORAL HEALTH REMAIN SILOED

Not surprisingly, survey respondents with greater prevalence of medical issues were more likely to report being previously diagnosed with a behavioral health condition though more than half still remained

Where Respondents Would Go First if They Were Seeking Help for Anxiety, Depression, or Stress By Age Group*



* = *Respondents could select >1 response*

undiagnosed. And for those who had been officially diagnosed with depression, anxiety or stress by a medical professional, two thirds were still not receiving any treatment at all.

The survey data corroborated existing knowledge about commonly used avenues for seeking help with behavioral health concerns such as via primary care providers, mental/behavioral health professionals, and online resources.[11] Primary care physicians remained the most common resource where an individual might go first if he or she was seeking help, though still only about half of individuals responded they would first seek help via a primary care physician. Furthermore, there were clear generational differences with younger individuals age 25-34 years significantly less likely to seek diagnosis and treatment first through a primary care physician compared with survey respondents age 50 years or more (32% versus 56%), and more likely than older respondents to seek information from online resources or from trusted friends and family.

This suggests that a 'one-size-fits-all' approach to engagement and treatment may not work and that there is an opportunity to increase awareness through a diversified approach to helping individuals get the care they need when they need it. Over the past several years, there has been an influx of innovative and promising solutions to identify, engage, and treat individuals with medical and behavioral health conditions. Employers and health plans are increasingly aware of the need to address behavioral health as part of overall health. As a result, many are increasing efforts to inform employees and members about the importance of addressing behavioral health and are making a broader suite of resources available to employees, adopting technology-enabled solutions to identify individuals at risk and engage them in high-quality virtual behavioral health care.[12]

COST AND STIGMA REMAIN PRIMARY BARRIERS TO MENTAL HEALTH TREATMENT

Symptomatic individuals may not actively seek or receive diagnosis and treatment for behavioral health conditions for a multitude of reasons. Our survey showed that cost and stigma remain the primary barriers to seeking help for behavioral health conditions, in addition to the fact that individuals may not even recognize the need to seek care. More than one in four respondents (27%) listed worry that treatment would be too expensive as one of the top three barriers to treatment seeking. This might seem counterintuitive given that all respondents had employer-provided health insurance and these individuals are typically known to have higher family income level versus those with public or no insurance.[13] This finding is consistent with National Comorbidity Survey-Replication (NCS-R) sample data where financial concerns were the most frequently endorsed structural barrier cited for not seeking treatment. These results are also consistent with research showing a rise in cost barriers to mental health care among individuals with private insurance.[7, 14] Survey respondents confirm that perceived financial barriers to treatment seeking remain present among insured employees.

A second top-cited barrier to seeking mental health treatment included concerns about stigma or the fear of being labeled. Prevalence of this well-established barrier to mental health treatment in a contemporary

Why Consumers Aren't Seeking Treatment

Perceived Barriers	% Selected*
Treatment is too expensive (inability to pay)	27%
The stigma or society's attitude toward mental health	25%
Fear of being labeled	25%
Unsure if condition is severe enough to need treatment	25%
The stigma of thinking something is wrong with me	24%
Fear of having to take medication	20%
No time to seek help, go to counseling, etc.	18%
Unsure if therapy is covered by health insurance	17%
Fear of revealing personal problems to doctor or therapist	16%
Most treatments aren't very effective	13%

* *Percentage represents percent of 665 respondents who listed this barrier as one of the top 3 barriers to treatment seeking.*

employer-insured sample further underscores a place for increased education about common mental health symptoms and indications for treatment as well as an improved culture around mental health. Stigma is a complex and multifaceted issue.[15] As a result, the burden of overcoming the barrier of stigma falls not only on the person with behavioral health needs, but also on society more broadly. There is a real opportunity for all stakeholders to come together to improve behavioral health literacy, educate about the high prevalence of behavioral health conditions, and the negative impact of not sufficiently addressing behavioral health needs for employees and others.

FOCUSING ON THE OPPORTUNITIES TO IMPROVE ACCESS

These survey results underscore the ongoing and significant challenges we face including the under-identification, under-treatment and multiple perceived barriers to behavioral health care. Data from this sample highlight the opportunity to do better to improve access to care, integrate physical and mental health, and focus on overcoming barriers that prevent individuals from seeking help when they need it most.

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ABOUT

AbleTo, Inc. is a market leader in providing technology-enabled behavioral health solutions. AbleTo has been treating patients for six years and improves patient outcomes and lowers costs by providing treatment that integrates behavioral and medical health care. AbleTo's structured therapy programs strengthen medical recovery and self-care among members with chronic or complex clinical needs. AbleTo analytics, coupled with our multi-channel engagement platform, identify and engage members with unmet, often undiagnosed, behavioral health needs. A proprietary platform connects individuals and their care teams with AbleTo licensed providers nationwide who deliver weekly sessions by phone or video supported by an integrated digital experience. AbleTo programs are clinically proven to improve both behavioral health and medical outcomes while lowering overall spending for higher-cost, higher-risk members. AbleTo's investors include .406 Ventures, Sandbox Industries, HLM Venture Partners, Horizon Healthcare Services, Inc., Bain Capital Ventures, and Aetna Ventures. Follow AbleTo on LinkedIn and Twitter (@AbleTo_Health).

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TELEBEHAVIORAL HEALTH CARE

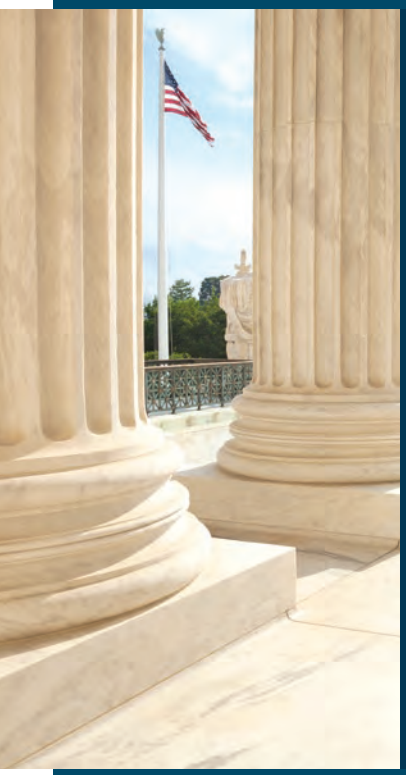
A Solution to Improve Cost, Access, and Quality of Care

ABHW | Able To

01

INTRODUCTION

Untreated behavioral health conditions, including both mental health and substance use disorders (SUDs), are a major public health concern. Over 44 million United States (U.S.) adults have a mental illness, and fewer than 50 percent receive treatment (1–5); treatment rates are as low as 1 in 10 among the almost 20 million adults diagnosed with SUDs each year (3). Furthermore, national prevalence statistics are known to grossly underestimate the true number of individuals with behavioral health conditions; for every individual diagnosed, one more may go undiagnosed and subsequently untreated (6).



44

MILLION

adults in the United States have a mental illness

FEWER THAN

50%

receive treatment for mental illness

The aim of this report is to describe the multidimensional value of telebehavioral health care.

Untreated behavioral health conditions are costly. Beyond the recognized cost of human suffering, behavioral health conditions also result in avoidable overall medical expenditures, lost productivity, and criminal justice costs. While a significant part of this burden is carried by those with severe mental illness, an additional burden is carried by those with chronic medical conditions who experience two-to three-fold higher risk for depression versus their peers, and face health-related limitations that further challenge access to behavioral health care (7–10). Among working adults age 18–64 years, this translates into measurably higher medical utilization and expenditures, as well as disability and impaired work productivity estimated to total more than $210 billion annually for major depressive disorder alone (11). Among older adults, such as Medicare beneficiaries aged 65 and older, those with depression have almost double the health care costs compared to those without depression (12). These higher medical costs are primarily driven by the cost of treating associated medical comorbidities and not by mental health care costs (11, 12), suggesting there is an opportunity to drive down total health care costs by treating behavioral health conditions.

Over the past decade, telebehavioral health care has gained recognition as a solution to enhance access to quality behavioral health care in the U.S. The aim of this report is to describe the multidimensional value of telebehavioral health care. In this report, telebehavioral health care is defined as evidence-based behavioral health care administered over the telephone or via secure video by a licensed or otherwise qualified practitioner. There are many other technology-enabled behavioral health interventions including computer or internet-based programs, mobile phone applications (apps), and automated telephone services that are not included in this review. Indeed, telebehavioral health care is a broad concept encompassing a heterogeneous collection of treatment modalities, providers, and clinical conditions. The scope of this report has been limited to telebehavioral health care as defined above in order to specifically describe the value of providing evidence-based telebehavioral health care in direct comparison to traditional face-to-face delivery.

BEHAVIORAL HEALTH CONDITIONS INCLUDED IN THIS REPORT

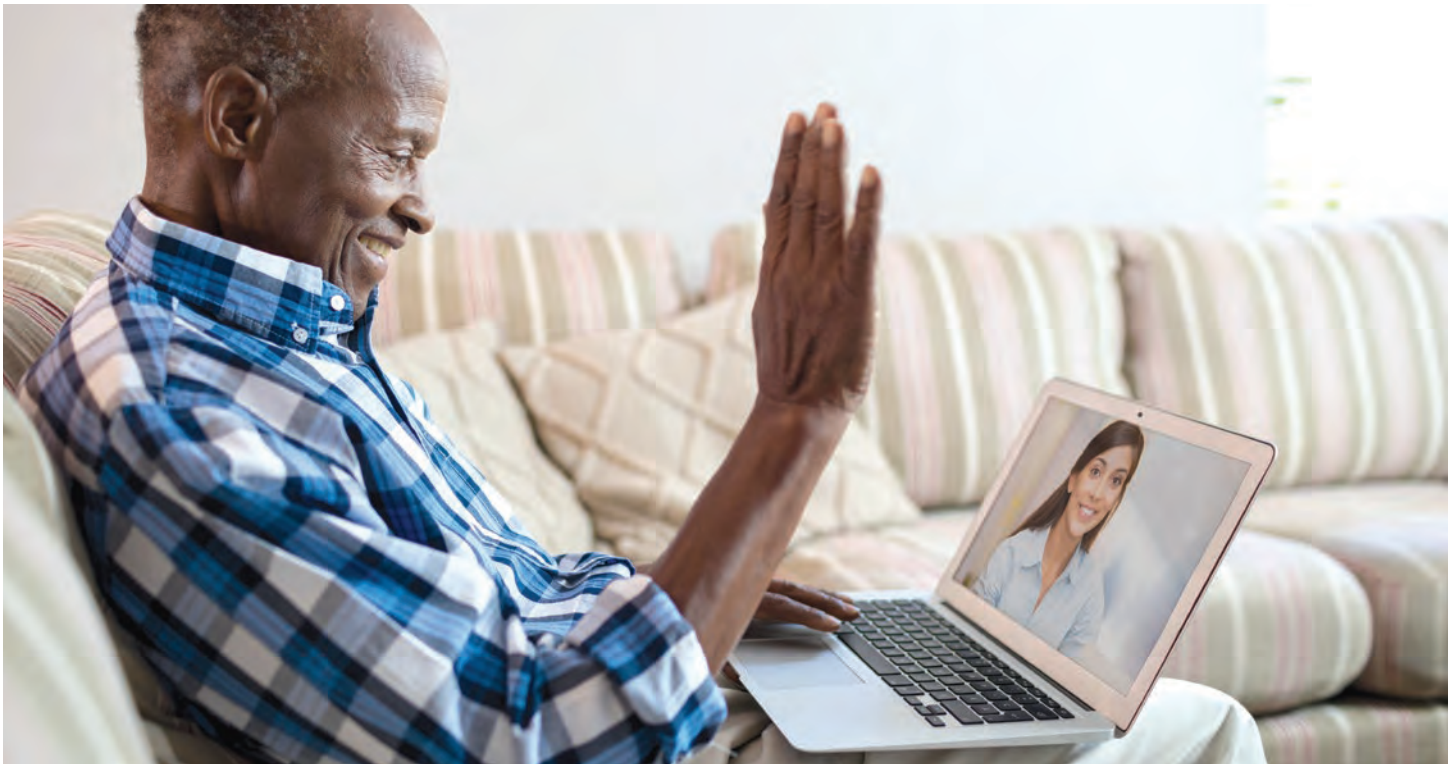
A wide spectrum of behavioral health conditions merit treatment, ranging from mild presentations of depression and anxiety to severe mental illnesses such as schizophrenia or bipolar disorder. Collectively, this is a group too broad to ensure adequate coverage of each and every condition in a single concise report. As such, this review focuses on those behavioral health conditions that are clinically amenable to telehealth care delivery

with the evidence summarized herein limited to common conditions formally studied in the context of evidence-based telebehavioral health care.

ADDITIONAL SPECIFICATIONS

The purpose of this report is to describe the value of telehealth delivery of behavioral health care. We recognize that value can be defined differently by different stakeholders, including consumers, providers, payers, policy makers, and others. Therefore, we aim to review varying dimensions of value including, but not limited to, cost-effectiveness, quality of care, and improved access to care.

In order to most directly translate this value for multiple stakeholders, we drew on academic, government, and industry data specifically collected in the U.S. health care system (with recognition that the value of telebehavioral health care has been demonstrated internationally as well). Additionally, this report will focus solely on telebehavioral health care for adults aged 18 and above. While there is value in telebehavioral health care for individuals under the age of 18 years, the treatment of children and adolescents with telebehavioral health care is more complex and has additional factors that are different from adult treatments and therefore merit a stand-alone report. Finally, quality behavioral health care delivered via telehealth as described in this report should meet the same standards as face-to-face delivery of the same care including that it is evidence-based, safe, effective, person-centered, efficient, and equitable (13–15).



02

CLINICAL EFFICACY OF TELEBEHAVIORAL HEALTH CARE

Evidence-based behavioral health care provided over telephone or secure video has been demonstrated effective and non-inferior to face-to-face care for a variety of common behavioral health conditions among adults of all ages (16–19).

For example, a 2012 randomized controlled clinical trial conducted by Mohr et al. documented clinically significant and similar improvements in depressive symptoms among participants receiving telephone administered cognitive behavioral therapy, versus their counterparts receiving the same intervention face-to-face (27 percent remission at 18-weeks; 16). Most of the research in this area has utilized cognitive behavioral therapy, or other evidence-based psychotherapy approaches, as the intervention (16–25).

Phone or video delivery has been demonstrated efficacious for multiple behavioral health and related conditions, including but not limited to:

- Major depressive disorder (16, 17)
- Generalized anxiety disorder (18)
- Posttraumatic stress disorder (22, 23)

Randomized controlled trials of telebehavioral health care interventions have documented clinically meaningful improvements in depressive symptoms (e.g. depressive symptom response) and anxiety symptoms (e.g. clinically reduced anxiety symptoms and worry) (16–18). When telebehavioral health interventions are utilized in populations with medical comorbidities (e.g., cardiovascular disease, HIV/AIDS, or multiple sclerosis), clinical benefit has also been demonstrated for additional outcomes including medication adherence and quality of life (26–30).

Telebehavioral health care also offers great potential to enhance treatment and recovery for individuals with SUDs (31–37). Several studies of telebehavioral health care for addiction, as well of the treatment of mental health conditions among individuals with SUDs, have found no statistically significant difference in the treatment results or patient satisfaction with care provided in person versus by telephone or video (32–35). Examples of treatment settings where utility of teledelivery of care for SUDs has been apparent include outpatient follow-up and medication assisted therapy (34, 36, 37).

03

COST-EFFECTIVENESS OF TELEBEHAVIORAL HEALTH CARE

Telehealth is increasingly viewed as a cost-effective modality for the delivery of care across multiple clinical condition areas. For behavioral health care, remote delivery of easily accessible treatment options may avoid higher cost urgent or emergent mental health care services and also avoid unnecessary medical utilization by addressing behavioral health in individuals with comorbid medical conditions. Moreover, multiple studies have demonstrated the impact of depression on impaired work productivity, and treatment of depression may reduce cost attributable to lost productivity. As with other chronic conditions, early identification and treatment of behavioral health issues can prevent higher cost, severe, and debilitating manifestations of mental illness in the future.

TELEBEHAVIORAL HEALTH CARE AND HEALTH CARE COSTS

Assessment of the impact of telehealth on health care costs should include both the cost of telehealth services themselves and the impact on reducing avoidable and incremental expenditures arising from unaddressed behavioral and medical health issues. Telebehavioral health care need not cost more than on-site services (38, 39). As one example, a recent study among U.S. Veterans with depression treated via telehealth demonstrated that the trajectory of health care costs was not significantly different versus in-person delivery (39). In fact, an original goal of telehealth was to offer easy-to-access and lower cost alternatives to higher cost care environments (such as in an emergency department).

When the focus is on future cost avoidance, greater access and greater utilization of high value clinical behavioral health services—whether in person or via telehealth—has the potential to significantly reduce medical expenditures. The opportunity for telebehavioral health programs to save money for the health care system has been most evident for individuals with medical and psychiatric comorbidities (24). For example, telebehavioral health for individuals with comorbid behavioral health and/or chronic health conditions has been shown to reduce medical and psychiatric hospitalizations by as much as 25–30 percent and promote overall medical cost savings (22, 29, 40). In the collaborative care setting, inclusion of telebehavioral health providers has been shown to be cost-effective for primary care and post-operative care as well (41, 42).

TELEBEHAVIORAL HEALTH CARE AND WORKPLACE COSTS

Working adults comprise another consumer group where telebehavioral health care yields a cost benefit (43, 44). In an intervention described by Wang et al that included telephone-delivered coaching, care coordination, and cognitive behavioral therapy for employed individuals with depression resulted in reduced depression symptoms, higher job retention, and more hours worked at six months to one year (43). And a telebehavioral health care intervention for adults with depression and decreased work productivity developed by Lerner et al improved

Telebehavioral health for individuals with comorbid behavioral health and/or chronic health conditions has been shown to reduce medical and psychiatric hospitalizations by as much as 25–30 percent and promote overall medical cost savings.

> Collaborative care-based telebehavioral therapy for coronary artery bypass surgery recipients with depression has been shown to improve quality of care and to be cost effective compared to physician care as usual.

depressive symptoms, at-work productivity loss, and absences compared to usual care, estimated to translate into thousands of dollars saved annually per employee (44, 45).

TELEBEHAVIORAL HEALTH CARE AND FUTURE BEHAVIORAL HEALTH RISK

Earlier intervention via telebehavioral health care has potential to impact prevention of severe and debilitating mental illness. Prevention of major depressive disorder in older adults is projected to reduce the risk of excess mortality after acute medical events, support maintenance of health-related quality of life, and lower risk of disability (46). It is expected that by treating mild behavioral health conditions early, the risk of developing full clinical psychiatric disorders that are less reversible is lowered; ultimately all of these benefits may be cost-effective and impactful if they can be achieved at scale (46). Telehealth delivery provides a viable mechanism to reach more individuals in need of treatment earlier in the disease life course.

04

IMPROVING ACCESS TO BEHAVIORAL HEALTH CARE THROUGH TELEHEALTH

Millions of U.S. adults suffer from mental illness, yet nearly one half remain undiagnosed and untreated. Though multiple challenges contribute to these statistics, insufficient access to quality behavioral health care is a major factor. Telehealth is poised to increase access to behavioral health care for those in need of treatment by overcoming limitations due to geography, stigma, system level challenges, and other factors.

TELEBEHAVIORAL HEALTH CARE OVERCOMES GEOGRAPHICAL CHALLENGES

Individuals with behavioral health disorders in rural areas are about half as likely as those in urban or suburban areas to receive behavioral health treatment; and when they do receive treatment, it is less likely to be delivered by a licensed mental health professional (47). Rural counties of the U.S. are more than twice as likely to have no behavioral health providers than metropolitan counties, resulting in the need to travel long distances to access health care services (48, 49). And in the U.S., lowest income communities are less likely to have any office-based practices for mental health specialists (physicians and non-physicians) versus higher income communities (50). Telebehavioral health care can increase access to treatment by making providers that reside in distant geographic locations available to individuals in need. For example, designated facilities where individuals can securely videoconference with a provider have been demonstrated effective to improve access to behavioral health care in sustainable fashion over a two-year period (38, 51). Moreover, the provision of telebehavioral health care in an individual's own home or convenient location of one's choosing (e.g., at work) may improve access further by avoiding the costs and time associated with travel to a facility. These opportunities are also relevant in more suburban settings where transportation or traffic to reach providers may sometimes prove challenging, or the ability to take time off from work to seek care may prove a limitation.

TELEBEHAVIORAL HEALTH CARE SOLVES FOR INDIVIDUAL-LEVEL CHALLENGES

Telebehavioral health care also holds promise to overcome many of the myriad reasons that keep individuals from seeking behavioral health care including personal challenges (e.g. related to one's own thoughts, perceptions, or emotions) and external challenges (e.g. related to day-to-day activities). Stigma remains a powerful barrier to seeking mental health treatment due to stereotypes and prejudice, concerns about discrimination in the workplace, and fear regarding privacy concerns, collectively leading to treatment avoidance (52–54). Telebehavioral health care can solve for concerns related to stigma and privacy by bringing behavioral health care to a private environment (55).

Adults with self-perceived need for treatment frequently cite financial concerns as obstacles to seeking treatment (4). Telebehavioral health care has potential to alleviate a portion of consumer costs associated with treatment, in particular transportation costs (if treatment is provided at home) and the costs associated with missed work hours or child care. Additionally, increasing awareness about the coverage for evidence-based telebehavioral health care services provided by health insurance companies may increase utilization among individuals in need of care.

Perceived and real lack of available treatment is another common barrier to seeking behavioral health care that could be ameliorated through increased penetration of evidence-based telebehavioral health care options (4). Increased awareness about availability of evidence-based telebehavioral health care services may boost utilization among individuals who recognize the need for care, but have not sought it out due to perceived lack of availability. Mental health literacy also plays a role. Provision of information or education about behavioral health conditions, symptoms, and telebehavioral health care treatment options could open the eyes of many individuals in need and increase treatment seeking (2).

Convenience/transportation concerns can impact the busy working professional as well as the homebound individual. Homebound adults may experience limited access to evidence-based therapy due to inability to travel or lack of transportation, that may be effectively overcome through telebehavioral health care (55, 56). In addition, individuals juggling multiple responsibilities such as jobs and caregiving may be confronted with the challenges with finding appointments during a time that they are free, or giving the time to commute to and from a behavioral health visit. Telebehavioral health care solutions can address these challenges, especially treatment options that are provided in the individual's own home (57).

> Telebehavioral health care can solve for individuals' concerns about stigma by bringing care into a private environment.

TELEBEHAVIORAL HEALTH CARE SOLVES FOR SYSTEM-LEVEL CHALLENGES

There are several health care system-level access challenges including qualified provider shortages and non-participation in health plan networks among available providers (49). A psychiatrist shortage has been identified by the Association of American Medical Colleges and projected to worsen by 2025 (58, 59). Additionally, the number of psychologists has remained stable and not growing with the need (60). As many as two out of three primary care physicians cannot access psychiatry referrals for their clients in need (61). Telebehavioral health care can address these challenges by further increasing the reach of available qualified providers to more individuals.

Telebehavioral Health Care Overcomes Challenges to Accessing Traditional Face-to-Face Behavioral Health Care

TRADITIONAL CHALLENGES	TELEBEHAVIORAL HEALTH CARE SOLUTIONS
Stigma	· In-home appointments
Privacy concerns	· Lower transportation or childcare costs
Long travel distance to provider	· Access to providers state-wide
National provider shortage	· Evening, weekend, and lunch-hour appointments
Low mental health literacy	· HIPAA compliant
Low in-network appointment availability	· Proactive education and outreach
Financial constraints	· Collaborative care integration
Time limits	· Care coordination
Physical health limitations	· Covered by health plan
Lack of transportation	· Reduced work time missed

Source: AbleTo

05

TELEBEHAVIORAL HEALTH AS AN OPPORTUNITY TO ENHANCE QUALITY OF CARE

There are several factors associated with quality of telebehavioral health care services that are important to mention including cybersecurity and adherence to evidence-based standards of care.

As telehealth has become mainstream practice, the need for specific telehealth quality guidelines has been recognized by accreditation organizations such as URAC and ClearHealth Quality Institute (CHQI). URAC recently released the first independent, third-party national telehealth accreditation (62); while not specific to behavioral health, the accreditation highlights that telehealth offers a unique opportunity for trained providers to administer standardized evidence-based treatment; engage in evidence-based practices; monitor, measure, and report on established performance indicators; ensure safety and privacy; and more (62). Similarly, CHQI in collaboration with the American Telemedicine Association recently drafted their first telehealth accreditation standards to help ensure that organizations providing telehealth services follow quality-based standards (63).

There are specific examples of how telehealth providers can ensure that the highest quality of care is provided. One is in considering the role that **technology** can play in standardizing telebehavioral health care delivery. While a telehealth platform in and of itself only serves to connect client and provider, technology has the unique potential to ensure quality and consistency in the delivery of behavioral health care. The use of electronic clinical records, for example, can facilitate standardized **evidence-based assessment** and follow-up through measurement of quality metrics, including documentation of adherence to behavioral therapy, symptom scores, self-management behaviors, and medication adherence and side effects where applicable (62). Protocols can be embedded within technology platforms to promote and ensure fidelity to evidence-based care in "real world" settings by establishing a defined intervention and trackable outcomes (64).

Consumer satisfaction is a fundamental determinant of health care quality.

Technology can also open channels for collaboration and integration of care allowing behavioral health providers to "plug in" with a medical provider. Examples of such settings where the utilization of telebehavioral health care is being evaluated as part of these integrated care models are among Veterans, primary care, and chronically ill populations for the treatment of depression, chronic pain, and other common behavioral health conditions (25, 51). In 2010, the Veterans Health Administration established a National Telemental Health Center; in 2013 alone the Center provided over 2,800 video encounters at 53 sites in 24 states (65). Care coordination among behavioral health providers, primary care providers, and other members of the care team is also facilitated by telehealth approaches, in particular those with technology-enabled platforms that support individual consent for information sharing and Health Insurance Portability and Accountability Act (HIPAA) compliant secure communication.

Finally, consumer satisfaction is a fundamental determinant of health care quality. The value of telebehavioral health care as an acceptable solution to individuals has been demonstrated by recent data, including high satisfaction scores and lower attrition rates among individuals who have engaged in telehealth delivered behavioral therapy versus face-to-face delivery (16, 20, 64). For example, telebehavioral health studies that have evaluated satisfaction using the client satisfaction scale have consistently shown very high satisfaction scores (20, 66, 67).

06

LEGISLATION, REGULATIONS, AND TELEBEHAVIORAL HEALTH CARE

Consumers, providers, employers, payers, regulators, and legislators have increasingly recognized the value of telehealth as a delivery modality with specific applications for behavioral health, and are supporting payment models to promote telehealth. Medicare regulations have traditionally been narrow in scope, supporting payment for telehealth only when furnished by an eligible practitioner; delivered or received in an "originating site," defined as certain hospitals, clinics, or health centers; and provided in a rural area or other designated area.

However, on February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 into law. Included in this law was the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act which seeks to expand access to telehealth services within several Medicare programs, the End Stage Renal Disease Program, select accountable care organizations, and for individuals with stroke (68, 69); further efforts will be needed to expand coverage more broadly. Another bill that has been introduced in the House and the Senate is the CONNECT for Health Act, which would increase the use of telehealth and eliminate many of the barriers to its accessibility (70). Specifically, it would expand telebehavioral health care by allowing the Secretary of Health and Human Services to lift current Medicare restrictions for some mental health services. Also, the Increasing Telehealth Access in Medicare Act passed a key House of Representatives committee and would allow telehealth services to be included as a basic benefit for Medicare Advantage recipients, rather than a supplemental service (71). Additionally, the Medicare Telehealth Parity Act of 2017 includes proposals to expand the types of practitioners who can provide telehealth services, expand services offered in certain geographic locations including Metropolitan Statistical Areas, and add homes as a covered originating telehealth site (72).

Licensure of providers for telehealth has also proven a challenge and opportunity. Traditional in-person care delivery requires the provider to be licensed in the state in which they are providing care with extension of similar regulations even if the care is by telephone or secure video. Loosening of licensure regulation would enable providers to deliver care across state lines optimizing the availability and reach of telehealth services. This barrier is being addressed though interstate collaborations such as the Psychology Interjurisdictional Compact (PsyPACT) to facilitate tele-psychology practice across jurisdictional boundaries (73). Similar legislation has recently passed for nurses to practice telehealth in multiple states under one license, and the House Committee on Veterans' Affairs (VA) has proposed legislation to remove restrictions on the ability of VA providers to practice telehealth across state lines (74, 75). Changes to the Ryan Haight Online Pharmacy Consumer Protection Act which took effect in 2009, are also under consideration. The Ryan Haight Act does not allow physicians to use telemedicine to prescribe controlled substances without first having an in-person exam (76). Taken together, while regulatory barriers persist, recent legislation is moving toward increasing access and simplifying availability of telebehavioral health care.

Taken together, while regulatory barriers persist, recent legislation is moving toward increasing access and simplifying availability of telebehavioral health care.

07

CONCLUSION AND NEXT STEPS

High quality behavioral health care leads to the best mental and physical health outcomes; however, access to high quality and easily available behavioral health care is a necessary prerequisite. More than 50% of diagnosed behavioral health conditions, including mental health and substance use disorders, go untreated.

ABHW supports the use of telebehavioral health care where appropriate and advocates for the lifting of barriers that prevent its implementation and use.

Over the past decade, telebehavioral health care has gained recognition as a solution to enhance access to quality behavioral health care in the U.S. To underscore the value of working to overcome the challenges to telebehavioral health care implementation that remain, this report described what is known about the clinical efficacy and cost-effectiveness of telebehavioral health care, and how telebehavioral health care can improve access to high quality evidence-based care:

- **Clinical efficacy:** Telephone or video delivery of evidence-based therapy has been demonstrated effective for several behavioral health conditions including major depressive disorder, generalized anxiety disorder, and post-traumatic stress disorder.
- **Cost-effectiveness:** Telebehavioral health care can be comparable in cost to traditional face-to-face delivery of care and may result in cost savings attributable to reduced transportation costs, decreased work productivity impairment, avoided unnecessary medical utilization, and early identification and prevention of high-cost severe manifestations of untreated behavioral health conditions.
- **Access to care:** Telebehavioral health care has the potential to increase access to behavioral health care for those in need of treatment by overcoming challenges to care seeking and adherence related to geography, stigma, time constraints, physical health limits, transportation costs, privacy concerns, and provider shortages.

Federal policies related to telebehavioral health care remain narrow in scope to date, limiting implementation in places and populations where care is needed. Ongoing efforts by regulators and legislators to adapt federal legislation continue to extend the reach of telebehavioral health care to populations that require behavioral health treatment.

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ABHW & AbleTo

This report is the result of a collaboration between AbleTo, Inc. and Association for Behavioral Health and Wellness (ABHW), created out of a mutual passion for increased access to high quality, evidence-based behavioral health care and the desire to realize positive health outcomes by addressing behavioral health. This manuscript describes the great potential of telebehavioral health care to address and solve for many of the challenges that prevent progress on improving population health today. We hope this report informs our broad audience of readers about the multidimensional value of telebehavioral health care to improve cost, access, and quality of care.

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Research article

Comparison of DASS-21, PHQ-8, and GAD-7 in a virtual behavioral health care setting

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ABSTRACT

Background: Validated depression and anxiety symptom screeners are commonly used in clinical settings. How results from different brief depression and anxiety symptom assessment tools compare to each other is not well established, especially in real world healthcare settings. This study aimed to compare the Depression Anxiety Stress Scales 21 Depression scale (DASS-Depression) and Anxiety (DASS-Anxiety) scale to the Patient Health Questionnaire 8 (PHQ-8) and Generalized Anxiety Disorder 7 (GAD-7) respectively, in a real-world virtual behavioral healthcare setting.

Methods: This was a retrospective comparison study of clinical data from a population of adults who completed a consultation via telephone or secure video with a licensed therapist as part of a standardized, evidence-based, virtual behavioral therapy program for individuals with comorbid medical and behavioral health conditions. The joint distributions and correlations between scores yielded by each depression and anxiety scale were assessed using descriptive and Spearman correlation statistics.

Results: The DASS-Depression and PHQ-8 were highly correlated ($r = .71$; $p=<.001$); the DASS-Anxiety and GAD-7 correlation was also high ($r = .61$; $p=<.001$). The PHQ-8 categorized more individuals as having above-threshold depression scores versus the DASS-Depression (71.5% vs. 43.5%; $p < .001$). The GAD-7 categorized more individuals as having above-threshold anxiety scores versus the DASS-Anxiety (59.0% vs. 45.0%; $p < .001$).

Limitations: This study compared results yielded by validated screeners, precluding conclusions related to the validity of screener results.

Conclusions: The DASS-Depression and PHQ-8 and the DASS-Anxiety and GAD-7 similarly ranked symptom severity. The PHQ-8 and GAD-7 were more likely than the DASS-21 Depression or Anxiety scales to classify individuals as having above-threshold symptom severity.

Introduction

As the prevalence of comorbid general medical and mental health conditions is more broadly recognized, screening for depression and anxiety symptoms has become a more standard practice. Evidence-based treatment guidelines for several common medical conditions recommend screening for psychiatric comorbidity with validated brief assessment tools (American Diabetes Association, 2018; Andersen et al., 2014; Jha et al., 2019; Siu and US Preventive Services Task Force, 2016).

Which depression or anxiety assessment tool to use may depend on several factors including the clinical setting, practitioner type, patient characteristics, and how the results will be utilized. For example, results yielded from a tool that is used in the psychiatric setting to support accurate diagnosis may be interpreted differently than those from a tool used by non-mental health providers to screen for risk.

Most recently, increased availability of behavioral telehealth services has broadened mental health care access and treatment opportunities (FAIR Health, 2019; Centers for Medicare and Medicaid Services, 2019). With this shift to virtually delivered care, psychiatric symptom assessment tools are being routinely administered over telephone or video conference in both medical and behavioral health care settings (National Committee for Quality Assurance, 2019).

The COVID-19 pandemic has further amplified screening and referral into tele-delivered mental health care, increasing the utility of information that distinguishes and eases interpretation of results produced by different scales. While several commonly used depression and anxiety

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screeners such as the Patient Health Questionnaire 9 (PHQ-9) and the Generalized Anxiety Disorder 7 (GAD-7) have been used in telehealth clinical trials (Mohr et al., 2012; Salisbury et al., 2016; Titov et al., 2011), little is known about whether rates of identification of symptomatic individuals differ between these tools and those produced by other brief assessment tools used in the field, especially under real-world virtual care conditions. For example, the Depression Anxiety Stress Scales 21 (DASS-21) may be used to assess depression and anxiety symptom severity in clinical settings; but few data have compared the DASS-Depression scale to the PHQ screeners, and fewer have compared anxiety symptom severity as assessed by the DASS-21 Anxiety and Stress scales to those yielded by GAD-7 (Lambert et al., 2015; Orta et al., 2015; Sakakibara et al., 2009). This information is important, as it would inform interpretation and comparison of results yielded by different tools in the same population.

To address this gap in knowledge, we sought to compare the results from two commonly used depression symptom assessment tools (the DASS-21 Depression Scale (DASS-Depression) and the Patient Health Questionnaire-8 (PHQ-8)) and two common anxiety symptom assessment tools (the DASS-21 Anxiety and Stress scales (DASS-Anxiety and DASS-Stress) and Generalized Anxiety Disorder-7 (GAD-7)) in an adult population with medical and behavioral health issues being treated in a virtual behavioral health care setting. Specifically, we aimed to (1) determine the correlation and compare symptom severity classification between the PHQ-8 and DASS-Depression, and (2) determine the correlation and compare symptom severity classification between the GAD-7 and DASS-Anxiety and DASS-Stress Scales.

Methods

Study population

The present investigation was a cross-sectional comparison study of previously collected clinical data from a virtually delivered behavioral health program. The program comprised protocolized cognitive behavior therapy delivered in a fully remote telehealth setting by telephone or video to adults with comorbid medical (e.g. cardiovascular disease, diabetes, chronic pain) and mental health (e.g. depression, anxiety) conditions (Dent et al., 2018; Mochari-Greenberger et al., 2016, 2017; Pande et al., 2015). The clinical protocol consisted of sixteen clinical sessions delivered over approximately 8 weeks, starting with a comprehensive initial consultation conducted by a licensed clinical social worker (LCSW) and subsequent sessions alternating between psychotherapy and behavioral coaching (Dent et al., 2018). Participants were 18 years old or older and access to a telephone was required to enroll. The presence of acute suicidal risk, recent psychiatric hospitalization, or cognitive impairment precluded participation.

As part of a quality improvement initiative, a group of 9 LCSWs were uniformly trained to administer the PHQ-8 and GAD-7, in addition to the DASS-21 which was standard as part of the protocolized comprehensive clinical interview. The order in which the three tools were utilized was neither randomized nor prescribed. The initial consultation also included collection of sociodemographic characteristics (age, sex) and clinical information (past psychiatric and medical histories), and a comprehensive psychiatric risk assessment. De-identified data from a sample of 202 participants were abstracted for this analysis. The present study was approved by the Sterling Institutional Review Board.

Measures

DASS-21

The DASS-21, a brief version of the 42-item Depression Anxiety Stress Scales (DASS-21), is a 21-item clinical assessment with subscales for depression (DASS-Depression), anxiety (DASS-Anxiety), and stress (DASS-Stress) (Lovibond and Lovibond, 1995; Psychology Foundation of Australia, 2018a). Clinical severity categories and cut points of the DASS-21 are described in Supplemental Figure 1. The depression subscale assesses the loss of motivation and self-esteem. The anxiety subscale primarily measures symptoms of persistent anxiety and fear. The stress subscale addresses symptoms of persistent arousal and irritability (Lovibond and Lovibond, 1995). The DASS-21 has been validated in clinical and community populations against the gold-standard DSM-IV structured clinical interview (Antony et al., 1998). It has also been demonstrated to have excellent internal consistency in clinical populations (Cronbach's $\alpha = .94$ (DASS-Depression), .87 (DASS-Anxiety), and .91 (DASS-Stress)) (Antony et al., 1998).

PHQ-8

The PHQ-8 is a version of the Primary Care Evaluation of Mental Disorders (PRIME-MD) depression measure (PHQ-9), typically utilized to assess depressive symptom severity and to assess for the presence of major depressive disorder (Kroenke et al., 2001, 2008; Kroenke and Spitzer, 2002). Clinical symptom severity categories and cut points for the PHQ-8 are described in Supplemental Figure 1. A PHQ-8 score $\geq$5 is considered above minimal threshold and a PHQ-8 score $\geq$10 points is consistent with moderate or greater depressive symptoms. The PHQ-8 scale has been shown to have good internal reliability in medical populations (Cronbach's $\alpha = 0.82$) (Pressler et al., 2010).

A diagnostic algorithm is offered by the authors of the PHQ-8 as an alternative to using cut points to evaluate current depression (Kroenke et al., 2008). Using the PHQ-8 algorithm, the presence of "major depression" is indicated when: 1) 5 to 8 symptoms on the PHQ-8 are endorsed as having been present "more than half the days" (score $\geq$2 points for each item) in the past two weeks, *and* 2) one or more of the 5 to 8 symptoms endorsed is/are anhedonia and/or depressed mood (PHQ-8 questions 1 and/or 2). The presence of "other depression" is indicated when: 1) 2 to 4 of the eight symptoms measured by the PHQ-8 were present on "more than half the days" in the past two weeks (score $\geq$2 points for each item) *and* 2) one or more of the 2 to 4 symptoms endorsed is/are anhedonia and/or depressed mood (PHQ-8 questions 1 and/or 2). The PHQ-8 algorithm indicates *any* depression if criteria for *major depression* or *other depression* are met.

The PHQ-8 differs from the more commonly-used PHQ-9 in that it excludes the final question addressing suicidal ideation (Kroenke et al., 2008). In this study, the final question was not included because suicide risk was comprehensively assessed separately using a standardized risk assessment during the same session in which the PHQ-8 was administered. The intention was to reduce redundancy and number of questions to optimize the patient and clinician experience. The PHQ-8 has been shown to be similar to the PHQ-9 in identifying depression (Kroenke et al., 2008); a meta-analysis of PHQ-9 validation studies found that the PHQ-9 had a pooled sensitivity of 92% and a specificity of 80% compared to the DSM clinical interview, and has diagnostic properties comparable with longer diagnostic instruments (Gilbody et al., 2007). To assess the potential impact that utilizing the PHQ-8 versus the PHQ-9 could have had on study results, and allow for comparability of these results to those from past and future investigations which may utilize the PHQ-9, a supplemental analysis (described below under Data Analysis) was conducted to look at the data from the suicide risk screening alongside PHQ-8 data.

GAD-7

The GAD-7 is a seven item scale used to assess symptoms of generalized anxiety disorder (GAD). The GAD-7 was developed to reflect symptom criteria of GAD as defined by the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria and other validated anxiety measures (Spitzer et al., 2006). Clinical severity categories and cut points of the GAD-7 are described in Supplemental Figure 1. The GAD-7 has been shown to have high internal reliability (Cronbach's $\alpha = .92$) and validity to identify the presence of GAD when compared to structured psychological interview by a mental health professional (DSM-IV criteria) in medical care settings (sensitivity =

89%, specificity 82% to identify GAD when GAD-7 score is ≥10 points) (Spitzer et al., 2006).

Data analysis

The distribution of baseline demographic and clinical characteristics were calculated using means and proportions. The distribution of scores on the DASS-Depression, DASS-Anxiety, PHQ-8 and GAD-7 scales were evaluated against standard cut-points to identify above threshold scores (DASS-Depression ≥ 10, DASS-Anxiety ≥ 8, PHQ-8 ≥ 5 and GAD-7 ≥ 5) and scores of moderate or higher symptom severity (Kroenke et al., 2008; Lovibond and Lovibond, 1995; Spitzer et al., 2006). Internal consistency was quantified for each scale using Cronbach's alpha. The relation between DASS-Depression and PHQ-8 and between DASS-Anxiety and GAD-7 were assessed by Spearman rank correlation. Categorical distributions of DASS-Depression and PHQ-8 severity categories were compared using proportions (McNemar's test statistic for paired nominal data) and illustrated using a bubble plot; DASS-Anxiety and GAD-7 were similarly compared.

Two supplemental analyses were also conducted. First, because the DASS-Stress scale also assesses symptoms similar to the DSM-IV diagnosis of Generalized Anxiety Disorder (Lovibond and Lovibond, 1995; Psychology Foundation of Australia, 2018a, 2018b, 2018c), we conducted an exploratory analysis to compare symptom severity classifications yielded by 1) the DASS-Stress Scale versus the GAD-7, and 2) the DASS-Anxiety and the DASS-Stress Scale combined versus the GAD-7. Kappa statistics were used to describe agreement between scales. Second, because the difference in score between the PHQ-8 and the PHQ-9 could have affected results we conducted a supplemental analysis to estimate how results might have differed if the PHQ-9 was utilized. To do this, we imputed 3 points (highest possible item score) into the PHQ-8 score for each participant that endorsed any frequency or intensity of suicidal ideation in the past month during their initial consultation with their therapist to create a pseudo PHQ-9 score. The analyses to compare PHQ-8 and DASS-Depression described above were repeated replacing the PHQ-8 score with the pseudo PHQ-9 score. All data were analyzed using SAS statistical software (version 9.4). Statistical significance was set at $p < 0.05$.

Results

The baseline characteristics of the study population are described in Table 1. The 202 participants were 68.3% female; mean age was 51 years. More than half had been previously diagnosed with depression (55.9%) and almost half had been diagnosed with anxiety (45.0%). Almost two in five had a history of diabetes, 45.5% had a history of hypertension, and 16.8% had a history of heart disease.

Table 1. Baseline characteristics of a consecutive sample of virtual behavioral healthcare program participants (N = 202).

Baseline Characteristics	Distribution
Age	
Years (mean [±SD])	51.0 [±10.6]
Range (years)	24–68
Female (n [%])	138 [68.3]
Race/Ethnicity	
Black or African American (n [%])	36 [17.8]
Hispanic or Latino (n [%])	18 [8.9]
White (n [%])	129 [63.9]
Other/Declined to Answer (n [%])	19 [9.4]
Employment Status	
Currently Employed/Working for Pay (n [%])	119 [58.9]
Past Psychiatric History	
Depression (n [%])	113 [55.9]
Anxiety (n [%])	91 [45.0]
Panic Attacks (n [%])	35 [17.3]
Past Medical History	
Diabetes (n [%])	80 [39.6]
Heart Disease (n [%])	34 [16.8]
Hypertension (n [%])	92 [45.5]
Kidney Disease (n [%])	15 [7.4]
Symptom Severity	
Above Threshold DASS-Depression (≥10) (n [%])	88 [43.6]
Above Threshold PHQ-8 (≥5) (n [%])*	143 [71.5]
Above Threshold DASS-Anxiety (≥8) (n [%])	91 [45.0]
Above Threshold GAD-7 (≥5) (n [%])**	118 [59.0]

* N = 200; n missing = 2.
** N = 200; n missing = 2.

Comparison of DASS-Depression and PHQ-8

The DASS-Depression (Cronbach's α = .90) and PHQ-8 (Cronbach's α = .85) were highly correlated (Spearman r = .71; p < .001); however, the distribution of score severity varied between the two measures (Figure 1). The PHQ-8 identified more patients as having above threshold (PHQ-8 ≥5) depression symptom scores versus the DASS-Depression (≥10 points; 71.5% vs. 43.5%; p < .001). The PHQ-8 also classified more individuals as having moderate or higher depressive symptoms (PHQ-8 ≥10 points) versus the DASS-Depression (≥14 points; 44% vs. 31.5; p = 0.0002).

In order to better understand these differences in classification, we explored the specific items within each scale that may have contributed. Among the subset of participants with above threshold scores on the PHQ-8 but not the DASS-Depression (n = 60; 41.9% of those with above threshold PHQ-8 scores), PHQ-8 scale items related to somatic symptoms not expressly measured by the DASS-Depression were frequently endorsed (Table 2). Additionally, these participants reported the somatic symptoms with increased severity (indicated by scores ≥2) relative to non-somatic symptoms addressed by both the DASS-Depression and PHQ-8 such as anhedonia, dysphoria, and self-deprecation. Other symptoms measured by the PHQ-8 but not the DASS-Depression, such as difficulty concentrating and psychomotor retardation, were not endorsed with as great severity or frequency as the symptoms described above.

When the PHQ-8 algorithm was applied to the raw PHQ-8 data, almost half of participants with raw PHQ-8 scores ≥5 points were classified as having *any depression*, and the proportion with *any depression* rose to nearly three out of four when the sample was restricted to those with a raw PHQ-8 score ≥10 points (Table 3).

Of the participants with an above threshold DASS-Depression score (≥10 points), 65.5% were also classified with *any depression* by PHQ-8 algorithm. Among those with moderate or higher DASS-Depression score (≥14 points), 76.2% were categorized with *any depression* by the PHQ-8 diagnostic algorithm. When the PHQ-8 diagnostic algorithm was applied to the 60 participants with above threshold scores on the PHQ-8 but not DASS-Depression, only 16.7% met the criteria for *any depression*.

Our supplemental analysis to assess the potential impact of using the PHQ-8 (versus the PHQ-9) on these observed results identified ten out of 202 participants (5%) with thoughts of suicide in the past month (2/10 daily in the past month, 7/10 one to two times in the past month, 1/10 none in the past month but conversely endorsed low intensity ideation in the past week). Agreement between the original PHQ-8 scores and the pseudo PHQ-9 (calculated by adding 3 points to the PHQ-8 score of those participants with thoughts of suicide) to identify individuals with scores ≥5 points (elevated) on both scales was perfect (Kappa = 1.0); agreement to identify individuals with ≥10 points (moderately elevated or more) on both scales was close to perfect (Kappa = .99), with the pseudo PHQ-9 categorizing one additional individual as having moderate or more severe depression symptoms, supporting the conclusion that study

Figure 1. Comparison of within-person depression symptom severity: DASS-21 depression scale versus the PHQ-8.

results would not have materially differed if the PHQ-9 was used instead of the PHQ-8 in this population.

Comparison of DASS-Anxiety and GAD-7

The DASS-Anxiety (Cronbach's α = .72) and GAD-7 (Cronbach's α = .87) were moderately correlated (Spearman r = .61; p=<.001). Categorical data analysis of DASS-Anxiety and GAD-7 data documented a difference in the distribution of score severity between the measures (Figure 2). The GAD-7 classified significantly more individuals as having above threshold symptoms of anxiety than the DASS-Anxiety (59.0% vs. 45.0%; p < .001). Almost two-thirds (65.2%) of participants classified by the GAD-7 as having above threshold anxiety symptom scores were also classified as above

Table 2. Distribution of Within-Item PHQ Scores among Participants Who Screened Above Threshold on the PHQ-8 but not on the DASS-21 Depression Scale (n = 60).

PHQ-8 Question	PHQ-8 Item Score			
	0	1	2	3
	n (%)	n (%)	n (%)	n (%)
1. Little interest or pleasure in doing things	27 (45)	25 (42)	8 (13)	0 (0)
2. Feeling down, depressed, or hopeless	27 (45)	29 (48)	4 (7)	0 (0)
3. Trouble falling or staying asleep, or sleeping too much	5 (8)	12 (20)	12 (20)	31 (52)
4. Feeling tired or having little energy	5 (8)	17 (29)	18 (30)	20 (33)
5. Poor appetite or overeating	16 (27)	16 (27)	14 (23)	14 (23)
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	35 (58)	17 (29)	5 (8)	3 (5)
7. Trouble concentrating on things, such as reading the newspaper or watching television	28 (47)	19 (32)	6 (10)	7 (11)
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	47 (79)	8 (13)	2 (3)	3 (5)

Table 3. Proportion of participants meeting PHQ-8 diagnostic criteria at various DASS-21 depression scale and PHQ-8 cut points.

Above Threshold Scores On:	N	PHQ-8 Diagnostic Algorithm Classification Category		
		Any Depression[1] n (%)	Other Depression n (%)	Major Depression n (%)
PHQ-8 ≥ 5	143	67 (47%)	18 (13%)	49 (34%)
PHQ-8 ≥ 10	88	63 (72%)	14 (16%)	49 (56%)
DASS-Depression ≥ 10	87	57 (66%)	10 (11%)	47 (54%)
DASS-Depression ≥ 14	63	48 (76%)	8 (13%)	40 (64%)
PHQ-8 ≥ 5 & DASS-Depression ≥ 10	83	57 (69%)	10 (12%)	47 (57%)
PHQ-8 ≥ 5 & DASS-Depression < 10	60	10 (17%)	8 (13%)	2 (3%)
PHQ-8 < 5 & DASS-Depression ≥ 10	4	0 (0%)	0 (0%)	0 (0%)

[1] Any Depression is equal to the total of Major Depression plus Other Depression.

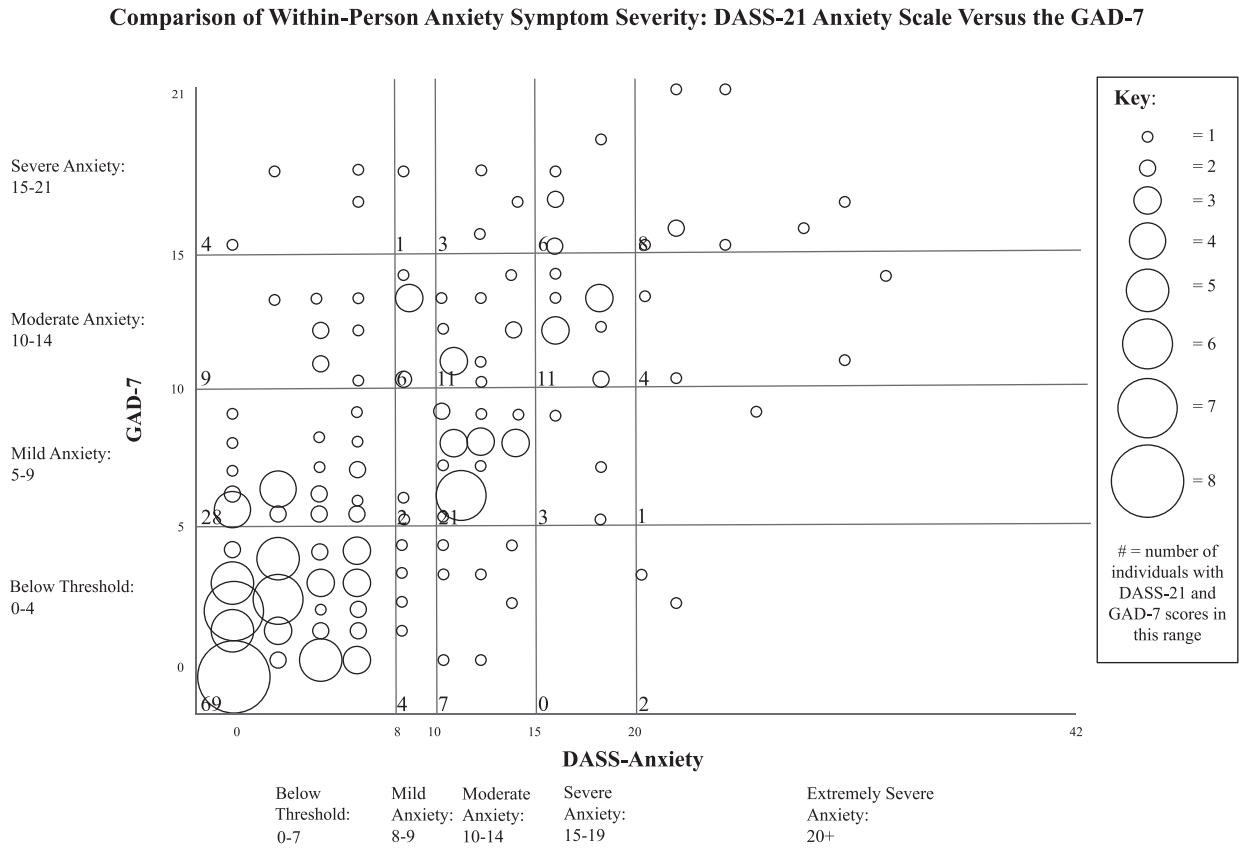

Figure 2. Comparison of within-person anxiety symptom severity: DASS-21 anxiety scale versus the GAD-7.

threshold by the DASS-Anxiety. Of the participants that were classified as below-threshold on the GAD-7, 84% of them were also classified as below threshold on the DASS-Anxiety. The GAD-7 classified a similar proportion of individuals as having moderate or more severe anxiety symptoms (GAD-7 ≥10) versus the DASS-Anxiety (32% vs. 39%; p = .06).

No striking clinical patterns or commonalities were observed in the GAD-7 item responses among participants with above threshold scores on the GAD-7 but not the DASS-Anxiety (n = 41; 34.7% of those with above threshold GAD-7 scores; Table 4). Review of the individual items on the GAD-7 scale and DASS-Anxiety scales suggest they assess different symptoms of anxiety. Participants who endorsed questions about worry on the GAD-7 also tended to endorse analogous questions on the DASS-Anxiety. However, scores on questions about worry on the GAD-7 were observed to be higher than scores about worry assessed by the DASS-Anxiety.

The DASS-Stress scale (Cronbach's α = .83) identified 38% of participants as above threshold (≥15 points) (versus the 59% originally identified by the GAD-7). However, when the DASS-Anxiety and the DASS-Stress scales were combined (i.e. if a participant was above threshold on either scale), 51% of participants were identified as above threshold; a proportion not statistically different from the 59% identified as above threshold by the GAD-7 (McNemar's p = 0.27). Agreement between the GAD-7 and the combined DASS-Anxiety and DASS-Stress scales to categorize individuals as above versus below threshold for anxiety symptoms was moderate (Kappa = 0.58) indicating the combined DASS scales were identifying many of the same individuals as above threshold as the GAD-7.

Table 4. Distribution of Within-item GAD-7 Scores Among Participants With an Above Threshold Score on the GAD-7 but not on the DASS-21 Anxiety Scale (n = 41).

GAD-7 Question	GAD-7 Item Score			
	0	1	2	3
	n (%)	n (%)	n (%)	n (%)
1. Feeling nervous, anxious, or on edge	7 (17)	23 (56)	5 (12)	6 (15)
2. Not being able to control or stop worrying	7 (17)	20 (49)	6 (15)	8 (19)
3. Worrying too much about different things	8 (19)	16 (39)	7 (17)	10 (25)
4. Trouble relaxing	6 (15)	16 (39)	7 (17)	12 (29)
5. Being so restless that it is hard to sit still	20 (49)	14 (34)	5 (12)	2 (5)
6. Becoming easily annoyed or irritable	3 (7)	25 (61)	7 (17)	6 (15)
7. Feeling afraid as if something awful might happen	23 (56)	10 (25)	5 (12)	3 (7)

Discussion

In this comparison study among adults with medical conditions who received behavioral therapy in a virtual behavioral health care setting, we documented significant correlation between commonly used screening tools for depression and anxiety as well as important differences in meeting thresholds and in grading severity. The PHQ-8 and the GAD-7 classified a higher proportion of individuals as above threshold versus the DASS-21. And, a significant proportion of individuals with above threshold PHQ-8 scores were not classified as above threshold for depression by PHQ-8 algorithm.

Few published studies have compared the PHQ to the DASS-Depression scale in medically comorbid populations (Lambert et al., 2015; Orta et al., 2015; Sakakibara et al., 2009). Those that have compared them directly have yielded patterns similar to those presented here. For example, in a study evaluating depression, anxiety, and stress comorbidity with the presence of migraines in a cohort of pregnant women, the PHQ-9 classified more participants as above threshold than the DASS-Depression (62.1% vs. 16.9%) (Orta et al., 2015). In another study evaluating the prevalence of depression in a cancer population, the PHQ-9 raw score also classified more participants as above threshold than the DASS-Depression, with authors concluding that the PHQ-9 raw score was identifying more individuals in the mild and moderate score severity categories (Lambert et al., 2015). This study adds to prior knowledge by corroborating these observations utilizing the PHQ-8, and in a virtual behavioral health care setting.

One possible explanation for why the PHQ-8 classified more participants as having above threshold symptoms versus the DASS-Depression is the difference in the depression symptoms the scales measure. In this study, participants with above threshold scores on the PHQ-8 but below threshold scores on the DASS-Depression were observed to endorse the PHQ-8 somatic symptoms (abnormal sleep behavior, lack of energy, and changes in appetite) more frequently and with higher scores than the PHQ-8 cognitive/affective symptoms. The DASS-Depression does not address these somatic depressive symptoms, which may in part explain the higher depression symptoms severity ratings observed on the raw PHQ-8 versus the DASS-Depression scale scores in this population.

Previous studies have also documented differences in the level of depression when assessed by the sum score of a standardized questionnaire (e.g. PHQ-8's raw symptom severity scores) versus clinical interview or applied algorithms (Hartung et al., 2019). This may also be attributable in part to the somatic symptoms associated with depression that medical populations may experience at a higher frequency than the general population in the presence or in the absence of cognitive/affective symptoms such as depressed mood or anhedonia (Ferrando et al., 2007; Grapp et al., 2019; Hartung et al., 2019). While the PHQ-8 diagnostic algorithm requires that depressed mood or anhedonia be present at least more than half the days for an individual to be classified with *any depression*, the standardized threshold scores for the same tool assigns all symptoms equal weight without this requirement. Our data had a much lower proportion of participants screening in as above threshold for *any depression* when the PHQ-8 diagnostic algorithm was used instead of the raw cut-off scores (i.e. $\geq$5 points and $\geq$10 points). The results suggest assessing depression symptom severity using only the raw PHQ-8 cut-off scores, could yield a higher estimate for prevalence and severity of depression in medical populations with somatic symptoms than the algorithm would in the same population. However, it should be noted that other research has determined somatic items to be no less valid than cognitive/emotional items as indicators of depression in medically comorbid populations (Simon and Korff, 2006). Differences in response pattern between medical and non-medical populations have been observed; for example, a medically comorbid population may be more likely to report fatigue at a milder level of depression than a non-medical population control (Simon and Korff, 2006).

In this study we also observed the GAD-7 categorized a higher proportion of patients as having above threshold symptoms of anxiety compared to the DASS-Anxiety scale. This discordance could be related in part to the scales being designed to measure different types of anxiety symptoms. Based on the DSM-IV diagnosis of Generalized Anxiety Disorder, the GAD-7 assesses symptoms of worry, irritability, and restlessness (Spitzer et al., 2006). The DASS-Anxiety also assesses symptoms of worry along with symptoms of panic such as trembling of the hands, breathing difficulties, and increased heart rate (Psychology Foundation of Australia, 2018a).

When assessing symptoms related to worry, the DASS-Anxiety uses language that is specific to panic disorder and anticipatory anxiety for panic attacks more focused on panic (e.g. panic and worrying about panic), while the GAD-7 uses terminology inclusive of symptoms of generalized anxiety disorder more focused on worry (e.g. worrying too much and not being able to control worrying). Participant responses to items concerning worry tended to be higher on the GAD-7 than analogous questions on the DASS-Anxiety related to panic and this may have contributed to the GAD-7 assigning more above normal threshold scores versus the DASS-Anxiety. When the DASS-Stress scale, which measures symptoms of restlessness, difficulty relaxing and irritability associated with generalized anxiety disorder, was added to the analysis, we observed greater concordance between GAD-7 and the combined DASS-Anxiety and DASS-Stress scales. These observations underscore the value in pre-specifying what symptoms/condition you aim to screen for, before selecting the optimal brief scale(s) to utilize.

A final contributor to the observed discordance between the PHQ-8, GAD-7, and DASS-21 scales, could also be lookback time frame. While the DASS-21 has a look back period of one week, the PHQ-8 and GAD-7 have a lookback of two weeks (Psychology Foundation of Australia, 2018b; Kroenke et al., 2008; Spitzer et al., 2006). It is not possible given these data to know with certainty which direction time frame could have biased results. For example, one might hypothesize that a shorter timeframe would exclude individuals with symptoms that were present one to two weeks ago, but not in the past week. Alternatively over a longer timeframe, one might argue that the average level of symptom severity could be diluted for those whose symptoms have intensified over the past week.

The results from this comparison study add to our knowledge about how the DASS-21 Depression scale and the PHQ-8, and the DASS-21 Anxiety and Stress scales and the GAD-7, categorize symptom severity relative to each other in an adult population with medical and behavioral health issues. A primary limitation in this study was the small and heterogeneous convenience sample of participants with varying medical conditions which limits our ability to draw conclusions about the distribution of measures in specific medical populations. Additionally, the order in which the tools were utilized in each session was not randomized, which could have affected results; however the order was not prescribed either and the data represent results from a real-world clinical care setting. Though comparing results from these assessment tools administered in a virtual behavioral health setting is novel, this study was not designed to determine if results differ from those yielded by administration of the same tools in traditional health care settings. An important next research step will be to link these data to diagnosis yielded by clinical interview and to compare the criterion validity of the scales. The present study also aimed to compare different screeners to one another, not to a gold standard, which precludes us from drawing conclusions about validity. Nonetheless, this information may be informative to clinicians as they interpret results yielded by these tools in the populations they serve.

In this comparison study, we documented moderate to high correlation between the DASS-21 depression and anxiety scales with the PHQ-8 and GAD-7 respectively in a population with medical comorbidities receiving virtual behavioral health care. We also documented differences in the way the screeners categorized symptom severity, with the PHQ-8 and GAD-7 including more participants as above threshold than the corollary DASS-21 scales. The data underscore the importance of distinguishing what above-normal threshold scores indicate on each scale when selecting a brief tool to support assessment of depression and anxiety symptoms. Further research is needed to validate and examine the performance of these tools for screening and ongoing measurement in different clinical settings.

Declarations

Author contribution statement

Heidi Mochari Greenberger, Reena L Pande, Aimee Peters: Conceived and designed the analysis; Analyzed and interpreted the data; Contributed analysis tools or data; Wrote the paper.

Lila Peters, Evie Andreopoulos, Naomi Pollock: Conceived and designed the analysis; Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

L.P. is an employee of AbleTo. A.P. is an employee of and holds an equity interest in AbleTo. E.A. is an employee of AbleTo; N.P. is an employee of and holds an equity interest in AbleTo; R.L.P. is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Medical Officer. H.M.G. is an employee of and holds an equity interest in AbleTo.

Additional information

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of psychological distress on subsequent physical health outcomes. Such studies are possible given that evidence-based treatments are available for PTSD and other forms of psychological distress. Important remaining questions could also be addressed by including assessment of chronic disease or disease-related biomarkers as secondary outcomes in mental health treatment trials.

Third, we need to communicate more effectively about the importance of psychological well-being for population health. Conveying this message to a range of audiences, including healthcare providers, payers, employers, policymakers, and the public, has the benefit of reducing the stigma frequently attached to experiencing PTSD and other forms of psychological distress, motivating the integration of mental and physical health care services, and reducing the sense that mental and physical health must compete for resources. Effectively communicating this message will also increase political will to prioritize prevention and early determinants of population health, and thereby allocate resources to address structural and other factors that shape risk and resilience. Notably, many structural factors that have resulted in disproportionate burden of COVID-19 on low-resource communities are also known to adversely affect mental health.

The pandemic exposes some hard truths about our health system and health priorities. In our current system, mental and physical health are treated as separate entities, addressed by different medical and public health disciplines. However, we must now attend to mental health in order to promote a sound mind and body. During this time of much uncertainty and fear, we see a unique opportunity to harness our increasingly sophisticated understanding of the inter-relationship between mental and physical health. Reducing the mental health burden of the COVID-19 pandemic has the potential to have lasting benefits for mental *and* physical health. Already researchers are mobilizing the evidence base to address the mental health impact of COVID-19,[7] pointing to phased intervention approaches to meet differing needs of affected individuals. Mental health interventions at the individual-, organizational, and population-level should be prioritized and supported not only to mitigate acute psychological distress, but also to evaluate whether and how such interventions improve subsequent physical health. Additionally, effects of other population-wide interventions (e.g., economic stimulus package) that are not targeted specifically at mental health but have substantial implications for health and functioning should be evaluated.

While considering mental health in the context of the COVID-19 pandemic is particularly relevant now, this is not the only context in which these considerations and efforts will have impact. Indeed, the vast majority of individuals will be exposed to a trauma during their lifetimes, with sizable proportions subsequently experiencing psychological distress. By recognizing the critical interplay between mental and physical health, debunking the false dichotomy between them (and the corresponding competition for resources and attention), and identifying upstream social determinants of how these relationships play out, we can make more substantial progress to improving population health in the context of a pandemic and beyond.

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Behavioral Health in America During the COVID-19 Pandemic: Meeting Increased Needs Through Access to High Quality Virtual Care

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The impact of the COVID-19 pandemic on mental health in America has been profound and is still unfolding. In the year 2020, social distancing, school and business closures, and limits on in-person health care services became the new normal. At the same time, we witnessed a tripling in national levels of depression and anxiety symptoms both in the context of having COVID-19 infection itself and the public health measures put in place to limit COVID-19 spread.[1-3] As clinician scientists in the virtual health care space, we have been

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observing the COVID-19 pandemic through the lenses of history, epidemiology, policy and patient care. In this article, we describe trends in mental health care, efforts to meet the increasing need since the pandemic, and the specific value of virtually-delivered behavioral health care on clinical and workplace outcomes during this unprecedented time.

Mental Health in America During the COVID-19 Pandemic

Stress and worry are expected responses from real or perceived health threats and uncertainty. We know from 2 prior notable coronavirus events, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), that anxiety, depressed mood, and other mental health conditions may rise during and following an outbreak.[4,5] Rapid synthesis of research from across the globe during the first several months of the COVID-19 pandemic has already documented significant increases in psychological distress worldwide, especially among females, younger age groups ($\leq$ 40 years), those with chronic illnesses, and the unemployed.[5]

In the U.S., mental illness prevalence was high even before the pandemic, affecting more than 1 in 5 (20.6%) U.S. adults in 2019.[6] However, as of November 2020, studies have demonstrated that almost 2 in 5 U.S. adults were living with anxiety or depression symptoms and the prevalence of substance use and suicidality have also increased, with no sign of abating.[1,7] The public health measures instituted to control spread of COVID-19, such as physical distancing requirements and closure of workplaces and schools, as well as fear of exposure risk are contributing to social isolation, reduced physical activity, workplace strain, and may as a result be contributing to the higher rates of mental health issues seen in 2020.[8] This may be expected to continue as long as COVID-19 remains a threat and even for a time period after that.

In our experience at AbleTo, an organization that provides virtually-delivered behavioral health care and coached digital behavioral therapy across the U.S., we have witnessed higher severity of psychological symptoms among individuals participating in our clinical programs during COVID-19 compared to those participating prior to the pandemic. We have also observed high levels of work-related burnout in certain populations (e.g., health system employees) engaged in AbleTo digital behavioral therapy programs during the pandemic.

As with the physical health outcomes of COVID-19, the mental health impact of COVID-19 has disproportionately affected certain populations.[7-9] Centers for Disease Control data show that members of diverse racial/ethnic communities, younger adults, essential workers, and unpaid adult caregivers reported worse mental health, increased substance use, and higher suicidal ideation versus their counterparts.[1,7] And while barriers to mental health care have been seen across all age, sex, and race/ethnic groups, younger adults have been more likely than older adults to report high rates of symptoms as well an inability to access mental health services despite an identified need during the pandemic.[7]

Virtually-Delivered Mental Health Care Overcomes Barriers

Barriers to, and disparities in, access to mental health care in the U.S. are not new problems. For decades, provider shortages, geographic challenges, cost, and other issues have meant that fewer than half (42.6%) of U.S. adults with a behavioral health condition received any treatment in the past year.[6,10,11] For those who do receive treatment, finding treatment that is of high quality is an additional challenge.[12] This means that, even pre-pandemic, far too many individuals with behavioral health conditions were not receiving needed treatment. COVID-19 brought additional challenges with in-person care posing risk of contracting COVID, new time constraints with many adults working from home and balancing parenting and homeschooling responsibilities, and additional strains on capacity given the increase in mental health prevalence during the pandemic.

Prior to the pandemic, we were already witnessing a shift toward acceptance of innovative approaches to delivery of behavioral health services. Telebehavioral health care (i.e., synchronous interaction with a licensed mental health professional by telephone or secure video) was increasingly being recognized as a solution to overcome access barriers by eliminating geographic and health system challenges such as clinician shortages. Delivering care in a private remote environment and making care available during non-working hours also has the advantage of overcoming barriers posed by stigma.[13] Telehealth can connect individuals to care quickly, reducing long wait times associated with care in the community.[11] As such, virtual solutions of this nature were optimally poised to serve the increased mental health needs of patients that have arisen during the pandemic (Figure 1).

Amid COVID-19, rapid regulatory changes have further reduced barriers to accessing telehealth services. The Centers for Medicare and Medicaid Services (CMS) has issued waivers to increase access by health care provider type and geographic location, and invoked payment parity for tele-delivered services (versus in person) for Medicare members. Specifically, under these new waivers, Medicare can pay for mental health visits provided by licensed psychologists and clinical social workers via telehealth including in a patient's home.[14] Additionally, the Health and Human Services office of the Inspector General has provided flexibility for health care providers to reduce or waive cost-sharing for telehealth visits paid for by federal health care programs,[14] thus reducing cost-related barriers to mental health care. A Medicaid Telehealth Toolkit has been released by CMS to support policy makers to navigate the complex state-level regulatory framework, and enable more rapid expansion of high quality telehealth services utilization.[15] These types of policy changes were designed with the intention of decreasing disparities in access to care; for example telehealth visits on a whole eliminate transportation barriers, and care delivered by telephone eliminates the need for stable internet.[9] Professional associations such as the American Psychiatric Association and the American Psychological Association have released practice guidance for delivery and billing for telehealth services to distil and disseminate these policy changes for providers and to the public.[16,17]

Ease of access coupled with increasing acceptability and utilization of telebehavioral health care before COVID-19 has contributed to a rapid adoption of virtually-delivered mental health care over the past year apparent as early as the first months of the pandemic. The Department of Veterans Affairs, the largest health care system in the United States, reported a 556% increase in telebehavioral health encounters between March and April 2020 alone.[18] At our organization, we observed a significant increase in engagement in our telebehavioral health care services as early as April 2020 and across all age groups, health plan types, and U.S. regions. Clinician survey results from the American Psychiatric Association corroborate these utilization data and document more than 10-fold increases in the proportion of clinicians practicing via telehealth all or most of the time.[19]

Digital mental health technologies are another virtual mental health resource that could help many due to ease with which they can be accessed at scale.[20] The support provided by the numerous

Established Barriers to Behavioral Health Care	How Virtual Care Delivery Solves for Barriers
• Cost of treatment	★ Increasingly covered by health insurance plans ★ Low or no childcare or transportation costs / needs ★ Providers anywhere in the state in which you reside ★ Appointments at home or in preferred private location ★ Private and secure ★ Care can be provided outside of traditional office hours, including nights and weekends ★ Integration with physicians and other care health care professionals in your care team ★ Quality accreditation available ★ Care delivered in different languages and adapted to health literacy level
• Geographic distance to nearest provider	
• National provider shortages	
• Poor physical health	
• Privacy concerns	
• Stigma	
• Time constraints during weekday hours	
• Transportation challenges	
• Uncertainty about how treatment could help	
• Challenges finding high quality care	
Additional COVID-19 Related Challenges	
• Risk of contracting COVID-19	
• Increased strain on mental care system capacity	
• Additional time constraints due to caregiving	

Figure 1. Barriers to behavioral health during COVID-19 overcome with virtual health care delivery.

currently available mental health apps ranges from psychoeducation to self-guided therapy programs to evidence-based digital cognitive behavioral therapy supported by a coach. Like virtually-delivered behavioral health care, mental health apps also help overcome many of the barriers to mental health care noted above. As these solutions continue to evolve, focus should remain on ensuring they are high quality and evidence-based and integrated into a larger behavioral health solution set to meet the needs of patients across the spectrum of clinical need.

Virtually-Delivered Mental Health Care Is Effective to Improve Outcomes

While the rapid embrace of telehealth during the pandemic was borne out of necessity, there is indeed a rich evidence base demonstrating that virtual behavioral health delivery is effective and equivalent to face-to-face care in diverse populations and in a variety of settings. Virtual behavioral therapy has been demonstrated to be effective in treating depression, anxiety, post-traumatic stress disorder, and other common conditions.[21] When high quality virtually-delivered interventions are utilized in populations with medical comorbidities, clinical improvement in quality of life and chronic disease self-management behaviors can also be achieved, promoting reduction in avoidable hospital admissions.[22-24] Improved workplace productivity outcomes, such as reduced absenteeism and presenteeism, have also been demonstrated.[25,26] Achieving these outcomes associated with treating mental health conditions are all the more important during a time when preventive care and optimal lifestyle behaviors may be more challenging. For individuals undergoing existing mental health treatment who were concerned about risk of COVID-19 exposure, telehealth has also allowed for continuity of mental health care. That continuity is critical to mitigating adverse mental health outcomes that could have otherwise occurred as a result of delayed mental health and substance use treatment.

Simply shifting care from in-person to virtual does not guarantee quality care delivery, but utilization of technology platforms has the potential to actually maximize delivery of high-quality care by incorporating evidence-based protocol and practice guidelines. Technology platforms can also embed validated assessment tools to measure patient outcomes, enabling true measurement-based care and collection of additional patient data elements to identify high-risk patients in need of additional care resources and support care coordination efforts known to promote better mental health care outcomes.[12] Organizations supporting virtual care delivery can further optimize quality by ensuring therapist workforce training, performance management, and continuing education. Accrediting bodies have taken the opportunity to establish quality standards for telehealth. As an example, URAC (Utilization Review Accreditation Commission) became the first independent, third-party national program to offer comprehensive oversight of telehealth programs, establishing a Telehealth Accreditation designed to evaluate key pillars of quality including data privacy and patient safety and recognizing telehealth organizations that uphold these quality measures.[27]

For the last decade, we have incorporated these key quality elements into our work at AbleTo to ensure the benefits of telehealth can be truly realized and that we can deliver meaningful clinical outcomes for patients. Having a standardized platform with high-touch interactions with our national provider community proved particularly advantageous during the pandemic when we were able to deploy COVID-19 specific resources and care planning guidelines, along with training and standardized pulse surveys to gauge therapist needs and trends in patient concerns and challenges. During COVID-19, these established capabilities enabled us to quickly address behavioral health needs of patients across the nation and to drive clinically meaningful outcomes across a diverse patient population. For example, in a cohort of 2,356 adults with depression symptoms consecutively enrolled in AbleTo programs between April 1 and June 30 2020, mean reduction in symptom severity was greater than 50% overall and within demographic subgroups after $\sim$8 weeks of telebehavioral therapy (Figure 2).

Like telebehavioral healthcare, digital mental health apps are also positioned to improve the behavioral health symptoms affecting many during the pandemic. The need for more research on effectiveness of app-based programs to improve behavioral health has been acknowledged, as have features that distinguish the more efficacious apps. Quality features include apps that are cognitive behavioral therapy-based, address both anxiety and low mood, and are designed for non-clinical populations.[28] These quality features are incorporated into

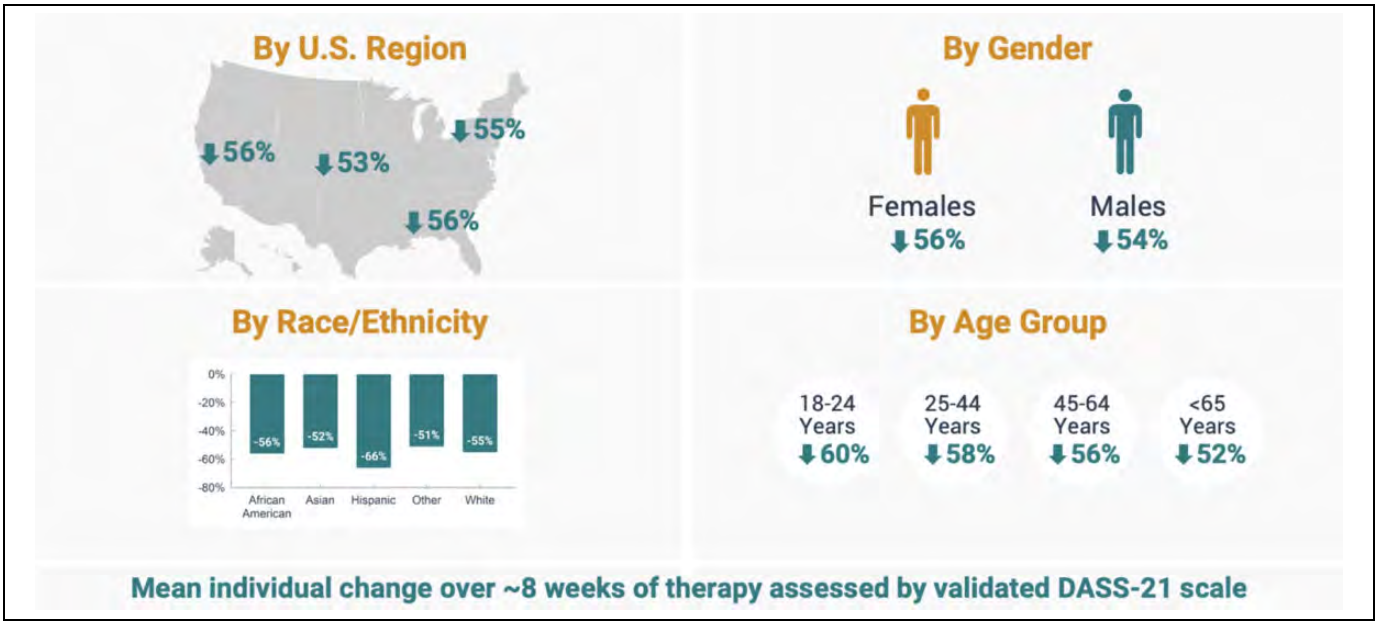

Figure 2. Observed reductions in depression symptoms after telebehavioral therapy during COVID-19.

AbleTo's digital cognitive behavioral therapy solution, which is designed to address depression, anxiety, and social anxiety. All users have the support of a coach, which has also been associated with increased adherence and efficacy versus digital programs without human support.[29] With mental health apps, one size does not fit all. OneMind PsyberGuide and the American Psychiatric Association have each published resources to inform mental health app selection for individuals, clinicians, and organizational leaders.[30,31]

Health and Well-Being Leaders Can Improve Access to High Quality Behavioral Health Care During COVID-19

Mental health has been and should remain top of mind for organizational health and well-being leaders given rapid changes to life and work arising during the COVID pandemic. Working-age adults are facing new challenges as the lines between work and home life have become more blurred. Income and job loss due to the pandemic have created new stressors and have been linked to depression and anxiety symptoms, as well as changes in sleep and dietary habits and increased substance use.[8]

Health and well-being leaders have an opportunity to positively impact the long-term physical and mental health of the nation by optimizing mental health and well-being through culture and resources available in the workplace and in communities.[32,33]

Workplace best practices associated with employee mental health and well-being were recently highlighted in a report by the Health Enhancement Research Organization (HERO; 33) and include:

- **Raise awareness** about the importance of mental health and available mental health benefits. This is a vital step toward reducing stigma and may be most effective coming from senior leadership.
- **Manage psychosocial risks related to work, environment, and culture**. This includes considerations of work-life integration, diversity and inclusion, and health and psychological safety.
- **Assess mental health needs and measure intervention impact**. Mental health is closely tied to workplace and health outcomes. Improved mental health may be associated with improved productivity and overall health.
- **Promote and provide access to high quality, evidence-based mental health care**. High quality, evidence-based mental health care is associated with the best outcomes. Access to timely and equitable care can be promoted through telebehavioral health and digital behavioral health tools.
- **Integrate of mental health into a comprehensive wellness program** that addresses multiple dimensions of wellness including social, occupational, financial, environmental, physical, intellectual, spiritual and emotional wellness.
- **Partner with local/national organizations to extend and share mental health and well-being practices** (e.g., leverage resources available through public health departments).

Each of these best practices has the potential to be positively amplified through increased awareness and by making evidence-based virtually delivered mental health solutions available and accessible to employees. These efforts are especially important to address the higher level of need seen during the COVID-19.

Future Directions

The COVID-19 pandemic has brought uncertainty, stress, and anxiety, coupled with public health measures that necessarily lead to social isolation. We are witnessing significant rates of mental health conditions and expect this trend to continue for the foreseeable future. Virtually-delivered behavioral health care is well established as an effective treatment modality, but there is still work that can be done to make it easier for those with behavioral health needs to identify high quality care and access it in a timely manner. Regulatory changes during the pandemic have made it easier for providers and individuals to engage in virtually delivered care; it is the hope of many mental

health care providers and professional organizations that these positive changes potentially associated with increased access to timely care, be made permanent. Health and well-being leaders play a vital role in reducing stigma and promoting care solutions through clear communication and an organization-wide well-being culture that prioritizes mental health. Connecting individuals with high quality mental health care, including virtually delivered solutions, during COVID-19 and beyond may help mitigate adverse workplace and health outcomes associated with untreated mental health conditions.

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Addressing the Addiction Crisis During a Pandemic

Gary Mendell, BA, MBA[1]

The addiction crisis is pervasive and is certainly intensifying due to COVID-19—up by as much as 42 percent[1] in May compared with last year. Alcohol use is up significantly,[2] and many who were in recovery have had relapses. We do not know the full implications at this time, but I can say anecdotally that there is a big increase in those suffering from substance use disorder and/or mental health issues.

Family gatherings have been postponed and casual outings with friends canceled. Not only has access to treatment and recovery supports become more difficult to access, but physical distancing is also intensifying the existing isolation those addicted already feel, due to the stigma unjustly associated with this illness. Add, COVID-related unemployment is anticipated to lead to millions more people becoming uninsured, which will make it more difficult for people with substance use disorders (SUDs) to access treatment. With an opioid-related death occurring every 11 minutes, the opioid epidemic is devastating and just getting worse. Sadly, the pandemic will have a lasting, tragic impact on many.

For many, this addiction crisis is something that happens to other people. For me, it is personal. My son Brian's struggle with addiction began in high school. Over 8 years, Brian battled his disease courageously, attending 8 different treatment programs. On October 20, 2011, I was awakened in the middle of the night and told my son had just died. Perhaps more tragic, it was not addiction that took my son's life. On his last day alive, Brian researched suicide notes, wrote one of his own, lit a candle, and took his life. Alone.

When you lose a child, you spend countless hours revisiting what you could have done differently—the moments that may have made the difference. Shatterproof, like so many other philanthropic organizations, was born from profound loss and pain. For me, dedicating the remainder of my life to helping others avoid the tragedy my family had suffered started as a tribute to my son's life and has now grown to be a tribute to millions of Americans.

And while our nation has responded to the addiction epidemic—changing prescribing practices for dangerous opioid, increasing funding for treatment and expanding the use of naloxone, a medication that can instantly reverse an overdose, there are 3 areas Shatterproof is focused—transforming addiction treatment, ending the stigma around addiction, and educating and empowering our communities.

The true key to ultimate change that must occur lies in changing the way that people think about this disease. It lies in addressing and eliminating the stigma that causes so much shame, loneliness, and ultimately, so much tragedy. In many respects, the work we are doing at Shatterproof is needed more today during the pandemic than ever before.

Transforming Addiction Treatment

We are transforming the healthcare delivery system so that every person facing addiction has access to quality care and treatment based on science, just like any other disease.

Shatterproof formed the Substance Use Disorder Treatment Task Force, with a mission to completely transform the addiction treatment system in the United States. With advice from members of the Task Force, our team developed a 5-point plan to achieve our mission to significantly improve the quality of and access to addiction treatment.

The 5-Point Plan

National Principles of Care©. Shatterproof partnered with Pew Charitable Trusts and other leading experts and established a national standard of quality care for addiction treatment that is being widely and consistently adopted by health care practitioners and payers. To date, 23 insurers representing over two hundred million Americans have adopted our Principles of Care. We are just getting started. With your ongoing support, these Principles of Care will be fully integrated into our healthcare system over the coming years.

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Prevalence of COVID-19 Related Concerns and the Association with Psychological Symptom Severity Among U.S. Adults Engaged in Telebehavioral Therapy During the Pandemic

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Prevalence of COVID-19 Related Concerns and the Association with Psychological Symptom Severity Among U.S. Adults Engaged in Telebehavioral Therapy During the Pandemic

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ABSTRACT

This study quantified and described COVID-19-related concerns and associated mental health symptom severity among a cohort of adults consecutively enrolled in a telebehavioral therapy program during the COVID-19 pandemic (N = 2,588). Demographic and clinical data were collected by standardized therapist-led interviews. COVID-19 concerns were abstracted from clinical notes. Anxious feelings (14.5%), work-related stressors (10.2%), and isolation (10.1%) were the most prevalent concerns. COVID-19 concern was associated with significantly higher stress symptom scores. These data add to our understanding of the links between pandemic-related stressors and mental health among individuals engaged in telebehavioral health care.

KEYWORDS

Mental health; psychosocial intervention; depression; social work; cognitive behavior intervention

Introduction

The Coronavirus Disease 19 (COVID-19) global health pandemic has impacted individuals and communities, with a staggeringly high and growing case rate in the United States (U.S.) (Cases in the U.S., 2020) and internationally. Individuals have been adapting to the rapidly changing and unpredictable conditions as a result of the pandemic. Adverse psychological implications, including a near tripling in the prevalence of depression and anxiety symptoms, have been documented (Czeisler et al., 2020; Dubey et al., 2020; Ettman et al., 2020; Wang et al., 2020). Furthermore, factors including social isolation, job or income loss, and general worry about COVID-19 have each been linked to the rise in symptom prevalence, in particular, among those with poor physical health (Panchal et al., 2020).

To meet the growing mental health-care need, the availability of telebehavioral health-care services (i.e., behavioral health care delivered by licensed clinicians via telehealth technology) has eased access to psychotherapy

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(Centers for Disease Control and Prevention, 2020; Rosen, Glassman, & Morland, 2020). Access is eased through the reduction of traditional barriers to face-to-face delivery (e.g., provider shortages, transportation challenges, physical health limitations, and stigma) as well as through providing a care delivery modality during a time when face-to-face delivery may not be a viable option due to limitations to in-person health-care services and physical distancing protocols.

Little is known about the clinical presentation of individuals who have engaged in telebehavioral therapy during the COVID-19 pandemic and data from standardly delivered telebehavioral health services provide a new opportunity to evaluate and learn at scale. Understanding of the common concerns reported by individuals receiving remotely delivered psychological services during the COVID-19 pandemic is important to optimize and inform clinical program development and patient outcomes.

Accordingly, this study aimed to quantify and describe the common presenting concerns among a cohort of adults with medical and behavioral health comorbidities who engaged in telebehavioral therapy during the pandemic. A second aim was to describe the association between having a COVID-19-related concern and depression, anxiety, and stress symptom severity in the same cohort.

Method

Program participants and setting

In this retrospective cohort study, we analyzed previously collected and de-identified clinical data from a consecutively enrolled cohort of 2,588 adults who completed an initial consultation in a protocolized telebehavioral therapy program (AbleTo) comprised of therapy by licensed therapists supported by trained behavioral coaches, for individuals with preexisting medical conditions and coexisting behavioral health conditions during a 3-week period of the COVID-19 pandemic (March 23, 2020-April 11, 2020 inclusive). AbleTo is a U.S.-based telebehavioral health-care provider with a network of over 1,700 licensed therapists and trained behavioral coaches. Specific details of this program have been previously described (Dent, Peters, Kerr, Mochari-Greenberger, & Pande, 2018); briefly, the initial consultation consisted of a standard psychosocial interview and mental health evaluation completed by a licensed therapist (clinical social worker [LCSW] or equivalent), including a standardized psychometric assessment. At the time of the initial consultation, eligible participants, who were ≥18 years old and had access to a telephone, were enrolled in a behavioral health program specific to their given diagnosis, presenting concerns, and treatment goals. All sessions were completed in approximately 45 minutes and conducted via the Health Insurance Privacy

and Accountability Act (HIPAA)-compliant secure video or telephone based on participant preference. Some individuals who completed an initial consultation were deemed clinically ineligible for program enrollment for factors such as acute suicidal risk, recent psychiatric hospitalization, or cognitive impairment; these individuals were directed to the appropriate community resource per standard protocolized guidelines.

HIPAA-trained research staff performed a retrospective record review to extract de-identified participant data for this analysis. The Sterling Institutional Review Board (IRB) approved the protocol for this research.

Measures

Participant characteristics

The initial consultation included structured validated assessments with psychiatric and medical history completed by licensed therapists. Participant sociodemographic characteristics including age, race/ethnicity, sex, U.S. region, health plan type, relationship status, household members, and employment status were systematically collected as part of this standardized clinical assessment. A standardized question was used to assess self-rated health: In general, would you say your health is: 1. excellent, 2. very good, 3. good, 4. fair, or 5. poor (36-Item Short Form Survey, n.d.).

COVID-19 concerns

Per protocol, primary concerns were assessed during the initial consultation by asking the participant about current physical and emotional health conditions that are most pressing at that time; concerns noted in this conversation were documented in the participants' clinical chart.

COVID-19-related concerns were abstracted from clinical progress notes from the initial consultation via clinical chart review (Sarkar & Seshadri, 2014). Prior to data abstraction, an a priori list of codes was gathered from the literature to guide a thematic analysis (Braun & Clarke, 2006). Major themes within the therapist notes that aligned with the a priori list were systematically documented in a de-identified electronic form and refined during data abstraction. This coding process allowed for the abstraction and sorting of the notes by themes, which exposed the range of participant concerns. Codes were continuously refined during the data collection process. The final list of themes (Health, Isolation, Finances, Anxiousness, Barriers to Care, Work, COVID-19 Diagnosis, Other) along with definitions and subthemes can be found in Figure 1.

Behavioral health symptoms

Psychiatric symptoms were measured at the initial consultation using the Depression Anxiety Stress Scales 21 (DASS-21) (Depression Anxiety Stress

Theme	Definition	Subtheme
Health	Any comments that reveal that the participant is concerned about the health of themselves and/or health of their loved ones due to COVID-19	Concerned about their own health Concerned about the health of their loved one(s) Concerned about their own heath and the health of their loved one(s)
Isolation	Any comments that reveal that the individual feels isolated, lonely, or restricted as a result of quarantine due to COVID-19	N/A
Finances	Any comments that reveal current struggle or worry about finances due to COVID-19	N/A
Anxiousness	Any comments that reveal current stress or worry (but details are not specified) due to COVID-19	N/A
Barriers to Care	Any comments that reveal that the participant cannot access medical services due to COVID-19	N/A
Work	Any comments that reveal that the participant has concerns about work due to COVID-19	Concerns about layoffs, unemployment, furloughs, pay cuts, time cuts, as it relates to themselves or a loved one Concerns about a stressful work environment (i.e., increased work hours, larger workload) Concerns about being an essential employee and having to go into work Other work-related concerns such as general changes to the work environment (i.e. working from home)
COVID-19 Diagnosis	Any comments that reveal that the participant has been or is currently diagnosed with COVID-19	N/A
Other	Any comments that reveal the participant has concerns related to COVID-19, but do not fall into any of the above categories	N/A

Figure 1. Themes, definitions, and subthemes of COVID-19 concerns among U.S. adults engaged in telebehavioral health care during COVID-19.

Scales [DASS], 2018). The DASS-21 is a 21-item instrument that contains three seven-item scales to assess symptoms of 1) depression, 2) anxiety and 3) stress. The validity of the DASS-21 has been documented across various populations (Antony, Bieling, Cox, Enns, & Swinson, 1998; Henry & Crawford, 2005; Norton, 2007). Scores within each 7-item domain range from 0 to 42 points, with higher scores indicating greater symptom severity. Established cut-points used to classify above-normal symptom scores were a

depression score >9 points, an anxiety score >7 points, and/or a stress score >14 points (Depression Anxiety Stress Scales [DASS], 2018).

Statistical analysis

Baseline characteristics were presented overall and stratified by the presence of a COVID-19-related concern (yes versus no) using descriptive statistics. Differences in the distribution of baseline characteristics by the presence of COVID-19-related concern(s) were assessed using t-tests and chi-square statistics for continuous and categorical variables, respectively. Multivariate linear regression was used to model the association between DASS-21 symptom score severity and the presence of having a COVID-19-related concern at initial consultation, adjusted for age (years), race/ethnicity, sex, U.S. region, health plan type (commercial/Medicare Advantage), relationship status (partner/no partner), living alone (yes/no), and employment status (unemployed/not unemployed). The factors included in the multivariate model were selected based on a significance level of p <.05 in the univariate analyses of the association between each variable and DASS-21 score; age, race/ethnicity, and U.S. region were included in the model regardless of significance level as an a priori specification. Analyses were conducted using SAS statistical software, version 9.4, SAS Institute, Cary NC.

Results

Baseline characteristics

Baseline demographic and clinical characteristics, overall and stratified by the presence of a COVID-19-related concern, are described in Table 1. Overall, one-quarter (26.0%) of the participants were males and the median age was 61.0 [46.0–74.0] years. The participant cohort was 34.8% nonwhite race/ethnicity and participants were geographically distributed across the U.S. Over half (56.3%) of the participants were members of a commercial health plan, while the remaining portion (43.7%) were members of a Medicare Advantage health plan. Approximately one-quarter (22.1%) of the participants lived alone and more than one in three reported their health as fair or poor (35.0%).

COVID-19 concerns

Almost half (42.5%) of the participants reported at least one COVID-19-related concern at baseline. Females and participants living alone were more likely to report a COVID-19-related concern versus males and those not living alone, respectively (Table 1). The most common concerns reported

Table 1. Baseline characteristics of participants engaged in a telebehavioral health program during COVID-19, stratified by the presence of a COVID-19-related concern (N = 2,588).

Baseline characteristic	Overall *n*	COVID-19 Concern (Yes) *n*	%	*P value*
Age				.07
18–40	494	227	46.0	
41–55	525	235	44.8	
56–65	485	206	42.5	
66–75	540	227	42.0	
75+	544	205	37.7	
Sex				<.0001
Male	674	243	36.1	
Female	1914	857	44.8	
Race/Ethnicity[a]				.19
African American	450	178	39.6	
American Indian	8	3	37.5	
Asian	39	16	41.0	
Hispanic or Latino	189	83	43.9	
White	1686	735	43.6	
Pacific Islander	9	5	55.6	
Mixed	38	22	57.9	
Other	67	24	35.8	
Decline to Answer	100	34	34.0	
Health Insurance Type				<.0001
Commercial	1456	674	46.3	
Medicare Advantage	1132	426	37.6	
U.S. Region				.02
Midwest	438	198	45.2	
Northeast	612	279	45.6	
South	1159	453	39.1	
West	379	170	44.9	
Living Alone [c]				.02
Yes	570	266	46.7	
No	2015	832	41.3	
Employment				<.0001
Full or part time employed	1072	511	47.7	
Disability leave	208	69	33.2	
Retired	1055	404	38.3	
Not currently working for pay	163	69	42.3	
Maternity leave	16	7	43.8	
Other	74	40	54.1	
Relationship Status				.04
Divorced	359	152	42.3	
Married	1304	547	42.0	
Married, but separated	53	19	35.9	
Partnership	120	61	50.8	
Single	412	194	47.1	
Widow or widower	340	127	37.4	
Self-Rated Health				.01
Poor or fair	905	355	39.2	
Good, very good, excellent	1683	745	44.3	

[a]Analytic sample comprised 2586/2588 participants; n = 2 missing
[b]Analytic sample comprised 2585/2588 participants; n = 3 missing

included anxious feelings associated with the pandemic (14.5%), work-related stressors (10.2%) and isolation (10.1%). Health-related COVID-19 concerns were reported by approximately 8.5% of the participants. Meanwhile, compared to the common concerns, fewer participants were concerned about barriers to care (5.3%), financial stressors (1.5%), and/or

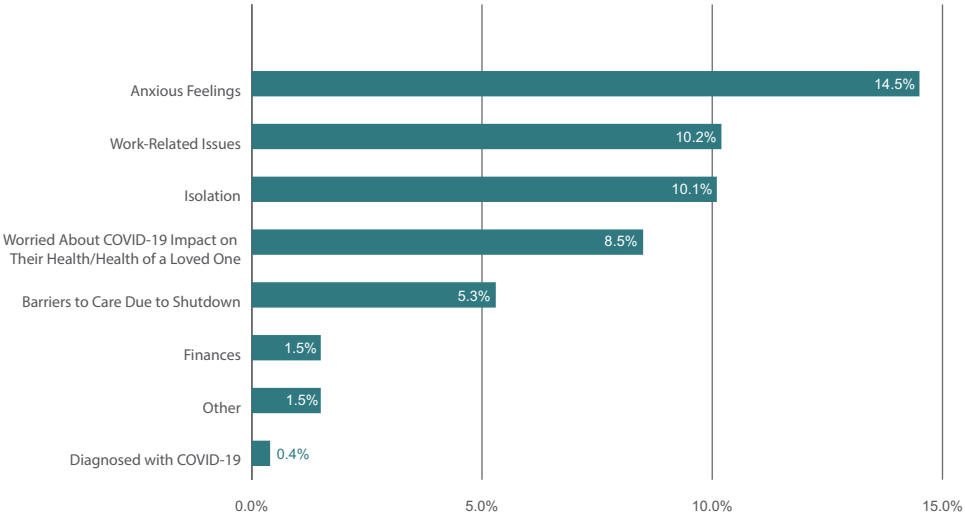

Figure 2. Prevalence and types of COVID-19 concerns among U.S. adults engaged in telebehavioral health care during COVID-19 (N = 2588).

a COVID-19 diagnosis at baseline (<1.0%) (Figure 2). When limiting the study sample to include only those participants with one or more COVID-19 concerns at baseline, more than one in three participants was noted to have pandemic-related anxious feelings (34.2%); work-related concerns and concerns about isolation were reported by one in four (23.9% and 23.7%, respectively).

Clinical symptom severity and COVID-19 concerns

Participants with a COVID-19-related concern were more likely than those without a concern to have above-normal threshold DASS-21 stress scores (45.3% versus 41.0%; p = .04); prevalence of above-normal DASS-21 anxiety scores was also proportionally higher but not statistically associated with having a COVID-19-related concern (43.1% versus 42.1%; p = .59). Conversely, the prevalence of above-normal DASS-21 depression scores was proportionally lower among participants with versus without a COVID-19-related concern (41.3% versus 43.5%; p = .28). Similar patterns were observed when comparing the mean DASS-21 scores among participants with and without COVID-19 concerns (Figure 3).

In multivariate analysis, the presence of a COVID-19-related concern remained significantly associated with higher DASS-21 stress symptom scores after adjustment for covariates (Table 2). Female sex, having a partner, and having poor or fair self-rated health were also independently associated with higher stress scores.

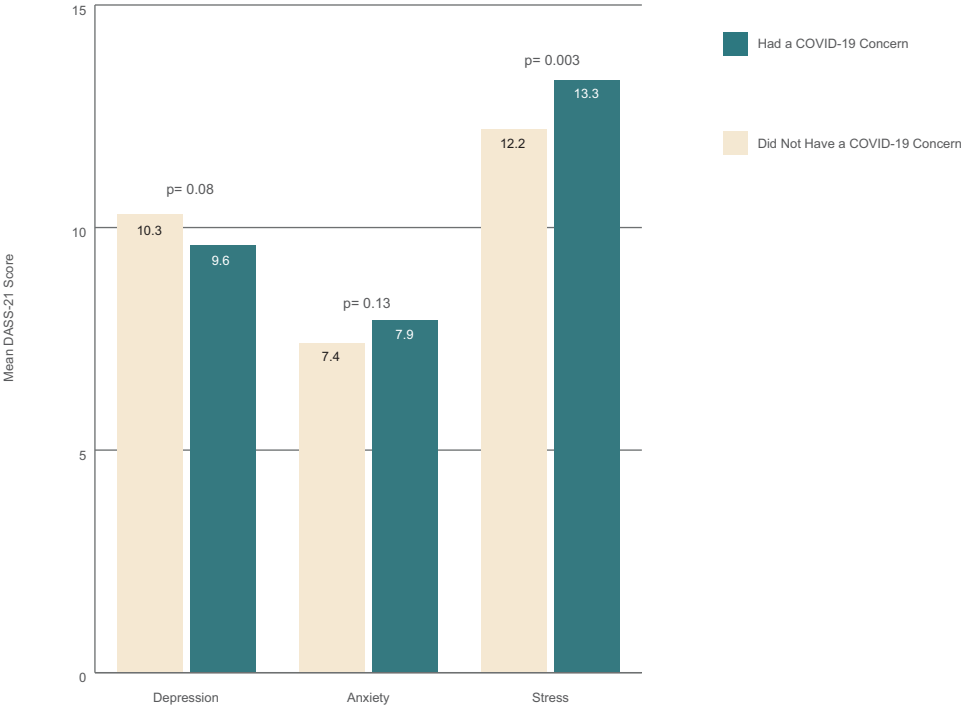

Figure 3. Mean baseline depression anxiety stress scales scores stratified by the presence of a COVID-19-related concern (N = 2579).

Table 2. Multivariate associations between the presence of a COVID-19-related concern, adjusted for sociodemographic and clinical characteristics.

Effect	DASS-21 Depression			DASS-21 Anxiety			DASS-21 Stress		
	Estimate	*SE*	*p*	Estimate	*SE*	*p*	Estimate	*SE*	*p*
Fixed effects									
Intercept	−0.9	0.82	0.291	2.4	0.67	<.001	10.3	0.76	<.001
COVID-19 Concern (Yes vs. No)	−1.2	0.27	<.001	0.3	0.22	0.179	0.8	0.26	0.001
Age (Years)	0.03	0.01	0.007	−0.02	0.01	0.013	−0.1	0.01	<.001
Female (Yes vs. No)	−0.2	0.31	0.518	0.5	0.25	0.049	0.9	0.30	0.004
White Race/Ethnicity (Yes vs. No)	1.3	0.29	<.001	−0.9	0.24	<.001	0.4	0.28	0.148
Region (Midwest)	0.4	0.48	0.381	−0.4	0.39	0.358	−1.0	0.46	0.032
Region (Northeast)	0.4	0.44	0.409	−0.4	0.36	0.280	−0.6	0.42	0.191
Region (South)	−0.1	0.40	0.741	−0.3	0.33	0.345	−0.2	0.39	0.587
Region (West)	0.0	-	-	0.0	-	-	0.0	-	-
Health Plan Type (MA vs. Commercial)	0.1	0.40	0.889	1.2	0.33	<.001	−0.5	0.38	0.168
Unemployed (Yes vs. No)	2.1	0.55	<.001	0.1	0.45	0.906	−1.1	0.53	0.040
Has Partner (Yes vs. No)	−1.2	0.32	<.001	−0.4	0.26	0.092	1.3	0.31	<.001
Lives Alone (Yes vs. No)	1.6	0.39	<.001	−0.7	0.32	0.028	−0.4	0.38	0.249
Self-Rated Health (Poor, Fair vs. Good, Very Good, Excellent)	2.1	0.28	<.001	1.2	0.23	<.001	−1.0	0.27	.001
Baseline Depression Score	-	-	-	0.2	0.02	<.001	0.4	0.02	<.001
Baseline Anxiety Score	0.3	0.02	<.001	-	-	-	0.5	0.02	<.001
Baseline Stress Score	0.5	0.02	<.001	0.4	0.02	<.001	-	-	-

The directional association between having a COVID-19 concern and lower DASS-21 depression scores observed in univariate analysis was statistically significant after multivariate adjustment. White race/ethnicity, not having a

partner, living alone, unemployment, and fair/poor self-rated health were each independently associated with higher depression scores.

Discussion

Our research conducted in a U.S.-based sample contributes new information to the field about prevalence and types of self-reported COVID-19-related concerns, as well as the association with mental health symptom severity among adults with medical and behavioral health comorbidities. Almost half of participants brought up at least one COVID-19-related concern during their initial consultation. These concerns were diverse in nature and ranged from health to social and economic stressors. The types of concerns observed illustrate the considerable impact of the COVID-19 pandemic.

The most prevalent concerns documented were anxious feelings related to the pandemic, work-related stressors, concerns about isolation, and concerns about one's own health and the health of family members. These top concerns are consistent with the early phase/acute concerns documented during COVID-19 and other pandemics that have resulted in quarantine guidelines (Brooks et al., 2020; Wang et al., 2020). Most recently, for example, a cross-sectional study conducted in a convenience sample in China during the beginning of the pandemic, documented moderate to severe self-reported psychological impact of the pandemic in over 50% respondents (Wang et al., 2020). Similar to our study, this study showed a high prevalence of concerns related to the health of family members and a link between having this concern and higher psychological impact of the pandemic (Wang et al., 2020). In a research conducted during the 2003 severe acute respiratory syndrome (SARS) epidemic in Toronto, Canada, close contacts of potential SARS cases also expressed concern about the health of others (Reynolds et al., 2008). Work-related concerns, common in our study (10.2%), were also common in a cross-sectional online survey conducted in 28 different countries to investigate fears associated with COVID-19 (9.6% of the respondents indicated worry related to job security) (Mertens, Gerritsen, Duijndam, Salemink, & Engelhard, 2020). Work-related concerns, such as missing work and not receiving a paycheck, were observed during the 2003 SARS outbreak as well (Blendon, Benson, DesRoches, Raleigh, & Taylor-Clark, 2004), as were concerns related to isolation during a time of quarantine (Cava, Fay, Beanlands, McCay, & Wignall, 2005; Hawryluck et al., 2004; Reynolds et al., 2008).

This research also documented that patients were able to express their concerns to a therapist in a virtual care delivery environment. Indeed, previous research has demonstrated that therapeutic alliance can be developed and maintained in telebehavioral health-care delivery settings, not limited to the landscape of a public health crisis (Jenkins-Guarnieri, Pruitt, Luxton, &

Johnson, 2015; Lopez, Schwenk, Schneck, Griffin, & Mishkind, 2019). For example, a review of 23 studies that evaluated therapeutic alliance in the context of virtual psychotherapy determined equivalence in how patients rated therapeutic alliance versus in-person treatment; patients with a diverse range of diagnoses rated their bond with the therapist, and therapist presence during virtual psychotherapy, at least equally as strongly as in-person care delivery (Simpson & Reid, 2014). Our research conducted in a U.S.-based sample contributes new information to the field about the frequency and types of concerns among adults engaged in telebehavioral health care during the COVID-19 pandemic.

In addition to outbreak-related concerns, the vast literature documents the mental health consequences that arise as a result of public health crises such as pandemics and national disasters (Brooks et al., 2020; Gibson, Walsh, & Brown, 2018; Goldmann & Galea, 2014; Makwana, 2019; Wang et al., 2020). A deep dive into the reviews of current and past public health crises on mental health shows that stress reactions and anxiety are commonly observed in the early phases of a pandemic (Goldmann & Galea, 2014; Wang et al., 2020). Our study may be one of the first studies to document a link between expressing a pandemic-related concern during therapy and stress symptom severity among adults engaged in mental health care during the early months of the COVID-19 pandemic. However, other studies have connected anxiety symptoms to COVID-19 concerns (Wang et al., 2020) and the DASS-21 stress scale is known to measure symptoms of anxiety, including difficulty relaxing, irritability, and nervous tension (Depression Anxiety Stress Scales [DASS], 2018; Peters et al., 2019). Importantly, these data may be added to the growing body of evidence linking COVID-19-related concerns to psychiatric conditions that may be used to optimize screening strategies to identify those in need of mental health care.

These data also highlight the effective use of standardized psychological symptom assessment instruments in a virtual care delivery setting. The value of measurement-based care is well established as this type of care allows for greater insight into patient progress, helps inform treatment-related decisions, facilitates care coordination or collaboration, enhances patient engagement in their treatment, and has been linked to improved clinical outcomes (Kilbourne et al., 2018; Lewis et al., 2019). Moreover, the utility of standardized assessment throughout treatment is potentially amplified during the COVID-19 pandemic when changes in symptom severity as a result of exposures and experiences related to the pandemic are less established or predictable. This research is timely due to the uncertainty and magnitude of the COVID-19 outbreak; nevertheless, longer term associations remain to be seen, and there is a need to understand whether the presence of pandemic-related concerns is linked to sustained behavioral health symptom severity.

In this study, participants with a COVID-19 concern showed patterns of lower average depression symptom severity versus those presenting to therapy without a COVID-19 concern. This observation was counter to our hypothesis that depression scores would be higher among individuals with a COVID-19-related concern; however, this may be due to the fact that these data were collected in the early phase of the pandemic and that depression symptoms may be more likely to be present in later phases or in the aftermath of the pandemic. A review of large-scale disasters of varying types (i.e., natural [e.g., hurricanes, tornados], human-made [e.g. terrorist attacks, mass shootings] and other incidents of mass trauma [e.g., disease outbreaks, oil spills]) show that such events are accompanied by a broad range of mental and behavioral health conditions, such as depression, substance use disorder, and/or post-traumatic stress disorder that can occur in the aftermath and persist over longer periods of time (Neria, Nandi, & Galea, 2008). Wilson-Genderson, Heid, and Pruchno (2018), investigated the long-term impact of natural disasters on depressive symptoms and documented a significant increase in depressive symptoms post-disaster that was predicted by peri-traumatic stress and disaster-related hardship, thus suggesting longer term risk for depression among those presenting with stress symptoms proximal to a tragic event.

While the observational design of this research did not allow for causal inferences related to the impact of COVID-19 on mental health symptoms, the finding that individuals with COVID-19-related concerns present with higher stress and anxiety symptoms and lower depression symptoms versus their counterparts without those concerns may be valuable to inform programs and care plans to support patients during the COVID-19 pandemic. Notably, data in this study were collected in the early phases of the COVID-19 pandemic and concerns could have been magnified by the uncertainty of disease progression, lack of basic household supplies, and vague information from media outlets (Li et al., 2020). While we aimed to mitigate risk of misclassification bias of COVID-19-related concerns through a second code reviewer, this is a known limitation in qualitative research (Lavrakas, 2008; Sarkar & Seshadri, 2014).

Although the effectiveness of telebehavioral therapy to improve access and reduce psychological symptom severity is well established for common mental health conditions (Hubley, Lynch, Schneck, Thomas, & Shore, 2016; Varker, Brand, Ward, Terhaag, & Phelps, 2019), a strength of this study was the opportunity to describe participant utilization and clinical presentation at scale in a large and diverse sample of participants seeking telebehavioral health care during the pandemic. The availability of results from standardized and validated symptom assessment, in conjunction with the ascertainment of primary concerns, provided a real-world example of how mental health symptoms and challenges can be considered and integrated into treatment planning as recommended in treatment guidelines (Kendrick & Pilling, 2012). This is important not only at initial assessment

but throughout the course of treatment as symptoms and patient needs may have been impacted by the evolving COVID-19 pandemic as well as other factors. We acknowledge that heterogeneity in our sample may limit our ability to draw conclusions about the prevalence of concerns among select subgroups (e.g., isolating the subgroup of the sample that is employed to study prevalence of work-related concerns) and this is a potential area for future study.

This study documented wide-ranging concerns among individuals presenting to telebehavioral health care during the early weeks of the COVID-19 pandemic. Common COVID-19 concerns and their link to behavioral health symptoms is new information that may be helpful for clinicians, researchers, and policy makers as they refine and develop resources and patient-specific care plans to address mental health needs during unprecedented public health crises. Future research should explore how COVID-19-related concerns and associated psychological symptom severity have changed over the course of the pandemic, as well as how individuals have responded to behavioral health treatment during the COVID-19 pandemic.

Disclosure statement

N.L. Kashine is an employee of AbleTo. H. Mochari-Greenberger is an employee of and holds an equity interest in AbleTo. E. Andreopoulos is an employee of AbleTo. R.L. Pande is an employee of and holds an equity interest in AbleTo; she serves as AbleTo's Chief Medical Officer.

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