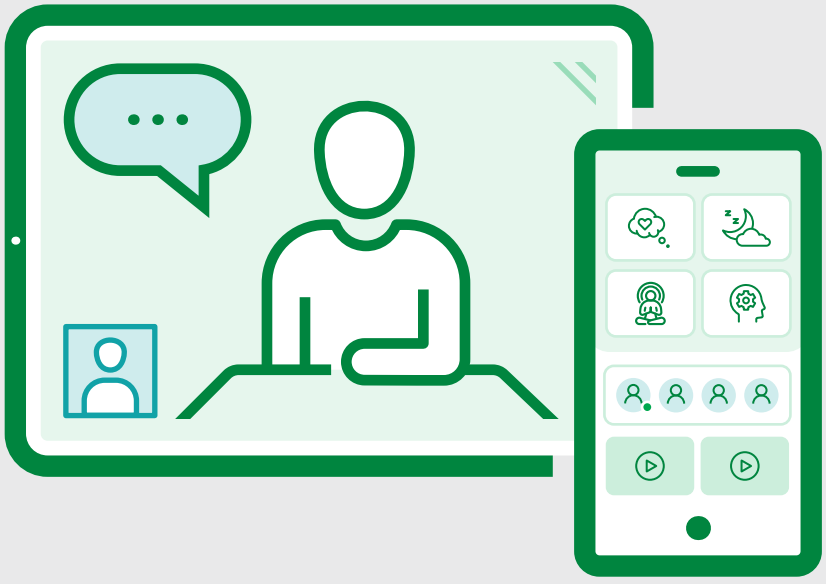
PETERSON HEALTH TECHNOLOGY INSTITUTE

Virtual Solutions for Depression and Anxiety

HEALTH TECHNOLOGY ASSESSMENT | MAY 2025 | V1.1



PHTI.org

About This Report

The Peterson Health Technology Institute (PHTI) provides independent evaluations of innovative healthcare technologies to improve health and lower costs. Through its rigorous, evidence-based research, PHTI analyzes the clinical benefits and economic impact of digital health solutions.

These evaluations inform decisions for providers, patients, health plans, and investors, accelerating the adoption of high-value technology in healthcare.

PHTI focuses on health technologies designed to replace or augment traditional care delivery, including digital therapeutics, chronic care management apps, and remote patient monitoring technologies.

PHTI selects assessment topics based on the:

- Burden of disease to the healthcare system;
- Investment and innovation in the digital health technology;
- Body of evidence about the effectiveness of the technology; and
- Stakeholder interest (purchasers, providers, and patients).

PHTI assessments evaluate evidence of the clinical and economic impact of these technologies using the ICER-PHTI Assessment Framework for Digital Health Technologies, which was designed by a team of experts specifically for digital health products and solutions. This is a secondary research review that relies on published literature and information, as well as proprietary data submitted directly from companies. PHTI did not conduct original testing of the products. All companies included in this report were notified and given an opportunity to submit clinical, commercial, and/or economic data, which were included in the evaluation if eligible.

The economic models used in this report are intended to compare clinical outcomes and expected costs at the population level. Model results represent average findings and should not be presumed to represent cost or outcomes for any specific patient or payer.

The findings and recommendations contained within this report represent the opinions of PHTI based on the information considered in this assessment. The findings are current as of the date of publication. Readers should be aware that new evidence may emerge following the publication of this report that could influence the results. Solutions are likely to evolve over time, which may impact their performance. PHTI may revisit its analyses in updates to this report in the future.

The Peterson Health Technology Institute

PHTI was founded in 2023 by the Peterson Center on Healthcare, a nonprofit organization dedicated to making higher-quality, more affordable healthcare a reality for all Americans. PHTI and the Center are wholly owned subsidiaries of, and are funded entirely by, the Peter G. Peterson Foundation. PHTI does not accept financial contributions.

V1.1 was posted on June 6, 2025.
It includes more information on Lyra's solution-specific economic analysis and a revision to reflect that Lyra does offer performance guarantees (p. 57).

Table of Contents

Letter From the Executive Director

Nearly all of us know someone—a family member, friend, or colleague—who has struggled to access mental healthcare when they needed it. Even for those with good insurance who live in well-resourced areas, finding a therapist can mean waiting weeks or months for an initial appointment. For those in rural areas or with limited resources, the situation is even more challenging, with many unable to access care at all.

Fortunately, research shows that with the help of technology, people can now access clinically effective mental healthcare at the times and places they need it. This extends well beyond a live, virtual therapy session and can include asynchronous video and messaging-based therapy, as well as self-guided videos and online activities that are shown to reduce symptoms of anxiety and depression.

The promising digital tools reviewed in this report demonstrate clinically meaningful reductions in depression and anxiety scores that are comparable to traditional therapy. These digital solutions can improve access to care and address workforce shortages by creating scalable, effective treatment options that do not depend on one-on-one engagement with a provider. They also offer a wider range of treatment modalities that may be more appealing to some users.

Yet, thoughtful deployment of virtual solutions must carefully consider which treatment options are appropriate for which users and how broader access will impact healthcare spending. Both self-guided solutions and prescription digital therapeutics improve users' symptoms enough to help reduce net health spending, because savings from health improvements offset the solution prices.

Employer purchasers, however, are largely gravitating to more comprehensive, blended-care solutions that integrate digital tools and networks of therapy providers. Most of these solutions currently charge access fees for all employees—not just those who sign up to use the solution. As a result, even though these solutions deliver strong clinical benefits, the avoided healthcare costs from users cannot offset the overall prices charged for the product.

To avoid a potentially significant increase in healthcare spending, health plans and employers need to play an active role in negotiating the prices for these mental health solutions and in determining how they are deployed to their members or workers. Employers should consider adopting these solutions in lieu of their existing employee assistance plans (EAPs) and should work to bring down across-the-board, per member per month fees.

Purchasers should partner with solution vendors to guide users who are experiencing more mild symptoms toward lower-cost digital content, to avoid overuse of therapy services. Vendors should also be using therapy to address more acute mental health episodes, subsequently relying on digital content to sustain symptom improvements over time.

As a healthcare system, we should champion the success of these virtual solutions at improving access and outcomes, and we must be diligent in supporting thoughtful, financially sustainable, and clinically appropriate growth of these solutions for the people who need them.

Sincerely,

Caroline Pearson, Executive Director
Peterson Health Technology Institute

Report Contributors and Reviewers

PHTI partners with a diverse set of contributors, advisors, and stakeholders. Those who directly contributed to this report are listed below. See our website for a full list of partners and advisors, including our Advisory Board and Purchaser Advisory Council, who offer general guidance but do not participate in the assessment process.

Clinical Advisors

The following clinical advisors provided expertise about usual clinical care for depression and anxiety, digital solutions, and primary and secondary health outcomes. The clinical advisors have no conflicts of interest with respect to this assessment.

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Evaluation Partners

The following independent evaluation partners contributed to this report. The evaluation partners have no conflicts of interest with respect to this assessment.

- Curta assessed the clinical and economic impact of these technologies, including a systematic literature review and budget impact assessment, using the ICER-PHTI Assessment Framework.
- Charm Economics developed insight into how different technologies work, what they cost to deliver, and their impact on patients and purchasers.
- The Institute for Clinical and Economic Review (ICER) codeveloped the ICER-PHTI Assessment Framework for Digital Health Technologies and reviewed the framework's implementation in this report.

Other Partners

Manatt Health provided consulting, research, and operational support throughout the development of the report.

Patient Perspectives

PHTI collaborated with The Center for Innovation and Value Research, Savvy Cooperative, and Survey Healthcare Global to conduct patient and focus group interviews.

Company Submissions

PHTI directly engaged companies included in the report and accepted submissions of public and proprietary information to inform the assessment. PHTI did not conduct any primary analysis of company data. PHTI applied the same standards for minimum evidence requirements and risk of bias reviews to company-submitted information as to all other studies included in the report. Companies did not influence the assessment methods or findings.

Report contributors and reviewers provided important expertise and insight throughout our process. PHTI is solely responsible for the report and its findings.

Executive Summary

Depression and anxiety are two of the most common mental health conditions in the United States, affecting more than one in five adults. For individual patients, these conditions can result in impaired focus, reduced motivation, disruptions to daily functioning, and suicidal ideation. Nationally, these disorders carry a significant economic burden—accounting for $240 billion in treatment costs,[1] as well as lost productivity.

Despite growing rates of depression and anxiety, many people with symptoms do not receive effective treatment. Provider shortages, out-of-pocket costs, limited insurance networks, social stigma, and poor follow-up care leave many patients with limited or no access to care.

Virtual solutions for depression and anxiety aim to improve patients' symptoms and expand access to timely care. The report evaluates 15 solutions that offer digital programs that include on-demand digital content libraries and activities. Some solutions also provide more comprehensive platforms that integrate care from clinical providers.

The solutions reviewed in this report can be grouped into three broad categories, based on both the primary purchaser and the components of the solution offerings.

1 **Self-Guided Solutions** offer a range of digital content, including lessons and activities, that users can access anytime and select topics that meet their needs. Some also offer coaching support to reinforce skills and increase engagement. These solutions are typically sold directly to employers or health plans.

2 **Prescription Digital Therapeutics (PDTs)** are FDA-cleared, software-based digital therapies that are sold to providers and must be prescribed to patients. Similar to the self-guided solutions, these solutions deliver digitized behavioral interventions, which can be used in conjunction with clinician-supervised outpatient treatment.

3 **Blended-Care Solutions** build on the self-guided digital content by integrating virtual care teams with licensed therapists and psychiatrists who can deliver comprehensive mental health treatment, including psychotherapy and medication management when appropriate. Blended-care solutions are primarily sold to employers or health plans.

INCLUDED COMPANIES BY CATEGORY

Self-Guided Solutions

- AbleTo*
- Dario
- Headspace*
- Learn to Live
- Meru Health*
- SilverCloud
- Talkspace*
- Teladoc*

Prescription Digital Therapeutics

- DaylightRx
- Rejoyn

Blended-Care Solutions

- AbleTo*
- Brightside
- Headspace*
- Koa Health
- Lyra
- Meru Health*
- Modern Health
- Spring Health
- Talkspace*
- Teladoc*

Note: * Companies offering both self-guided and blended-care solutions.

PHTI Assessment Approach

This evaluation has two primary components: clinical effectiveness and economic impact, as described in the ICER-PHTI Assessment Framework for Digital Health Technologies. Findings are based on evidence from a systematic literature review, company-submitted information, and company website review.

Clinical Effectiveness: The report assesses the clinical effectiveness of these virtual solutions in improving symptom severity, as measured by validated scales such as the PHQ-9 for depression and the GAD-7 for anxiety. The minimum clinically important difference in outcomes is a reduction of five points or more in PHQ-9 scores for depression or a reduction of four points or more in GAD-7 for anxiety compared to patients' baseline scores. The evaluation also reviews other measures like psychosocial functioning, workplace productivity, engagement metrics, and health equity outcomes. The evidence base was sizeable with 130 articles meeting inclusion criteria, including many comparative studies with low risk of bias. All studies had a relatively short duration of follow-up, typically 6 to 12 weeks.

Economic Impact: The evaluation measures economic impact on total healthcare spending using a one-year budget impact model for commercial payers, which is the primary market where these solutions are being sold. The model estimates the number of adults who could be eligible for virtual solutions for depression and anxiety, the gross reduction in expected healthcare spending resulting from improved mental health outcomes for patients participating in these programs, and the net impact on health system spending once such savings are offset by the cost of the virtual solutions. The model also estimates spending impacts for Medicare and Medicaid.

Stakeholder Engagement: During the assessment process, PHTI partnered with clinical advisors, experts in health technology assessment, and health economists. PHTI also conducted interviews with patients with anxiety and/or depression who had experience with virtual solutions. All companies included in the report were given an opportunity to submit clinical, economic, and other commercial information to inform the assessment; 14 of the 15 companies engaged with PHTI during the assessment process, and 10 submitted evidence.

Summary of Findings

Based on PHTI's review of the clinical evidence, virtual solutions that include digital content improve symptoms of depression and anxiety, particularly for people who are not otherwise receiving mental health therapy. These solutions have the potential to improve access to care and health outcomes. Users who experience improvements in depression and anxiety symptoms also reduce their healthcare spending. However, the net impact on overall spending varies by payer and category.

Self-Guided Solutions: For people not otherwise receiving psychotherapy, self-guided solutions demonstrate clinically meaningful improvements in depression symptoms (6.9-point reduction in PHQ-9) that significantly outperform control conditions (3.9-point difference). In most studies, these solutions also deliver clinically meaningful improvements in anxiety symptoms for people not receiving therapy. Improvements in depression and anxiety symptoms were more modest for people receiving usual care. At a relatively low price point (estimated at $2 per member per month [PMPM]), these solutions reduce net healthcare spending in commercial settings by $0.30 PMPM, or $3.6M per million members, making them an economically attractive option for broad-based expansion of mental health treatment for commercially insured populations.

Prescription Digital Therapeutics: Evidence reviewed indicated that PDTs used in conjunction with usual care produce clinically meaningful improvements in depression and anxiety symptoms that exceed outcomes with usual care alone. Because these solutions are expected to be reimbursed on a per user basis (estimated at $280 per episode) rather than across all plan members, they generate net savings of $0.72 PMPM, or $8.7M per million commercial members. At these reimbursement rates, PDTs would also reduce total healthcare spending in Medicare. PDTs could deliver additional savings if used to reduce the frequency or duration of patients' therapy sessions.

Blended-Care Solutions: These solutions that combine digital content and clinician-led care suggest strong clinical effectiveness, particularly for depression (average 7.7-point reduction in PHQ-9 for people not previously receiving psychotherapy). However, there is more limited comparative data and most solution-specific findings come from single-arm studies. These solutions have a much higher price point (estimated at $6 PMPM plus approximately $792 in annual therapy costs per engaged user) that increases total health spending by $2.10 PMPM, or $25.2M per million members in the commercial market, with even greater estimated spending increases if solutions were deployed in Medicare or Medicaid. Despite this short-term cost increase, the potential superior clinical benefits warrant careful consideration, particularly for people with moderate to severe symptoms, scenarios where solutions can serve as EAP replacements, or if payers negotiate lower per member solution prices.

PHTI RATINGS BY CATEGORY FOR VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY

● Positive ● Moderate ● Negative
● Higher Evidence Certainty ○ Lower Evidence Certainty

Category	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Self-Guided Solutions AbleTo,* Dario, Headspace,* Learn to Live, Meru Health,* SilverCloud, Talkspace,* Teladoc*	● **Results:** Clinically meaningful improvements in depression and anxiety symptoms for people not receiving psychotherapy **Evidence Certainty:** Higher	● Decreases net health spending for commercial payers	● **Evidence supports broader adoption for people not otherwise accessing therapy**
Prescription Digital Therapeutics DaylightRx, Rejoyn	● **Results:** Clinically meaningful improvements for depression and anxiety symptoms as part of usual care **Evidence Certainty:** Higher	● Decreases net health spending for commercial payers and Medicare at anticipated reimbursement rates	● **Evidence supports broader adoption due to improved efficacy of mental health treatment**
Blended-Care Solutions AbleTo,* Brightside, Headspace,* Koa Health, Lyra, Meru Health,* Modern Health, Spring Health, Talkspace,* Teladoc*	○ **Results:** Larger, clinically meaningful improvements for depression and anxiety symptoms for all users **Evidence Certainty:** Lower	● Increases net health spending for payers because savings from users' health improvements do not offset total solution costs	● **Positive clinical outcomes and net savings for users would support broader adoption, if prices were lower**

Source: PHTI, Virtual Solutions for Depression and Anxiety, May 2025. See PHTI.org for complete report, methods, and recommendations.

Notes: [a] Not all solutions have clinical data that meet the inclusion standards for this report. [b] Summary rating reflects the combination of clinical and economic results.
* Companies offering both self-guided and blended-care solutions.

Next Steps

Despite demonstrating positive clinical benefits, virtual solutions for depression and anxiety have yet to fully realize their potential in mental healthcare delivery. Improved evidence generation, strong engagement rates, and outcome-based payment models can help these solutions gain adoption. Rising rates of depression and anxiety and limited provider access suggest that clinically and economically effective digital solutions can play a role in expanding treatment options.

PHTI's recommendations include:

- **Improve evidence generation** by developing more comparative studies examining long-term durability of clinical effects, effectiveness across diverse populations, and outcomes for patients with mild symptoms.
- **Enhance engagement** by researching and implementing features that increase sustained user participation, which correlates strongly with better clinical outcomes.
- **Focus on efficient care delivery** through appropriate triage and stepped-care models that match patients to the most clinically appropriate and cost-effective support.
- **Align payment models with clinical benefits** by creating variable pricing structures and value-based contracts that reduce per-member fees and shift toward outcome-based reimbursement.

These findings are based on the criteria set forth in the ICER-PHTI Assessment Framework and the currently available evidence. Please see the full PHTI report, appendices, and online data supplement for complete assessment, methods, and recommendations.

The Case for Innovation

Depression and anxiety are two of the most common mental health conditions. In the United States, one in five adults experience depressive symptoms in a given two-week period, and roughly one in six experience symptoms of anxiety.[2] For individual patients, the symptoms of depression and anxiety can result in impaired focus, reduced motivation, disruptions to daily functioning, and suicidal ideation. Nationally, these disorders carry a significant economic burden—both to the healthcare system in direct treatment costs and to the economy as a whole from indirect costs, such as lost productivity and absenteeism.[3] In 2020, approximately $240 billion was spent in the United States on treatment alone for mental health disorders.[4]

Despite efforts to expand screening, many people with symptoms of anxiety or depression do not receive effective treatment. Clinical treatment guidelines and quality measure programs have encouraged more routine screening for depression and anxiety. Patients who are able to access evidence-based treatments, such as cognitive behavioral therapy (CBT) or prescription drugs, show significant symptom improvement. Unfortunately, many individuals who are diagnosed with depression and anxiety do not receive effective treatment because of access barriers, such as provider shortages, costs and insurance challenges, social stigma, and poor follow-up.

Virtual solutions for depression and anxiety aim to expand access to treatment. These solutions offer a wide range of digital content, including lessons and activities, that users can access anytime and select topics that meet their needs. Some solutions also integrate coaching and live therapy from licensed professionals. These solutions are designed to address current access challenges in the mental health delivery system by more rapidly connecting patients with appropriate care. By offering an always available service covered by insurance or paid for by their employer, these solutions may help more patients to quickly access treatment when they need it.

This report incorporates scientific evidence, company data, and budget impact modeling to answer three fundamental questions: **How well do these virtual solutions work? For whom? Are they worth it?**

COMPANIES WITH VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY REVIEWED IN THIS REPORT

Amwell (SilverCloud) | **Big Health (DaylightRx)** | **Brightside Health** | **DarioHealth** | **Headspace** | **Koa Health** | **Learn to Live** | **Lyra Health** | **Meru Health** | **Modern Health** | **Optum (AbleTo)** | **Otsuka Precision Health (Rejoyn)** | **Spring Health** | **Talkspace** | **Teladoc Health**

Condition Overview

Depression and anxiety are serious mental health disorders that, if left untreated, can substantially impact patients' quality of life. In the United States, 21.4% of adults reported depression symptoms and 18.2% reported symptoms of anxiety in 2022.[5] Depression and anxiety disorders frequently co-occur, with 45.7% of individuals with depression also experiencing anxiety disorders.[6] Rates of depression and anxiety have steadily increased over the past decade, with a sharp spike during the COVID-19 pandemic.[7]

Depression and anxiety disproportionately impact women, younger adults aged 18–29, and those who live in rural areas (Exhibit 1).[8] The prevalence of significant depressive and anxiety symptoms is similar among Black, Hispanic, and non-Hispanic white populations, but lower among Asian populations. Although racial and ethnic differences in rates of depression and anxiety symptoms are modest, Black and Hispanic people are much less likely to receive treatment than other populations.[9]

Gender differences in diagnosis rates are also more pronounced. While women report symptoms of depression somewhat more frequently than men, they are diagnosed at almost twice the rate.[10] Even though 18% of men reported symptoms of depression in 2022, only approximately 11% received treatment.[11] In addition, men experienced crisis events at rates nearly four times as high as women, highlighting a significant gap in diagnosis and care.

The lived experience of depression and anxiety varies considerably in terms of acuity, intensity of treatment needed, and duration. In 2022, 13.9% of U.S. adults reported mild symptoms of depression in the previous two weeks, while approximately 8% reported moderate or severe symptoms (Exhibit 2).[12] Patient-reported anxiety symptoms in the previous two weeks in 2022 were similar, with 11.4% of U.S. adults reporting mild anxiety symptoms and approximately 8% reporting moderate or severe symptoms (Exhibit 2).[13] Mild symptoms of depression and anxiety may result in impaired focus and motivation. Poor management or lack of adherence to treatment may occur as a result of symptoms, such as extreme fatigue or poor concentration.[14, 15] More severe cases can elevate the risk of substance use disorders[16] and suicide[17] and can also lead to absenteeism and significant impairment of daily functioning.[18]

Defining Depression and Anxiety

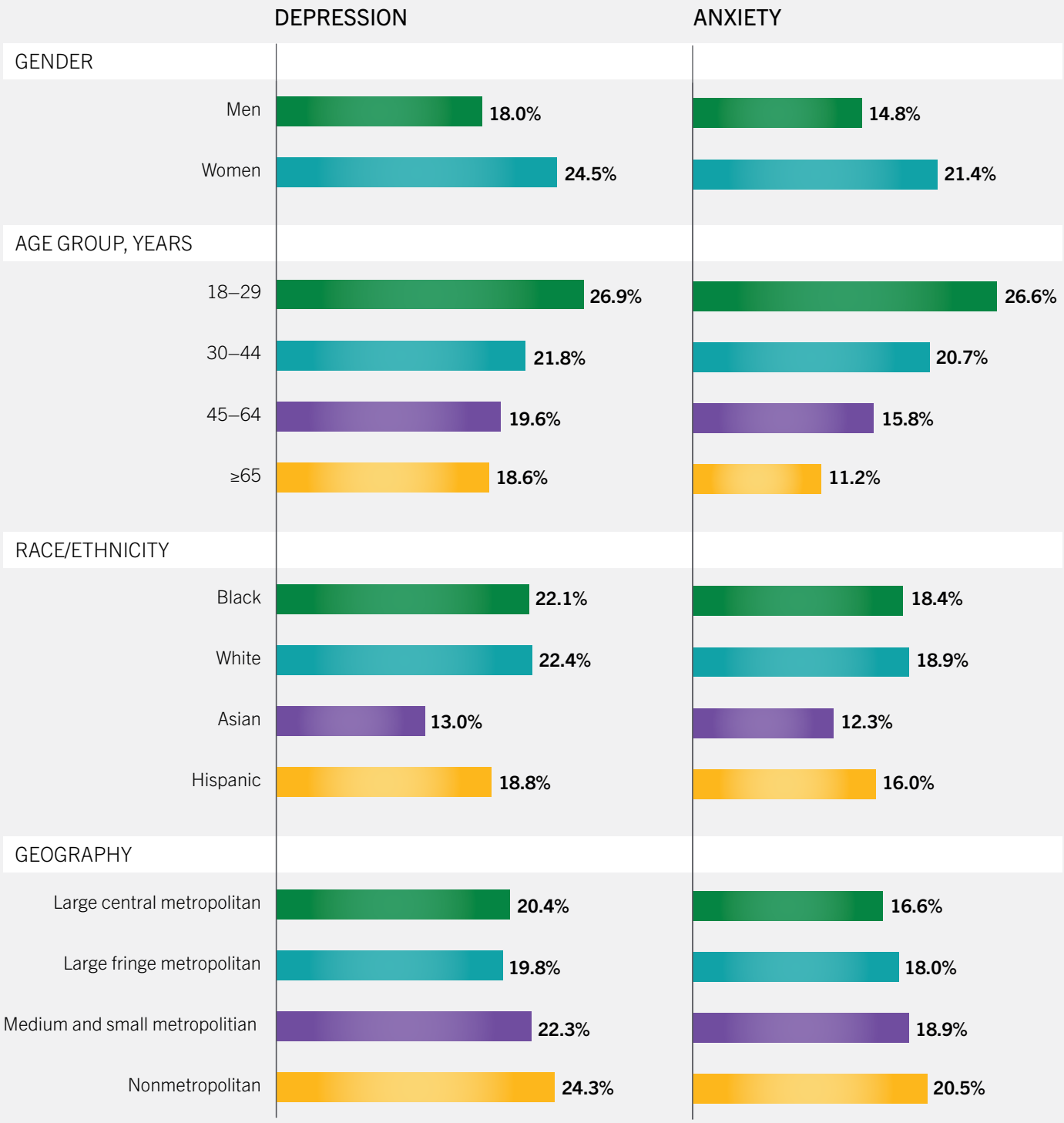
Depression and anxiety are prevalent mental health disorders that emerge from complex interactions of genetic predisposition, environmental factors, and psychological processes.

- Depression manifests as a persistent mood disturbance characterized by pervasive sadness, loss of interest in previously enjoyable activities, fatigue, sleep disruptions, and suicidal ideation.
- Anxiety disorders, particularly generalized anxiety disorder (GAD), present with excessive and uncontrollable worry disproportionate to actual threats, accompanied by physiological manifestations such as psychomotor restlessness, concentration deficits, and persistent muscle tension.

> **"There are many barriers to receiving effective care for depression** and other common mental health conditions—cost, insurance limitations, provider shortages, and geographic access. Digital therapeutics have the potential to overcome those barriers and dramatically improve the delivery of effective treatments. But it's critical to examine if the digital therapeutics available actually deliver on that potential."
>
> —Dr. Gregory Simon

Exhibit 1

PREVALENCE OF DEPRESSION AND ANXIETY SYMPTOMS IN THE UNITED STATES IN 2022, BY DEMOGRAPHIC GROUP*

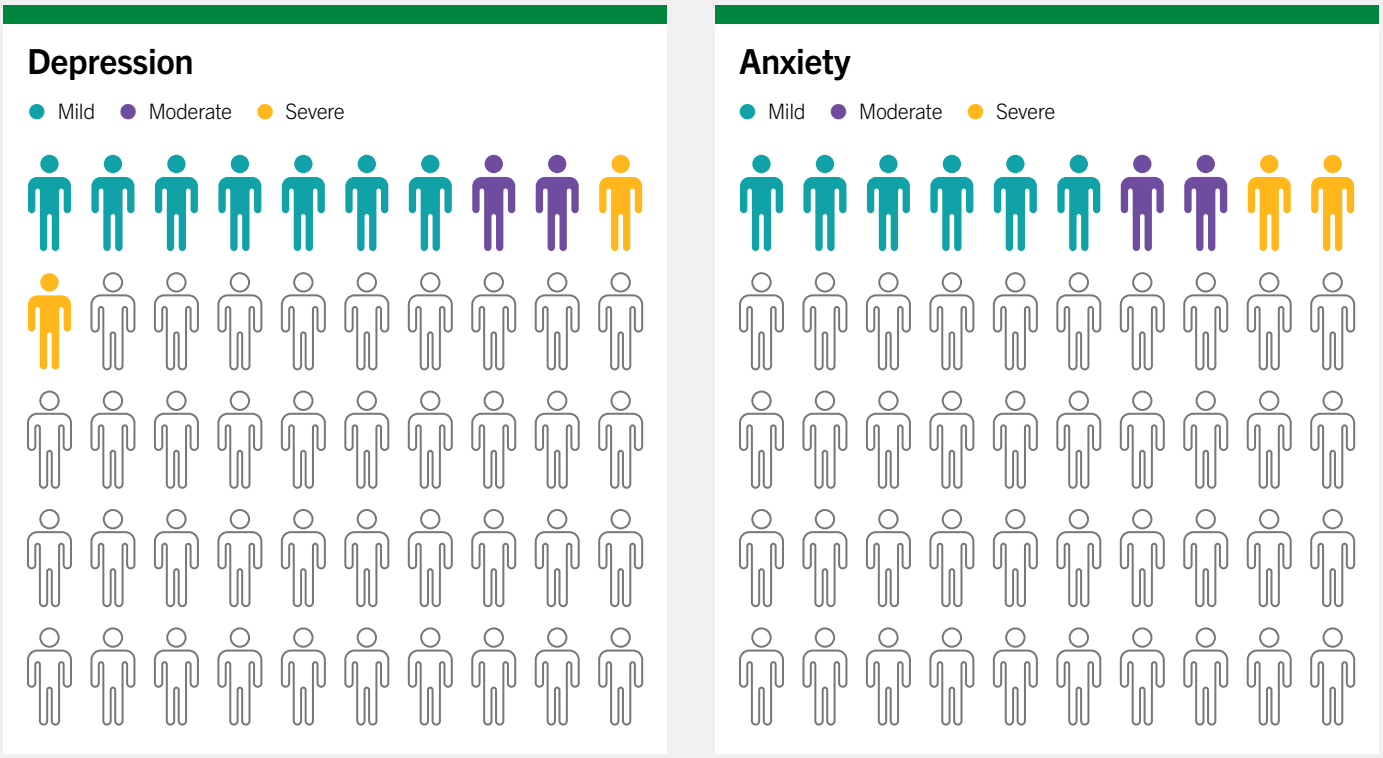


Source: Terlizzi, Emily P., and Benjamin Zablotsky, "Symptoms of Anxiety and Depression Among Adults: United States, 2019 and 2022," *National Health Statistics Reports*, no. 213 (November 7, 2024). https://www.cdc.gov/nchs/data/nhsr/nhsr213.pdf

Note: * Percentage distribution of adults aged 18 and older by severity of depression and anxiety symptoms in the past two weeks.

Exhibit 2

PREVALENCE OF U.S. ADULTS WITH MILD, MODERATE, AND SEVERE SYMPTOMS OF DEPRESSION AND ANXIETY, 2022*



Source: Terlizzi, Emily P., and Benjamin Zablotsky, "Symptoms of Anxiety and Depression Among Adults: United States, 2019 and 2022," *National Health Statistics Reports*, no. 213 (November 7, 2024). https://www.cdc.gov/nchs/data/nhsr/nhsr213.pdf

Note: * Percentage distribution of adults aged 18 and older by severity of depression and anxiety symptoms in the past two weeks.

Standard of Care

Screening and Diagnosis

Screening for depression and anxiety is conducted using standardized, patient-reported screening tools. The most commonly used and studied screening tools are the Patient Health Questionnaire-9 (PHQ-9) for depression and the Generalized Anxiety Disorder scale-7 (GAD-7) for anxiety. These standard tools also play a role in the diagnostic process, helping to assess symptom severity and guide treatment plans.[19,20]

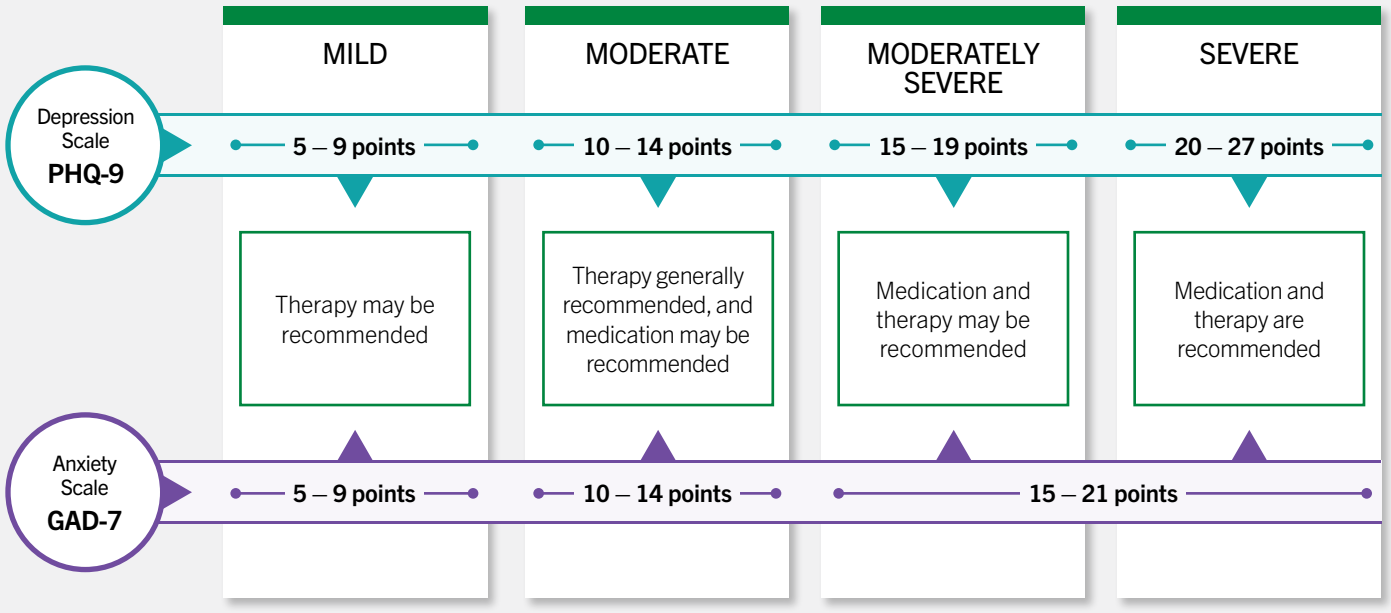
For depression, the PHQ-9 includes nine questions that assess frequency of symptoms in the previous two weeks, such as low mood, fatigue, sleep disturbances, and thoughts of self-harm. Each item is scored from 0 to 3, yielding a total score between 0 and 27, with higher scores representing more severe symptoms (Exhibit 3). Similarly, the GAD-7 consists of seven questions that measure indicators of generalized anxiety, such as excessive worry, restlessness, and difficulty relaxing, resulting in scores ranging from 0 to 21. Major Depressive Disorder (MDD) is formally diagnosed when these symptoms persist for at least two weeks and substantially impair daily functioning.

Depression and anxiety are not always continuous: They can occur in distinct episodes or cycles, either in response to stressors or without identifiable triggers. This episodic nature means individuals may experience relapse—the return of symptoms after a period of improvement or remission. Accordingly, individuals' scores on assessment measures may fluctuate over time, highlighting the importance of regular screening to monitor changes in symptoms.

Primary care providers (PCPs) play a critical role in the identification and treatment of depression and anxiety. Current public health guidelines recommend routine screening of all adults so that people experiencing symptoms may be referred to care.[21] Even when a diagnosis is given, follow-up care can be inconsistent.[22] Approximately 40% of people with a diagnosed

Exhibit 3

SYMPTOM SEVERITY FOR DEPRESSION AND ANXIETY AS MEASURED BY PHQ-9 AND GAD-7 SCORES



Source: Qaseem, Amir, Douglas K. Owens, Itziar Etxeandia-Ikobaltzeta, et al., "Nonpharmacologic and Pharmacologic Treatments of Adults in the Acute Phase of Major Depressive Disorder: A Living Clinical Guideline from the American College of Physicians," *Annals of Internal Medicine* 176, no. 2 (2023): 239–252. https://doi.org/10.7326/M22-2056; and DeGeorge, Katharine C., Molly Grover, and Gregory S. Streeter, "Generalized Anxiety Disorder and Panic Disorder in Adults," *American Family Physician* 106, no. 2 (2022): 157–164. https://www.aafp.org/pubs/afp/issues/2022/0800/generalized-anxiety-disorder-panic-disorder.html

Notes: Point values are assigned to each question on the basis of patient's reported frequency of depression and anxiety symptoms in the previous two weeks: 0 points = not at all; 1 point = several days; 2 points = more than half of the days; 3 points = nearly every day. All responses are summed to calculate the total GAD-7 and PHQ-9 scores.

mental health condition receive no treatment whatsoever.[23] For those who do begin treatment, the structured, continuous support needed to maintain improvements during an episode—such as regular therapy sessions or medication monitoring—may not be readily available.

Management and Treatment

Depression and anxiety are primarily managed with psychotherapy, medications, or both.[24] The therapeutic objectives for these interventions include improved symptoms, functional capacity, and overall quality of life.[25, 26] Both the American College of Physicians guidelines for depression and the American Academy of Family Physicians guidelines for anxiety recommend using psychotherapy—specifically CBT—as a first line of treatment for patients with mild symptoms.[27, 28] Patients with moderate or severe symptoms may be recommended to try either psychotherapy, medication, or both (Exhibit 3).[29, 30]

Psychotherapy—or talk therapy—is an evidence-based, clinical intervention for mental health conditions that utilizes structured therapeutic interventions through dialogue as treatment. Providers of psychotherapy have a range of training and licensure levels, including psychologists, licensed counselors, therapists, and social workers. Psychiatrists can prescribe prescription medications and may also provide psychotherapy.[31]

There are numerous psychotherapy approaches, such as CBT, dialectical behavior therapy, interpersonal therapy, behavioral activation strategies, and acceptance and commitment therapy.[32] CBT is one of the most well-studied and commonly used types of therapy practiced today. CBT is typically delivered as a structured, time-limited intervention lasting approximately 12 to 16 weeks.[33] Additional mental health support may include coaching and skill-building by certified metal health coaches and trained peer support specialists.

Cognitive Behavioral Therapy

Cognitive Behavioral Therapy (CBT) is a well-established form of psychotherapy that targets the functional relationship between thoughts, feelings, and behaviors. It aims to help individuals recognize thought patterns and how they influence emotional states and behavioral responses. CBT seeks to replace negative thought patterns and provide patients with strategies that promote improved mental health.

- CBT is considered a first-line treatment and is designed to equip individuals with skills to identify cognitive distortions and implement adaptive coping mechanisms.
- Throughout CBT practice, patients work with providers to recognize negative thought patterns with the goal of developing a more-balanced perspective.
- The behavioral component of CBT, such as behavioral exposures for anxiety[34] and behavioral activation strategies for depression,[35] are critical to addressing avoidance patterns and increasing engagement in meaningful activities.
- CBT is typically delivered as a structured, time-limited intervention lasting approximately 12 to 16 weeks. Booster sessions may also be offered to reinforce skills learned during initial sessions.[36]
- Homework is a core component of evidenced-based CBT. Structured homework, such as modules or worksheets focusing on cognitive restructuring or mood tracking, is essential to reinforce skills and promote behavioral change.[37]
- Approximately 40–50% of patients receiving CBT show a more than 50% reduction in their reported depression scores on the PHQ-9 scale.[38]
- CBT has demonstrated effectiveness in preventing symptom recurrence, with research showing it successfully reduces anxiety relapse rates to 14% following symptom remission.[39]

Antidepressants, such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors, and norepinephrine-dopamine reuptake inhibitors are commonly prescribed to treat depressive and anxiety disorders.[40] Prescription drugs may be prescribed by PCPs or psychiatrists. PCPs generally rely on pharmaceutical interventions and often have difficulty connecting patients with other outpatient mental health providers.[41] More than 60% of depression cases and 80% of antidepressant prescriptions nationwide are managed by PCPs.[42] Medication-based treatment, while used broadly, has substantial adherence challenges, with nearly 70% of patients discontinuing SSRI therapy within three months of initiation.[43]

> **"Cognitive behavioral therapy is one of the most widely and carefully studied families of approaches for treating anxiety and depression,**
>
> with decades of rigorous research supporting its efficacy. Guided by clear principles of change that can be readily explained and learned, CBT provides a replicable framework to deliver meaningful symptom reduction across diverse clinical presentations and patient populations."
>
> —Dr. Bethany Teachman

Treatment Effects

Conventional mental health interventions establish important benchmarks on effectiveness for improving depression and anxiety symptoms: Approximately 40–45% of patients receiving CBT show significant responses for depression symptoms (≥50% symptom reduction).[44] Studies show that CBT and pharmacotherapy have comparable average response rates (>50% improvement between baseline and endpoint scores) for treating depression and anxiety.[45, 46] Notably, many patients who achieve symptom reduction have a relapse within 1–2 years.[47] While response rates vary across different study populations, both treatment modalities typically yield average response rates of 40–50%,[48, 49] and combined treatments often produce superior results than either approach alone.[50, 51]

Even without any formal treatment, depression symptoms typically improve by 10–15% over 2 to 20 weeks,[52] establishing a natural recovery baseline against which mental health interventions must demonstrate added benefit. Therefore, placebo effects may play a role in the perceived effectiveness of mental health interventions, as evidence has suggested that individuals who anticipate positive outcomes report improvement in well-being even without active therapeutic components.[53] Recent meta-analyses indicate that digital

solutions are effective for improving depression and anxiety symptoms compared with those not receiving an intervention (i.e., waitlist controls) but show more modest advantages relative to placebo.[54]

Barriers to Care

In addition to gaps in screening and diagnosis, patients seeking mental healthcare face significant barriers to accessing care.

Nearly half of the U.S. population lives in areas designated as having a shortage of mental health providers.[55] This shortage is particularly acute in rural communities, where residents face a higher prevalence of mental health conditions.[56,57] Further, many providers are not accepting new patients: More than half of psychologists (56%) report having no openings for new patients,[58] and those who can accommodate new clients often have wait times that average 67 days to initiate therapy.[59]

Even for those able to access mental health services, the cost of traditional therapy can be prohibitive and finding available in-network providers can be challenging. Many therapists do not accept insurance, and mental health visits typically have higher copayments than primary care.[60] These financial obstacles cause many individuals to either forgo treatment entirely or discontinue care prematurely.[61]

Some individuals hesitate to pursue mental healthcare out of fear of judgment or embarrassment—concerns that are particularly pronounced in certain racial and ethnic communities.[62] Social stigma can delay diagnosis and treatment initiation. Collectively, these factors create barriers that prevent people from accessing and initiating care.

Economic Burden

The economic impact of depression and anxiety includes both direct healthcare costs and indirect costs due to reduced productivity. Approximately $240 billion was spent in the United States on mental health treatment alone in 2020—nearly two thirds by public payers.[69] Mental health problems also increase absenteeism and reduce productivity at work and at home. Absenteeism, stemming from depression and anxiety, alone results in nearly 10 days of additional unplanned absences annually, translating to an estimated $47.6 billion in lost productivity nationwide.[70]

People suffering from depression and anxiety also experience higher healthcare spending both for mental health services and other medical care. Outside of direct mental healthcare, patients with more severe depression and anxiety incur higher healthcare costs and utilize more medical services. One study found that patients with severe depression had $12,433 in depression-related, direct medical costs—more than 50% higher than people with minimal or mild depression (Exhibit 4).[71] Similarly, patients with severe anxiety had total direct medical costs of $11,067, more than 60% higher than those incurred by those with minimal to no anxiety symptoms (Exhibit 5).[72] Further, patients with mental health conditions and other comorbid conditions incurred 2–3 times higher medical and surgical costs than those without co-occurring mental health needs.[73]

The Impact of COVID-19 on Mental Health and Telehealth Expansion

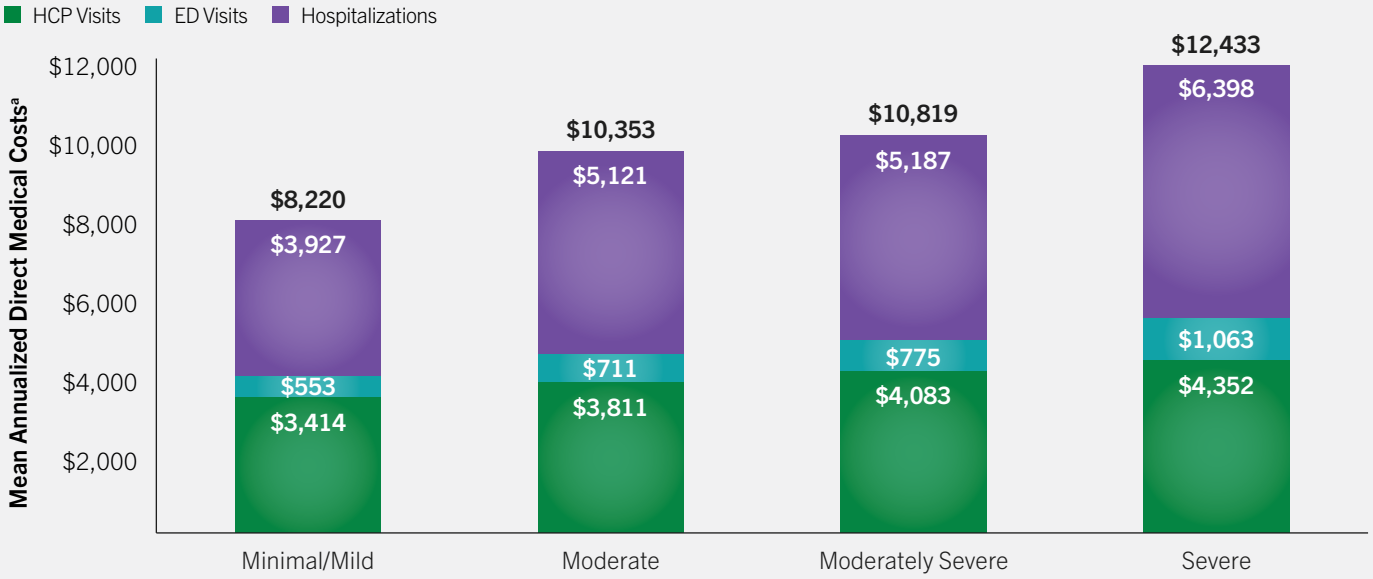
The COVID-19 pandemic drove substantial increases in depression and anxiety due to isolation, employment disruption, financial instability, illness exposure, and grief experiences.[63] Early pandemic estimates indicated approximately four in 10 U.S. adults exhibited anxiety or depression symptoms.[64]

This crisis catalyzed unprecedented telehealth adoption by mental healthcare providers. By 2021, virtual care accounted for nearly 40% of outpatient mental health and substance use disorder treatment, including particularly robust implementation in rural communities.[65] Community health centers serving predominantly low-income and medically underserved populations had a substantial increase in the volume of mental health visits directly attributable to telehealth implementation.[66]

Since the end of the public health emergency (May 11, 2023), the percentage of adults reporting symptoms of depression and anxiety has improved modestly.[67] Policymakers have extended many telehealth regulations permanently, with the goal of sustaining pandemic-driven access gains while addressing persistent care delivery gaps.[68]

Exhibit 4

DEPRESSION-RELATED DIRECT MEDICAL COSTS BY SEVERITY, COMMERCIAL, 2018



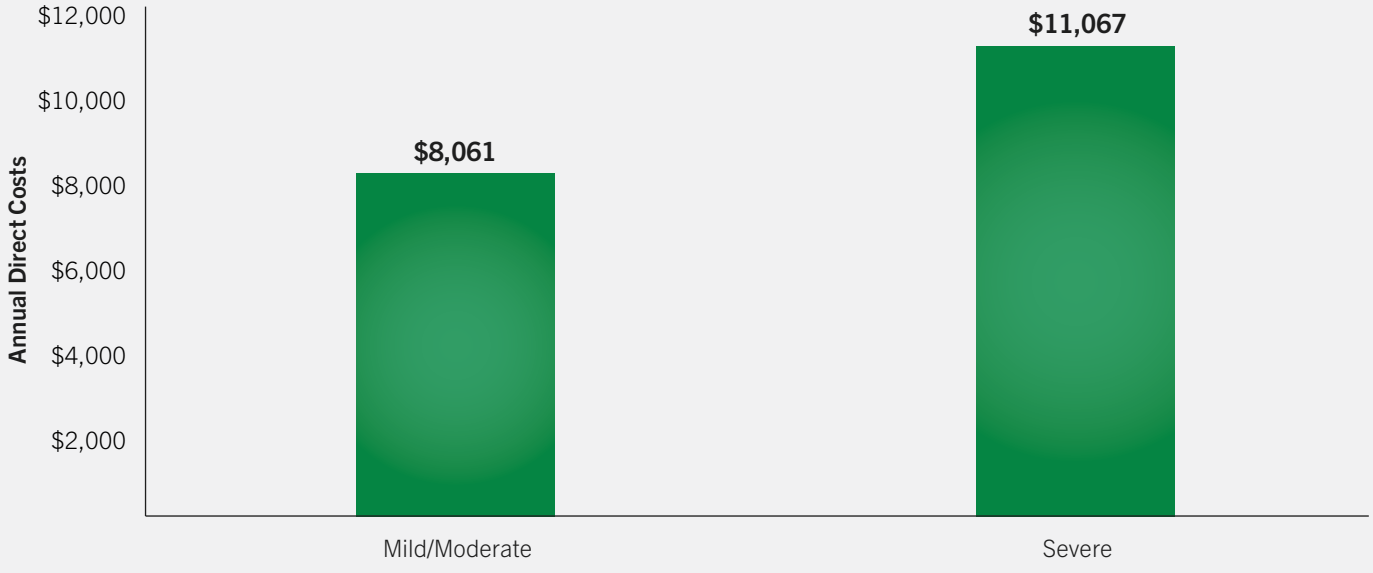
Source: Culpepper, Larry., Ashley Martin, Nadia Nabulsi, et al., "The Humanistic and Economic Burden Associated with Major Depressive Disorder: A Retrospective Cross-Sectional Analysis," *Advances in Therapy* 41, no. 5 (2024): 1860–1884. https://doi.org/10.1007/s12325-024-02817-w

Notes: ED = emergency department. HCP = healthcare provider. Annualized direct medical costs of participants across MDD severity levels.

[a] Estimates shown were derived from separate models predicting the cost of HCP visits, ED visits, hospitalizations, and total costs; therefore, individual component costs may not add up to total costs. Further, model covariates for comparing with the general population included additional covariates relating to early-onset MDD diagnosis status, number of comorbid mental health conditions, and current medication use for MDD.

Exhibit 5

ANXIETY-RELATED DIRECT MEDICAL COSTS BY SEVERITY, COMMERCIAL, 2021



Source: Kavelaars, RuthAnne, Haley Ward, Kushal M. Modi, et al., "The Burden of Anxiety Among a Nationally Representative US Adult Population," *Journal of Affective Disorders* 336 (2023): 81–91. https://doi.org/10.1016/j.jad.2023.04.069

Digital Solutions

This assessment includes 15 companies that offer combinations of self-directed digital content and virtual live therapy to treat depression and anxiety. These virtual solutions aim to expand access to treatment by delivering asynchronous, digital content that can be used instead of or in addition to therapy or other treatment. Some solutions also integrate a network of therapy providers. Most solutions are focused on symptoms of MDD or GAD, though patients do not need a previous diagnosis to use the virtual solutions.

The solutions in this assessment were identified through an initial market scan, a search of published literature, and a detailed company-by-company review. The final list was informed by company meetings, detailed company research, and input from stakeholders, including health plans, employers, providers, and virtual health experts.

All of the solutions included in this report:

- Are sold by companies that have clinical evidence of treating anxiety and/or depression or indicate they target people with anxiety and/or depression;
- Offer anxiety and/or depression CBT-based modules or content, either as a stand-alone solution or as part of a larger offering;
- Are not exclusively focused on patients with severe depression, high risk of suicide, or treatment of post-traumatic stress disorder;
- Are sold in the United States;
- Are sold either to employers, payers, or health systems/providers; and
- Are sold by companies that are publicly traded or have raised at least $25 million in private funding (see Exhibit 6).

Companies that primarily serve a network of providers without offering additional self-guided programs of digital content were not included in this report. Companies that primarily offer mental health chatbots were also excluded from the report.

Exhibit 6

COMPANY HISTORY AND FUNDING

Company	Year Founded	Ownership	Total Private Investment/Market Cap[a]
Amwell (SilverCloud)	2012	Public[b]	$107M
Big Health (DaylightRx)	2010	Private	$131M
Brightside	2017	Private	$109M
DarioHealth	2011	Public	$29M
Headspace	2010	Private	$321M
Koa Health	2016	Private	$68M
Learn to Live	2012	Private	$25M
Lyra Health	2015	Private	$907M
Meru Health	2016	Private	$51M
Modern Health	2017	Private	$192M
Optum (AbleTo)[c]	2008	Public	$355,900M
Otsuka Precision Medicine and Click Therapeutics (Rejoyn)	2019	Collaboration	N/A[d]
Spring Health	2016	Private	$467M
Talkspace	2011	Public	$508M
Teladoc Health	2008	Public	$1,200M

Source: PitchBook Data, Inc. Otsuka, "Otsuka and Click Therapeutics Collaborate to Develop and Commercialize Digital Therapeutics for Patients with Major Depressive Disorder," accessed March 20, 2025. https://www.otsuka-us.com/discover/otsuka-and-click-therapeutics-collaborate

Notes: N/A = not applicable. [a] Market cap for public companies, as of May 7, 2025. [b] Acquired by Amwell in 2021 for $226 million. [c] Acquired by Optum , a subsidiary of UnitedHealth Group, in 2020 for $470 million. $355,900M represents the market cap for UnitedHealth Group. [d] Rejoyn is a product developed via collaboration between Otsuka America, Inc. and Click Therapeutics, Inc. Otsuka paid Click Therapeutics $30 million upfront for regulatory and development funding. Additional milestone payments ($272 million) and` additional royalties are contingent on regulatory approvals and global sales. Total private investment and market capitalization may reflect multiple lines of business not discussed in this report.

Investment in virtual mental health solutions has been significant.

Since 2016, more than $10.2 billion has been invested in companies providing digital mental health solutions. Of note, in 2021, eight U.S. mental health start-ups reached "unicorn" status by securing valuations of more than $1 billion each.[74]

Source: PitchBook Data, Inc.

Solution Components

The virtual solutions in this assessment include combinations of the following four components.

Assessment and Care Plan

All virtual solutions for depression and anxiety begin with an initial assessment that uses validated clinical tools, such as the PHQ-9 or GAD-7, or similar screeners. Results from these screenings serve multiple purposes: determining eligibility for the program, guiding the creation of individualized treatment plans, and identifying which type of clinician and/or digital intervention would most appropriately address the patient's needs. Screenings are repeated periodically throughout the care plan.

Leveraging the patient assessment, virtual solutions guide patients toward care options. Care plans may be developed entirely digitally or in consultation with a coach or a clinician. Recommendations may include a self-directed digital care plan, direct connection with a clinical provider, or a combination of both approaches.

Digital Content

All solutions in this report include digital content or tools, which are based in CBT methods, that users can access anytime and select topics that meet their needs. They include interactive elements, such as guided lessons, journaling exercises, cognitive restructuring activities, thought-challenging exercises, quizzes, and practical assignments, which mirror interventions a patient might experience in traditional, clinician-led therapy sessions. The on-demand availability of this content allows individuals to access therapeutic support whenever needed, though the specific length, sequence, and interface vary significantly across solutions.

Coaching and Engagement

Most solutions also include a range of approaches to increase user engagement with the digital content. This may include automated reminders or "nudges," motivational messages, chat bots, progress trackers, personalized feedback systems, and content recommendations based on user data and assessments. Some solutions also have coaches or other nonclinical personnel who facilitate goal-setting, encourage consistent participation, and promote accountability for completing therapeutic activities.

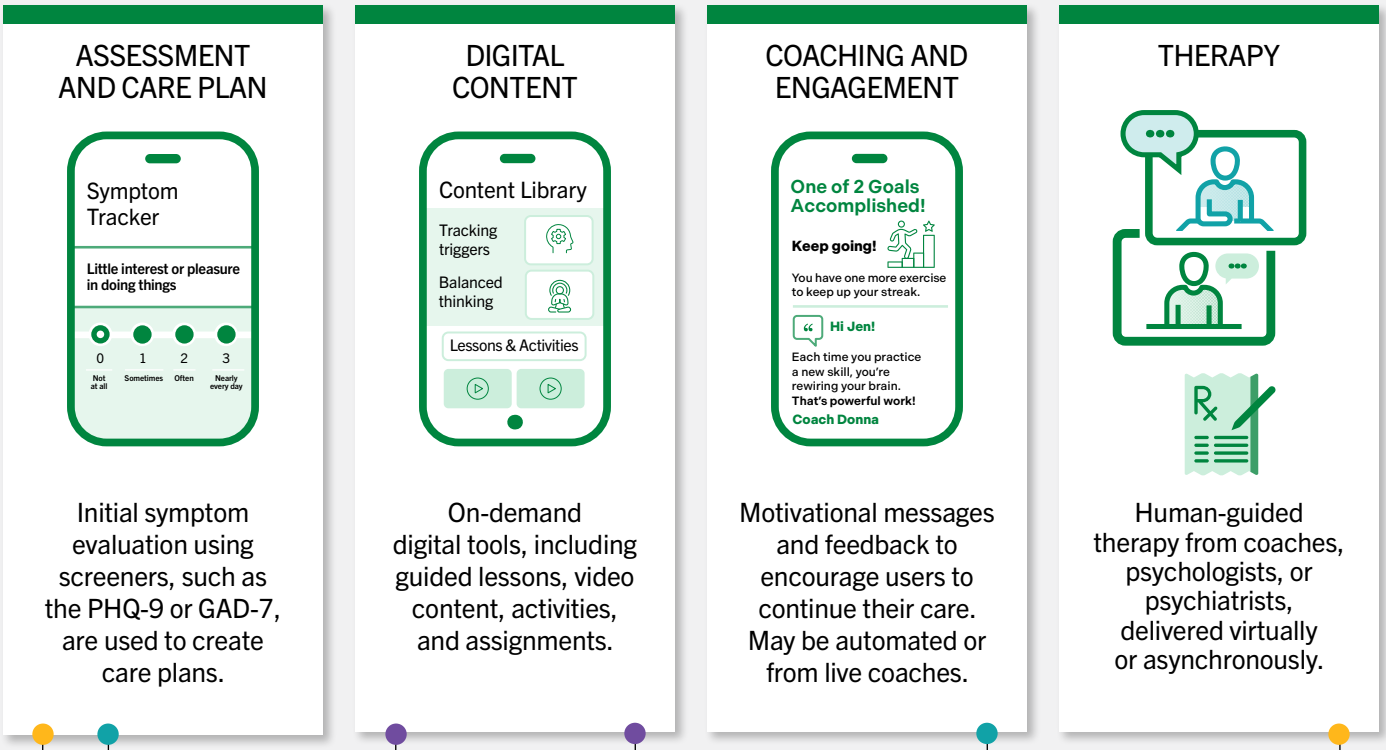
Therapy

Beyond self-guided, digital content, many solutions integrate virtual care teams with certified coaches, licensed psychologists, and psychiatrists. Some solutions primarily facilitate asynchronous clinician communication (e.g., text messaging) supported by digital content, while others connect patients with clinicians for real-time telemedicine sessions or text-based therapy interactions. Some solutions include access to psychiatrists who can prescribe medications.

Providers' clinical autonomy also differs across solutions. Some have specified treatment plans that they use to direct provider practice, while others give providers wide latitude to determine their approach to care. Some employ custom electronic health record systems and conduct ongoing notes analysis for clinical oversight. Others implement financial incentives designed to promote adherence to evidence-based, treatment guidelines.

Exhibit 7

COMPONENTS OF VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY



AI Chatbots

Several academic groups and companies are developing AI-driven chatbots that use large language models and are trained in talk therapy and CBT methods. There are also other generative AI tools (e.g., ChatGPT) which are not specifically developed to be wellness chatbots but are often used as such. These chatbots can support patients while they are waiting to see a therapist or supplement care between therapy sessions. Studies show AI chatbots can help patients feel heard and provide crucial support during waiting periods for professional care.[75, 76] A 2025 randomized control trial found that Dartmouth's Therabot significantly reduced symptoms of depression and anxiety compared with a waitlist control group.[77] While these technologies offer promising alternatives to improve access to mental health treatment, they were not included in this assessment because few products are being marketed commercially and data about their clinical efficacy in the United States is limited.

Solution Categories

The solutions reviewed in this report can be grouped into three broad categories, based on both the primary purchaser and the components of the solution offerings.

All solutions included in the assessment offer CBT-based digital programs that include on-demand content libraries to help improve users' symptoms of depression and anxiety.

- **Self-guided solutions** offer a range of digital content, including lessons and activities, that users can access anytime and select topics that meet their needs. Some also offer coaching support to reinforce skills and increase engagement. These solutions are typically sold directly to employers or health plans.
- **Prescription digital therapeutics (PDTs)** are FDA-cleared, software-based digital therapies that are sold to providers and must be prescribed to patients. Similar to the self-guided solutions, these solutions deliver digitized behavioral interventions, which can be used in conjunction with clinician-supervised outpatient treatment.
- **Blended-care solutions** build on the self-guided digital content by integrating virtual care teams with licensed therapists and psychiatrists who can deliver comprehensive mental health treatment, including psychotherapy and medication management when appropriate. Blended-care solutions are primarily sold to employers or health plans.

Self-guided solutions primarily offer CBT-based digital content to help patients build skills to overcome symptoms of depression and anxiety. These solutions may be used with or without psychotherapy from a licensed practitioner outside of the virtual solution. Self-guided solutions are generally sold to commercial health plans or to employers through either the medical benefit or the employee assistance program (EAP).

These solutions include assessment and intake programs, a care plan and triage tool, and self-directed care content. Some of the solutions that use this approach also have digital or human coaches who help set goals, provide content recommendations, and encourage activity completion. The credentials of the coaches vary by solution.

Prescription digital therapeutics are FDA-cleared software as a medical device designed to prevent, manage, or treat medical conditions using evidence-based interventions.[78] Unlike other mental health apps, PDTs undergo clinical evaluation by the FDA to demonstrate safety and efficacy and must be prescribed by a clinician.[79] PDTs deliver digitized behavioral interventions, which can be used in conjunction with clinician-supervised, outpatient treatment. Similar to the self-guided solutions in this report, PDTs include digital CBT-based content, the Emotional Faces Memory Task (EFMT), mindfulness interventions, and symptom tracking to provide evidence-based treatment in a digital format.

PDTs may be prescribed by a wide range of providers, including psychiatrists, psychologists, clinical social workers, PCPs, and behavioral health providers. Providers may prescribe the solutions to complement and reinforce therapy, as an alternative to therapy, or to help maintain clinical improvement.

Blended-care solutions combine the digital content included in the self-guided care solutions with synchronous or asynchronous interactions with licensed coaches, therapists, and psychiatrists. Patients begin engaging with the solution by completing an intake assessment, which helps determine their recommended care pathway while still allowing them to select their preferred treatment approach. These solutions offer multiple ways for users to interact, including the digital content from the self-guided solutions, synchronous video therapy sessions, and asynchronous messaging with licensed clinicians. Solutions vary in how they structure the integration between digital content and human-delivered therapy, including treatment duration, whether digital content supplements or replaces traditional therapy, and the sequencing of digital and clinician-delivered interventions. Blended-care solutions typically sell to commercial health plans or to employers, through the medical benefit and the EAP.

Some companies that offer these blended-care solutions also sell their digital programs as a stand-alone product, akin to the self-guided solutions (Exhibit 8). For a detailed review of each solution and category, see the solution-specific analysis later in this report.

Exhibit 8

INCLUDED COMPANIES BY CATEGORY

Self-Guided Solutions

AbleTo*
Dario
Headspace*
Learn to Live
Meru Health*
SilverCloud
Talkspace*
Teladoc*

Prescription Digital Therapeutics

DaylightRx
Rejoyn

Blended-Care Solutions

AbleTo*
Brightside
Headspace*
Koa Health
Lyra
Meru Health*
Modern Health
Spring Health
Talkspace*
Teladoc*

Note: * Companies offering both self-guided and blended-care solutions.

Coverage for Virtual Mental Health Solutions

Employers may contract for virtual mental health solutions through either their **medical benefit** or **wellness benefit,** each with distinct implications for access, reimbursement, and clinical integration. Contracting through the **medical benefit** allows mental health solutions to be covered similarly to other healthcare services, meaning they may be billed as medical claims and reimbursed by insurance, integrated with provider networks, and subject to regulatory protections like parity laws.

Alternatively, some employers offer these solutions as part of their **wellness benefit,** typically as part of employee assistance programs (EAPs). EAP benefits are available to all workers, regardless of whether they are enrolled in the employers' medical insurance, and they do not require a clinical diagnosis for access. While EAPs historically offered short-term counseling, they have evolved to include higher levels of clinical care, including ongoing therapy, psychiatric consultations, and digital mental health platforms. EAPs, such as Lyra, Spring Health, Modern Health, and Headspace, contract to provide a baseline number of covered therapy sessions as part of their offering—ranging from three to 25 visits, averaging around 10[80]—at no cost to the employee, before transitioning therapy coverage to the medical benefit for continued treatment. While patients may be able to continue seeing the same therapy provider as part of their medical benefit, they will usually incur out-of-pocket costs, as required by their medical insurance plan design.

Patient Perspectives

PHTI conducted focus groups and interviews with 17 patients with anxiety and/or depression who had experience with virtual depression and anxiety solutions. Patients were recruited for diversity across age, gender, race and ethnicity, income level, geography, and insurance type.

Patients with depression and anxiety experience a wide spectrum of potentially debilitating challenges, and symptoms can recur even after successful treatment. Mental health conditions often persist over a lifetime and may require significant monitoring to control. Patients seeking care for anxiety or depression may turn to virtual therapy options or digital platforms as alternatives to or supplements for traditional care.

Convenience

Patients emphasized that virtual solutions for depression and anxiety helped them address gaps in in-person mental healthcare by offering accessibility, flexibility, and continuous support.

> **"It's hard to see a provider or get the energy to see a provider all the time.**
>
> You need something to support you between those visits. I think the digital tools really do a great job at guiding you in between those visits."
>
> —Patient Interview Participant

> **"Sometimes you have to take off almost a half day for therapy.**
>
> Now this is something you can do on your lunch hour or in the evenings. There's a whole platform set up for people who travel, who are busy, or who just don't have time to go in."
>
> —Patient Interview Participant

Engagement

Patients who engaged more with virtual solutions reported greater benefits. Patients feel less engaged when solutions are overly clinical, overwhelming, or lack an interactive and engaging design.

> **"In using digital apps, I'd gathered education, but it became too much.**
>
> It was like adding something on top of the feeling like I'm in an empty void and I can't do anything. I think if it was a little more fun, I would be more entertained and engaged but it became too clinical and boring."
>
> —Patient Interview Participant

> **"I wouldn't say that it has a hundred percent transformed my life,**
>
> but I really think that it gives a little push…on top of having therapy, on top of having my peers that help me out, and family, and my primary care doctor, this app is just a little push."
>
> —Focus Group Participant

Meeting Patients Where They Are

Patients value digital tools that support them throughout their care journey (subclinical to clinical symptoms). However, they had trouble with content often becoming repetitive, too generic, or lacking personalized support for ongoing mental health needs.

> **"It's kind of like trial and error, where I've tried some digital tools**
>
> using it for a day, and then either the platform wasn't user-friendly enough, or the help that it offered just wasn't specific enough to what I was dealing with, so I didn't bother with it anymore."
>
> —Patient Interview Participant

> **"When you're done with CBT, it ends, but the anxiety doesn't end.**
>
> I like the whole idea of being equipped with tools that you can pull out at any time if you still have ongoing issues."
>
> —Patient Interview Participant

Clinical Effectiveness

This report evaluates the effectiveness of virtual solutions for depression and anxiety by examining clinically significant health outcomes data, as well as with evidence related to health equity and user experience.

The systematic literature review identified a substantial evidence base, including numerous randomized controlled trials (RCTs). Most studies include 6 to 12 weeks of data. Detailed clinical methods and findings are described below.

Systematic Literature Review

Using the ICER-PHTI Assessment Framework, independent reviewers conducted a systematic literature review of scientific and gray literature on virtual solutions for depression and anxiety on the basis of the predefined criteria in Exhibit 9 (Prospero Registry Link). The review included published and unpublished evidence on clinical effectiveness from three data sources: online databases (EMBASE and PUBMED) and conference proceedings, company-provided data, and company websites. See **Appendix A** for a detailed methodology.

Exhibit 9

PICOS INCLUSION AND EXCLUSION CRITERIA

Criteria	Exclusion Criteria
POPULATION: • Adults with anxiety and/or depressive symptoms as reported in a validated measure or clinician judgement • Adults with a clinical diagnosis of generalized anxiety disorder (GAD) or major depressive disorder (MDD) as defined by DSM-5 • Race/ethnicity, sex, age ≥65 years, urban/rural location, and LGBTQ+[e]	• Patients with other subcategories of anxiety and/or depressive disorders as specified in DSM-5[a, b] • Patients with any other mental health disorder as categorized by DSM-5[c] • Patients <18 years of age • Patients with a self-determined diagnosis of GAD and/or MDD • Anxiety and/or depression secondary to another condition (e.g., pregnancy, physical condition, injury/trauma, substance use disorders)[d] • Subpopulations (e.g., healthcare providers, students, etc.)
INTERVENTIONS: CBT-based digital therapy including a human therapist/coach and/or app-based solution with artificial intelligence (e.g.,app-based messaging, educational modules, etc.)	• DHTs used to diagnose anxiety and/or depression only • Interventions used in context of specialized psychiatric care • Dyadic or group therapy
COMPARATORS: Usual Care • One-to-one provider-patient, in-person, or virtual therapy with or without pharmacological therapy • Pharmacological therapy/use only	N/A
OUTCOMES: See Exhibit 13	N/A
SETTING: • Outpatient setting • United States	• Inpatient setting • Residential programs • Outside of United States
STUDY DESIGN: • Randomized controlled trials and nonrandomized controlled trials • Observational studies • SLRs[f]	• Editorials, commentaries, study protocols, reviews, case reports, and narrative reviews • ≤20 study participants
DATE OF PUBLICATION: Databases: 2018–2024 and Conferences: 2021–2024	N/A

Notes: CBT = cognitive behavioral therapy. DHT = digital health technology. N/A = not applicable. SLR = systematic literature review. [a] Disruptive mood dysregulation disorder, persistent depressive disorder, premenstrual dysphoric disorder, substance/medication-induced depressive disorder, depressive disorder due to another medical condition, other specified depressive disorder, and unspecified depressive disorder. [b] Separation anxiety disorder, selective mutism, specific phobia, social anxiety disorder, panic disorder, agoraphobia, substance/medication-induced anxiety disorder, anxiety disorder due to another medical condition, other specified anxiety disorder, and unspecified anxiety disorder. [c] Neurodevelopmental disorders, schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, obsessive-compulsive disorders, trauma- and stressor-related disorders, dissociative disorders, somatic symptoms and related disorders, feeding and eating disorders, elimination disorders, sleep-wake disorders, sexual dysfunction, gender dysphoria, disruptive impulse-control and conduct disorders, substance-related and addictive disorders, neurocognitive disorders, personality disorders, paraphilic disorders, and other mental health disorders. [d] Applies to studies including only patients with severe symptoms; we will retain studies for mixed populations including severe patients (i.e., a mix of mild, moderate, moderate-to-severe, and severe) when results are stratified by severity. [e] No studies reported analyses based on LGBTQ+ subgroups. [f] SLRs are included for manual reference checks only for studies published between 2018 and 2024 and will not be included in the qualitative evidence synthesis.

The search of online databases and conference posters identified 5,364 pieces of evidence. Reviewers screened these for inclusion in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (see Exhibit 10) and identified 109 eligible articles (including peer-reviewed journal publications and conference posters/abstracts) and 30 systematic literature reviews/meta-analyses. References from the systematic literature reviews/meta-analyses resulted in nine additional eligible articles. Ten companies (Meru Health, Talkspace, Headspace, Koa Health, Lyra, Modern Health, Spring Health, Teladoc, Big Health, and Rejoyn) submitted 266 pieces of clinical evidence for review.

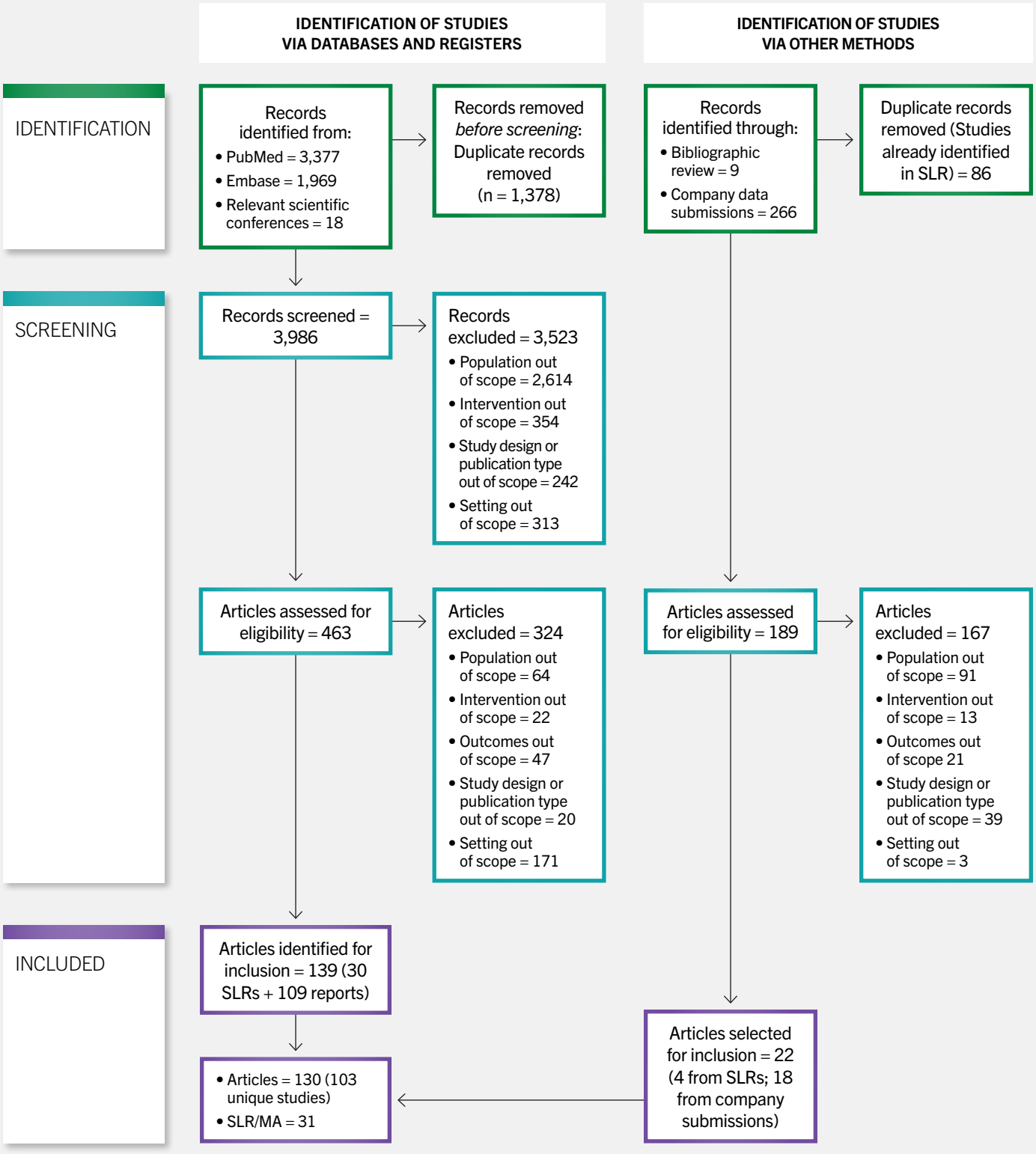
After screening using the PICOS criteria, 21 more articles were added, for a total of 130 articles based on 103 unique studies and 31 systematic literature reviews/meta-analyses.*

The 103 studies included in the systematic literature review included 56 interventional studies and 47 observational studies. Thirty-three interventional studies examined virtual solutions for depression and anxiety compared with a control arm and are referred to as "comparative studies" in this report, while other studies compared virtual solutions of varying modalities to one another.

* Of the 130 articles, six were not included in data extraction because of either limited data (3) or repetitive data (3), resulting in 124 articles from 102 studies in the analysis. For more detail, see **Appendix B-1**.

Exhibit 10

PRISMA DIAGRAM



Notes: SLR = systematic literature review. MA = meta-analysis. Systematic literature review (SLR) was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Articles include peer-reviewed publications, and conference abstracts and posters.

Evidence Requirements and Risk of Bias

According to the ICER-PHTI Assessment Framework for Digital Health Technologies, the digital health interventions in this report qualify as Tier 3a because they are professionally directed therapeutic services used in consultation with a medical professional. While not all digital solutions in this report have clinician involvement in their offering, they are intended to treat a clinical condition (i.e., anxiety or depression) that could be diagnosed by a healthcare professional.

Independent reviewers conducted study quality assessments, or risk of bias ratings, on 103 studies with sufficient detail to rate (see Exhibit 11). The 42 RCTs were rated with the Cochrane Collaboration Risk of Bias in Randomized Trials Version 2 (RoB2), of which 23 were rated with low risk of bias, 10 studies with moderate risk, and two studies with high risk (seven studies could not be rated). The 61 nonrandomized studies were rated with the Newcastle-Ottawa Scale (NOS) and 43 were rated with low risk of bias, six studies with moderate risk, and six with high risk (six studies could not be rated).

In comparison to previous PHTI reports, the evidence base for virtual solutions for depression and anxiety is more extensive, with most studies having low risk of bias; however, the study durations are shorter than those seen in other assessments, and recruitment methods and control conditions may impact outcomes.

Recruitment approaches among the studies ranged from active methods (e.g., community centers or physician referrals) to passive strategies (e.g., flyers or social media advertisements), with the latter potentially limiting generalizability because of selection bias toward highly motivated users who self-refer.

Control conditions also varied across studies, with some studies using active comparators like treatment as usual or sham apps, while others relied on passive controls, such as waitlists. Waitlist designs are vulnerable to differential dropout and disengagement, particularly in studies where participants actively signed up to participate but were randomized to receive no immediate intervention. In such cases, symptoms may worsen due to disappointment or lack of support. The Hawthorne effect may cause the opposite effect on symptoms, where participants experience improvement due solely to the attention received during a study. Moreover, studies without active comparators face difficulty distinguishing treatment effects from placebo response or spontaneous remission—the natural fluctuation and improvement over time in symptoms because of the episodic nature of the conditions.[81,82]

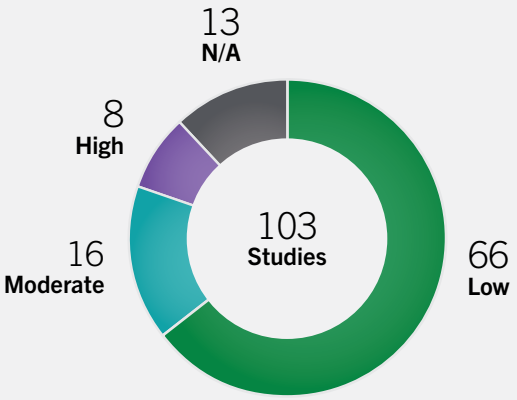
For the category-specific analysis, studies were matched to categories on the basis of the study design, including the intervention type and other mental healthcare users received. The evidence includes noncompany studies of digital mental health interventions. In some cases, company studies are matched to a different category on the basis of design: For instance, some blended-care solutions have studies testing only the self-guided portions of their product offering. Given the consistency in mechanism of action within similar approaches, findings for one company may apply to solutions using a similar approach, but differences in design, user interface, and care model may produce meaningful variations in outcomes.

There was substantially more robust evidence about the self-guided category than the blended-care solution category, which primarily consisted of noncomparative studies. PDTs have relatively strong comparative evidence, as is required for FDA review. Further evidence details are described in the category-specific clinical sections.

> **“ It can be especially challenging to evaluate the effectiveness of specific mental health interventions,**
>
> as this requires rigorous research designs to distinguish intervention-specific effects from other factors like hope and expectation that also drive symptom improvement. Self-selection bias, which can occur when individuals join a study because of an interest in the treatment being offered, can lead to better outcomes in the study than what might be experienced in real-world settings.
>
> —Dr. Adam Horwitz

Exhibit 11

RISK OF BIAS RATINGS FOR CLINICAL STUDIES



Notes: N/A = not applicable. N/A means that studies could not be rated. Risk of bias is assessed for studies, not articles. For ease of interpretation across risk of bias ratings, "Low" refers to original ratings of "Low Risk of Bias" (RoB2) or "Good Study Quality" (NOS), "Moderate" refers to original ratings of "Some Risk of Bias" (RoB2) or "Fair Study Quality" (NOS), and "High" refers to original ratings of "High Risk of Bias" (RoB2) or "Poor Study Quality" (NOS). See **Appendix C-1** and **C-2** for more detail on risk of bias ratings.

Minimal Clinically Important Difference (MCID)

To establish a benchmark for "clinically meaningful" change in treatment outcomes, clinicians and standards bodies typically define a "minimal clinically important difference" (MCID) for key measures. Among the studies included in this assessment, there are a range of definitions for MCID for depression and anxiety. This report uses an MCID threshold of a five-point reduction in PHQ-9 scores from baseline for depression and a four-point reduction in GAD-7 scores from baseline for anxiety.[85] MCID is applied on the basis of the average score improvement across participants in each study arm.

Understanding Clinical Outcomes

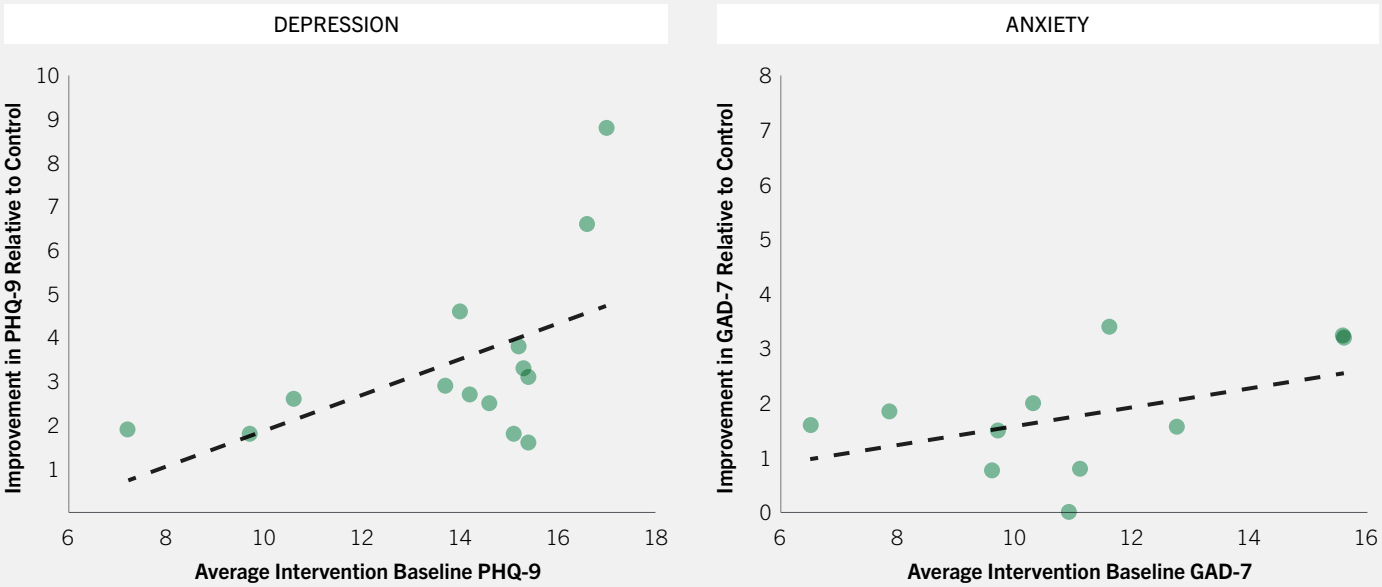
This evaluation reviewed evidence across eight outcome measures (See Exhibit 13). Outcomes considered in this assessment were informed by the International Consortium for Health Outcomes Measurement (ICHOM) depression and anxiety patient outcome measure sets. The primary clinical outcomes for depression and anxiety are focused on symptom improvement measured by validated assessment tools (i.e., GAD-7, PHQ-9), targeting clinically meaningful reductions in score change.[83, 84] The evaluation did not focus on depression and anxiety symptoms related to traumatic life events or patients with severe symptoms. The assessment prioritizes evidence from clinical studies with comparators over single-arm studies to understand the incremental impact of virtual solutions relative to usual care. As such, the assessment provides detail on comparator studies that utilize the GAD-7 or PHQ-9 (see **Appendix D** and **Appendix E**); comparator studies that utilize other assessment tools can be found in the **online data supplement**.

An important consideration when interpreting these findings is the relationship between baseline severity and the absolute change in PHQ-9 and GAD-7 scores. Exhibit 12 shows that studies that include patients with more-severe starting symptom scores tended to produce larger incremental improvements in PHQ-9 and GAD-7 scores relative to the control arm. The majority of studies in this assessment enrolled participants with moderate to moderately severe symptoms.

Secondary outcomes included a range of patient-reported measures, such as changes in psychosocial functioning and workplace productivity. These outcomes capture important aspects of patients' daily function and well-being and may support improvements in primary outcome measures. User experience metrics serve as important indicators of patient engagement with the solutions, while health equity considers solution efficacy for and deployment to underserved populations.

Exhibit 12

REPORTED IMPROVEMENT IN PHQ-9 AND GAD-7 RELATIVE TO CONTROL ARM IN COMPARATIVE STUDIES, BY BASELINE SEVERITY



Notes: Dots represent results from each of the comparative studies that report between-group differences from baseline for PHQ-9 and GAD-7 scores. Results are based on the last reported timepoint of the intervention period.

Exhibit 13

DETAILED SUMMARY OF CLINICAL, USER EXPERIENCE, AND HEALTH EQUITY OUTCOMES

Primary Clinical Outcomes		Secondary Clinical Outcomes	User Experience and Health Equity Outcomes
DEPRESSION Change over time and between-group differences in depression symptoms using validated, self-reported scales, including: • PHQ-9 • Beck Depression Inventory • Depression Anxiety Stress Scales-21 • Hamilton Rating Scale for Depression • Quick Inventory of Depressive Symptomatology • Montgomery-Åsberg Depression Rating Scale	ANXIETY Change over time and between-group differences in anxiety symptoms using validated, self-reported scales, including: • GAD-7 • Beck Anxiety Inventory • Hamilton Anxiety Rating Scale • Patient-Reported Outcomes Measurement Information System • Hospital Anxiety and Depression Scale • Depression Anxiety Stress Scales-21 • Penn State Worry Questionnaire	PSYCHOSOCIAL FUNCTIONING • Score change over time in validated outcome measures (e.g., SF-12 MCS, SDS) WORKPLACE PRODUCTIVITY • Score change over time using WPAI SAFETY • Adverse events • Crisis events (e.g., suicide attempts)	ENGAGEMENT • Sessions (e.g., number completed, mean weeks met with a therapist, average duration) • Communications (e.g., responses, total contacts, texts/messages sent, average duration) • App usage (e.g., features used, modules/activities/lessons/exercises completed, completed weekly measures) • Other (e.g., days to drop out, dose received, D-WAI/WAI-tech) SATISFACTION/USABILITY HEALTH EQUITY • Access and accessibility • Distribution

Notes: SDS = Sheehan Disability Scale. SF-12 MCS = SF-12 Mental Component Summary. WPAI = Work Productivity and Activity Impairment. D-WAI/WAI-tech = Digital Working Alliance Inventory.

Clinical Outcomes

Clinical outcomes in this assessment are examined in two ways. First, because all solutions include digital content, the analysis examines the clinical effectiveness of the use of digital mental health content for both depression and anxiety. This includes an examination of the effectiveness of digital content as an augmentation to usual care and as a standalone intervention. This section also includes a review of secondary outcomes from the evidence on digital content. Category- and solution-specific clinical evidence is presented in the second half of the clinical section.

Primary Outcomes

There is a well-established body of evidence supporting the clinical effectiveness of one-on-one psychotherapy.[86] Research has found that therapy can be highly effective when delivered in-person, via telehealth, and even using text messaging.[87,88] This assessment examines the effectiveness of virtual depression and anxiety solutions that include digital, CBT-based content as a stand-alone or in combination with therapy. These solutions may be used to improve access to care for those not receiving other treatment or to augment mental health treatment, including supporting patients between psychotherapy sessions. The following section reviews evidence about the impact of digital content on primary and secondary outcomes.

There is a large body of evidence examining the impact of digital content on symptoms of depression and anxiety for two distinct use cases:

1. **Augmenting Usual Care:** People receiving usual care who are using digital content to supplement other mental health treatment; and
2. **Expanding Access:** People who are not otherwise receiving mental health therapy (psychotherapy) for whom digital content can improve access to care.

In these studies, usual care or "treatment as usual" for depression and anxiety encompasses varied approaches, including medication, psychotherapy, primary care management, and combinations thereof. Across both groups, patients' use of mental health medications varied. Most studies include some patients taking medications in both the control and intervention arms. Neither the studies nor the solutions tested therein are designed to change medication use—either to increase access to prescriptions or to help patients stop taking medications. Only three studies assessed change in medication use over time and neither showed a significant change in medication use over time or between groups.[89–91]

The literature review identified 33 comparative studies that tested digital content against a control arm with no digital solution—16 that measured the change in depression symptoms using PHQ-9 and 13 that measured change in anxiety symptoms using GAD-7. Fourteen other comparator studies examined depression and anxiety using alternative scales (see **online data supplement**). An additional 36 single-arm studies examined how digital content impact PHQ-9 (36) and GAD-7 (27) over time.[†] When testing was conducted, all presented results are statistically significant unless specifically noted.

To help with interpretation of study results, this assessment presents findings from individual studies, as well as weighted averages of results based on study sample sizes (see **Appendix A**). All reported averages are weighted and are intended to support high-level comparisons across categories but are not adjusted to account for the quality of the study design or patient characteristics (including symptom severity) of study participants.

Augmenting Usual Care

When added to usual care, digital content demonstrates only small, incremental improvements in depression outcomes that do not consistently meet the threshold for clinically meaningful improvements from baseline. For anxiety, digital content performs comparably to usual care.

Depression Outcomes: Seven comparative studies (four with low risk of bias) examined the effect of digital content on depression symptoms relative to usual care (see Exhibit 14). The between-group differences show that PHQ-9 scores for patients using digital content improved by an average of 2.2 points more than for patients in the control arm.

Patients using digital content had an average PHQ-9 improvement from baseline of 4.6 points (range, 2.3–6.7) compared with 2.5 points (range, 0.5–5.1) for patients in the control arm.

In four of the seven studies, the average improvement in PHQ-9 scores from baseline in depression symptoms in the digital content arm met the MCID threshold (>5-point reduction in PHQ-9);[92–95] one study's control arm showed improvements from baseline that met MCID.[96] While not all studies achieved clinically meaningful improvements on average, digital content somewhat increased the likelihood that improvements among patients reached MCID.

[†] Studies in which the majority of patients were located outside the United States were excluded from the analysis.

Exhibit 14

DEPRESSION OUTCOMES FOR DIGITAL CONTENT COMPARED WITH USUAL CARE

		PHQ-9 CHANGE				CLINICALLY MEANINGFUL IMPROVEMENT FROM BASELINE	
Study (Risk of Bias)	**Baseline PHQ-9[a]**	**Digital Solution Arm**	**Control Arm**	**Between-Group Difference[b]**	**Last Reported Timepoint[c]**	**Digital Solution Arm**	**Control Arm**
Carl 2020[(L)]	15.4	–4.6	–1.6	–3.1	6 weeks	No	No
Schure 2019[(L)]	13.7	–6.5	–3.6	–2.9	8 weeks	Yes	No
Stuart 2022[(M)]	14.6	–6.5	–4.0	–2.5*	8 weeks	Yes	No
Segal 2020[(L)]	7.2	–2.8*	–0.9*	–1.9*	12 weeks	No	No
Hall 2024[(N/A)]	NR	–5.3	–3.8	–1.9[NS]	5 weeks	Yes	No
Moberg 2019[(M)]	9.7	–2.3*	–0.5*	–1.8	4 weeks	No	No
Rothman 2024[(L)]	15.4	–6.7*	–5.1	–1.6	6 weeks	Yes	Yes
Weighted Average	**12.1**	**–4.6**	**–2.5**	**–2.2**		**4 of 7**	**1 of 7**

Notes: NR = not reported. NS = not statistically significant. [(L)] Low risk of bias. [(M)] Moderate risk of bias. [(N/A)] Risk of bias could not be rated. Not all studies reported statistical significance for all outcomes; when reported, significance is noted. All values are rounded to one decimal place; differences may not sum due to rounding. * Statistically significant at p <.05.[a] Baseline PHQ-9 for the digital solution arm of the study. [b] Between-group difference from baseline at last reported timepoint of the intervention period. [c] Last reported timepoint indicates last reported timepoint of the intervention period. Values do not capture postintervention follow-up outcomes.

Baseline depression severity varied across studies. On average, starting PHQ-9 scores were 12.1 (moderate depression) for patients in the digital content arm but baseline scores ranged widely, from 7.2 (mild depression) to 15.4 (moderately severe). Study durations were short, ranging from 4 to 12 weeks, with most reporting outcomes at 6 to 8 weeks.

Nine single-arm studies[97–105] evaluated digital content added to usual care. Patients in these studies had a higher starting average PHQ-9 (13.0) but they only resulted in an average improvement of 2.7 points (range, 1.8–7.3) from baseline—less than the improvements seen in the comparative studies. Only two of these nine studies achieved MCID.[106, 107]

Five comparative studies that used other assessment scales to measure depression symptoms compared patients who used digital content with those receiving usual care. These studies found similar trends in depression outcomes, with all digital solution arms improving comparably or marginally better than control arms (see **online data supplement**).[108–112]

Anxiety Outcomes: Eight comparative studies (five with low risk of bias) examined the effect of digital content on anxiety symptoms relative to usual care (see Exhibit 15). Between-group differences show that GAD-7 scores for patients using digital content improved by an average of 1.4 points more than for patients in the control arm. Patients using digital content reported an average GAD-7 improvement from baseline of 3.5 points (range, 2.0–7.7), compared with 2.1 points (range, 0.8–4.5) for patients in the control arm.

Across these studies, the average starting GAD-7 score was 10.8, the lower end of the moderate anxiety range. Only two studies had improvements in anxiety symptoms that met MCID (GAD-7 improvement of >4 points), both of which had the highest starting scores at baseline. One of the control arms achieved clinically meaningful improvements from baseline in anxiety symptoms.

Anxiety results from the single-arm studies aligned closely with findings from the comparative studies. Eight single-arm studies examining digital content added to usual care reported an average weighted baseline GAD-7 score of 11.4 and an average improvement of 2.8 points. Only two of these seven studies met the MCID threshold.[113, 114]

Two comparative studies that used other assessment tools reported similar findings: Patients engaging with digital content showed modest improvements in anxiety symptoms relative to control groups.[115, 116]

Exhibit 15

ANXIETY OUTCOMES FOR DIGITAL PROGRAMS COMPARED WITH USUAL CARE

		GAD-7 CHANGE				CLINICALLY MEANINGFUL IMPROVEMENT FROM BASELINE	
Study (Risk of Bias)	**Baseline GAD-7[a]**	**Digital Solution Arm**	**Control Arm**	**Between-Group Difference[b]**	**Last Reported Timepoint[c]**	**Digital Solution Arm**	**Control Arm**
FDA 2024 (Daylight)[(N/A)]	15.6	–7.7	–4.5	–3.2	10 weeks	Yes	Yes
Carl 2020[(L)]	15.6	–6.1	–2.9	–3.2	6 weeks	Yes	No
Schure 2019[(L)]	10.3	–3.8	–1.8	–2.0	8 weeks	No	No
Segal 2020[(L)]	6.5	–2.3*	–0.8*	–1.6*	12 weeks	No	No
Moberg 2019[(M)]	9.7	–2.3*	–0.8*	–1.5	4 weeks	No	No
Stuart 2022[(M)]	11.1	–3.9	–3.1	–0.8	8 weeks	No	No
Rothman 2024[(L)]	9.6	–3.4*	–2.6	–0.8	6 weeks	No	No
Oser 2019[(L)]	10.9	–2.0	–2.0	0.0[NS]	24 weeks	No	No
Weighted Average	**10.8**	**–3.5**	**–2.1**	**–1.4**		**2 of 8**	**1 of 8**

Notes: NS = not statistically significant. [(L)] Low risk of bias. [(M)] Moderate risk of bias. [(N/A)] Risk of bias could not be rated. Not all studies reported statistical significance for all outcomes; when reported, significance is noted. All values are rounded to one decimal place; differences may not sum due to rounding. * Statistically significant at $p < .05$. [a] Baseline GAD-7 for the digital solution arm of the study. [b] Between-group difference from baseline at last reported timepoint of the intervention period. [c] Last reported timepoint indicates last reported timepoint of the intervention period. Values do not capture postintervention follow-up outcomes.

Expanding Access

For people without access to psychotherapy or who are not receiving treatment, digital content demonstrates more-substantial clinical benefits than when added to usual care. These solutions help users achieve clinically meaningful improvements in depression outcomes, more than they would otherwise. Comparative evidence is more limited for anxiety but suggests similar patterns of effectiveness.

Depression Outcomes: Seven comparative studies[‡] (five with low risk of bias) examined the effect of digital content on depression symptoms relative to patients not receiving psychotherapy (see Exhibit 16). Between-group differences show that PHQ-9 scores for patients using digital content improved by an average of 3.9 points more than patients in the control group.

Patients receiving digital content reported a substantial average PHQ-9 improvement from baseline of 6.9 points (range, 4.4–13.6) compared with 3.1 points (range, 1.8–4.8) in the control arm. In six of seven studies (86%), the average change in symptoms from baseline met the MCID threshold (>5-point reduction in PHQ-9) for digital content users. By comparison, none of the control arms achieved this MCID threshold.

Two smaller studies that focused on patients with moderate-to-severe depression showed larger relative reductions—improving PHQ-9 scores at least 6 points more than the control groups.[117,118] One single-arm study assessed the effect of digital content on patients not currently on psychotherapy and found similar decreases in PHQ-9 scores.[119]

These results suggest that patients who are not receiving psychotherapy have more consistent clinical benefits from digital content than patients who are already receiving mental healthcare. Accordingly, baseline depression severity was generally higher in these studies of "untreated" populations, with an average starting PHQ-9 score of 14.9, representing moderate to severe depression. Study durations ranged from 4 to 10 weeks, with most reporting outcomes at 6 to 8 weeks.

Four comparative studies compared patients using digital content with those receiving no psychotherapy and support the finding that those receiving the digital solution arm improve more than the control arm (see **online data supplement**).[120–123]

Anxiety Outcomes: Only three comparative studies—each with low risk of bias—examined the effect of digital content on anxiety symptoms relative to patients receiving no psychotherapy (see Exhibit 17). Between-group differences show that GAD-7 scores for patients using digital content improved by an average of 2.1 points more than for patients in the control group.

[‡] One study (Stiles-Shields 2019) assessed two types of digital content; outcomes for both solution arms are included in the exhibit.

Patients receiving digital content had an average GAD-7 improvement from baseline of 4.6 points (range, 2.8–5.0) compared with 2.5 points in the control arm (range, 0.9–3.4). In two of the three studies, the digital solution arm met MCID (>4-point reduction in GAD-7), compared with none of the control arms.[124, 125] The average starting GAD-7 score was 11.7, representing moderate anxiety. All studies had similar durations of 8 to 9 weeks and a low risk of bias. Two single-arm studies[126, 127] and two comparative studies reporting other assessment scales[128, 129] generally supported these findings.

Exhibit 16

DEPRESSION OUTCOMES FOR DIGITAL CONTENT COMPARED WITH PATIENTS NOT RECEIVING PSYCHOTHERAPY

		PHQ-9 CHANGE				CLINICALLY MEANINGFUL IMPROVEMENT FROM BASELINE	
Study (Risk of Bias)	**Baseline PHQ-9[a]**	**Digital Solution Arm**	**Control Arm**	**Between-Group Difference[b]**	**Last Reported Timepoint[c]**	**Digital Solution Arm**	**Control Arm**
Stiles-Shields 2019[d, (L)]	17.0	–13.6*	–4.8*	–8.8*	6 weeks	Yes	No
Stiles-Shields 2019[d, (L)]	15.2	–8.6*	–4.8*	–3.8[NS]	6 weeks	Yes	No
Forand 2018[(L)]	16.6	–10.1	–3.5	–6.6*	8 weeks	Yes	No
Graham 2020[(L)]	14.0	–6.8	–2.2	–4.6	8 weeks	Yes	No
Renn 2024[(L)]	15.3	–6.1	–2.8	–3.3	8 weeks	Yes	No
Hanuka 2023[(L)]	13.8	–6.5	–3.7	–2.7	10 weeks	Yes	No
Murillo 2020[(M)]	10.6	–4.4*	–1.8[NS]	–2.6	8 weeks	No	No
Davis 2024[(M)]	15.1	–6.4	–4.6	–1.8	4 weeks	Yes	No
Weighted Average	**14.9**	**–6.9**	**–3.1**	**–3.9**		**6 of 7[d]**	**0 of 7[d]**

Notes: NS = not statistically significant. [(L)] Low risk of bias. [(M)] Moderate risk of bias. Not all studies reported statistical significance for all outcomes; when reported, significance is noted. All values are rounded to one decimal place; differences may not sum due to rounding. * Statistically significant at p <.05. [a] Baseline PHQ-9 for the digital solution arm of the study. [b] Between-group difference from baseline at last reported timepoint of the intervention period. [c] Last reported timepoint indicates last reported timepoint of the intervention period. Values do not capture postintervention follow-up outcomes. [d] Stiles-Sheilds 2019 compared two types of digital content—one that utilized activity scheduling methods and one that utilized thought restructuring methods—to individuals not receiving psychotherapy. Both digital solution arms are included in the table; for the weighted average, baseline PHQ-9 scores and follow-up scores for the two arms were averaged to create a composite digital solution outcome for this study.

Exhibit 17

ANXIETY OUTCOMES FOR DIGITAL CONTENT COMPARED WITH PATIENTS NOT RECEIVING PSYCHOTHERAPY

		GAD-7 CHANGE				CLINICALLY MEANINGFUL IMPROVEMENT FROM BASELINE	
Study (Risk of Bias)	**Baseline GAD-7[a]**	**Digital Solution Arm**	**Control Arm**	**Between-Group Difference[b]**	**Last Reported Timepoint[c]**	**Digital Solution Arm**	**Control Arm**
Graham 2020[(L)]	11.6	–4.8	–1.4	–3.4	8 weeks	Yes	No
Xiang 2024b[(L)]	7.9	–2.8*	–0.9[NS]	–1.9	9 weeks	No	No
Renn 2024[(L)]	12.8	–5.0	–3.4	–1.6	8 weeks	Yes	No
Weighted Average	**11.7**	**–4.6**	**–2.5**	**–2.1**		**2 of 3**	**0 of 3**

Notes: [(L)] Low risk of bias. Not all studies reported statistical significance for all outcomes; when reported, significance is noted. All values are rounded to one decimal place; differences may not sum due to rounding. * Statistically significant at p < .05. [a] Baseline GAD-7 for the digital solution arm of the study. [b] Between-group difference from baseline at last reported timepoint of the intervention period. [c] Last reported timepoint indicates last reported timepoint of the intervention period. Values do not capture postintervention follow-up outcomes.

Effectiveness Across Intervention Types

An important consideration in the implementation of virtual solutions for depression and anxiety is whether specific modalities or therapeutic approaches provide differential benefits. The evidence base—which includes 20 interventional studies directly comparing different virtual solutions from evaluated programs—demonstrates that digital mental health interventions are largely interchangeable across modalities (e.g., in-person, video, digital) with minimal impact on effectiveness. Five randomized trials compared digital treatment approaches, including a range of digital apps, interventions with and without coaching support, and message-based versus video-based therapy.[130–134] In each study, patients achieved clinically meaningful improvements in symptoms with no statistically significant differences reported across interventions.

Evidence Limitations

Despite the growing body of evidence supporting digital interventions for depression and anxiety, additional research is needed to understand the durability of these clinical improvements beyond the relatively short study periods. Further, there is limited evidence specifically addressing treatment effects for people with mild symptoms, as most studies focused on populations with moderate to severe depression and anxiety symptoms. The increasing availability and accessibility of digital mental health solutions may lead individuals with mild anxiety or depression who otherwise would not seek care to do so, particularly if these treatments become more widely covered by employer health plans. Finally, studies disproportionately represent younger, white, female users (more details described in the health equity section). Researchers should work to expand the evidence base to include diverse users, including older adults, males, and nonwhite racial and ethnic groups.

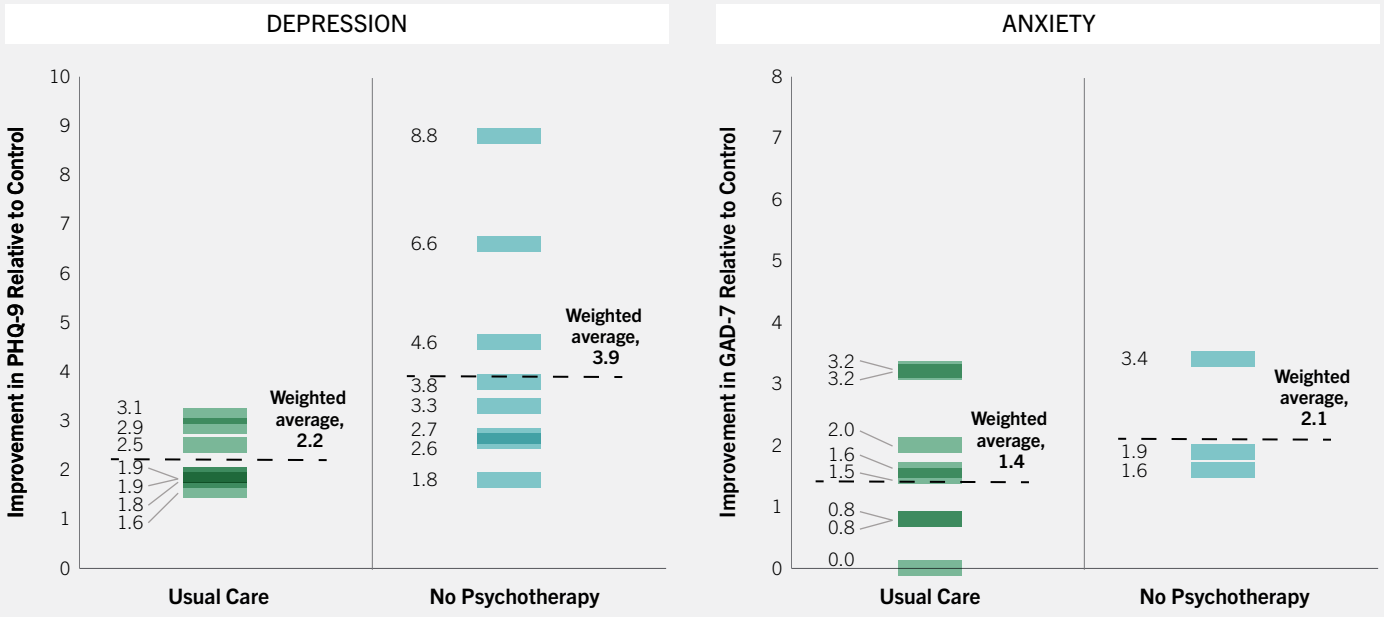
Summary of Primary Outcomes

Based on PHTI's review of clinical evidence, for people not otherwise receiving psychotherapy, virtual solutions that incorporate digital content make it more likely that patients will achieve clinically meaningful improvements in depression—and to a more limited extent anxiety—compared with control arms. On average, users improved depression scores by approximately 7 points relative to baseline, which is 3.9 points more than controls (Exhibit 18 and 19). Given the significant barriers to accessing traditional psychotherapy—including cost, provider shortages, geographic limitations, and stigma—such digital content may help address a critical gap in mental healthcare delivery.

For patients receiving usual care (typically including a mix of medication and therapy) for their mental health needs, adding digital content produces only small incremental improvements in depression symptoms that do not achieve MCID in most studies. On average, users improved depression scores by 4.9 points over baseline, which is only 2.1 points more than controls. The depression benefits appear more pronounced for patients with more severe baseline symptoms, suggesting that targeting these solutions to appropriate patient populations may enhance their clinical impact. For anxiety, digital content performs comparably to usual care.

Exhibit 18

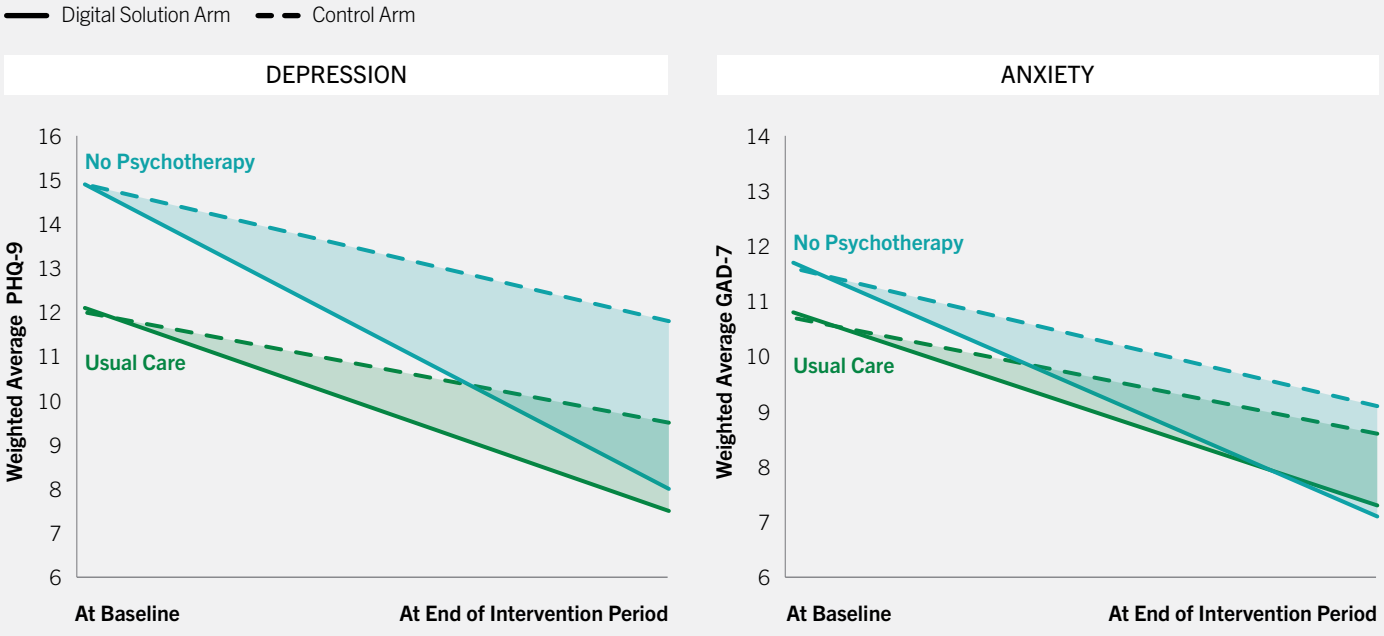
COMPARATIVE STUDY RESULTS OF BETWEEN-GROUP DIFFERENCE IMPROVEMENTS IN PHQ-9 AND GAD-7 SCORES FOR DIGITAL CONTENT VERSUS CONTROL ARMS (USUAL CARE AND NO PSYCHOTHERAPY)



Note: Bars represent the between-group difference results in PHQ-9 and GAD-7 at the last reported timepoint in comparative studies. Values are rounded.

Exhibit 19

WEIGHTED AVERAGE CHANGE FROM BASELINE IN PHQ-9 AND GAD-7 SCORES FOR DIGITAL CONTENT VERSUS CONTROL ARMS



Secondary Outcomes

In addition to improving their depression and anxiety symptoms, patients also want to be able to function well in their lives, relationships, and work. The evidence for these secondary outcomes varies considerably in quality and quantity, with most data coming from studies without a control arm. All studies reporting on secondary outcomes can be found in the **online data supplement**.

Psychosocial Functioning

Improvements in psychosocial functioning indicate whether symptom reductions translate to meaningful changes in patients' daily lives. The review identified 17 articles addressing this outcome. Digital solutions were generally shown to improve psychosocial functioning, although comparative evidence is limited and variability in assessment tools utilized across studies limits the strength of conclusions. Two studies using a mental impairment assessment tool found that patients using digital solutions experienced greater reductions in impairment than control arms.[135, 136] In two studies without a control arm, patients using digital solutions reported improvements over time in perceived impairment across key areas of daily functioning, including work, social interactions, and family life.[137, 138]

Workplace Productivity

Five articles examined changes in self-reported workplace productivity for individuals using virtual solutions for depression and anxiety. Single-arm studies show promising improvements in workplace productivity, with 20–41% reductions in impairment; however, the methodology and assumptions for measuring work impairment are not specified and make the conclusions difficult to assess.[139, 140] The sole comparative study did not find evidence that virtual solutions increased productivity more than in the control group.[141]

Safety Outcomes

The evidence suggests that virtual solutions for depression and anxiety present minimal safety risks, with adverse event rates similar to or lower than those observed in control conditions. Based on 19 articles, including 12 comparative studies, digital solutions were generally well-tolerated and not associated with material safety concerns. Adverse events were rare and typically not related to the digital interventions.

User Experience

To be clinically effective, virtual solutions must engage patients and deliver a strong user experience; however, user experience is highly dependent on the platform interface and how interactive, engaging, and relatable the content is to patients. Patient preferences for such user interface components such as navigation, visual layout, and ease of use can also significantly influence both user satisfaction and overall engagement. Across the studies in this report, users consistently reported high satisfaction and usability scores across solutions.

Engagement

Patient engagement with virtual mental health solutions varies considerably and appears to play a significant role in treatment outcomes. Companies have implemented various strategies to boost engagement, including personalized content recommendations, gamification elements, just-in-time adaptive interventions, and AI-driven reminders based on usage patterns.

The systematic review identified 78 articles that included engagement metrics, though these varied widely in their definition and measurement. The most common engagement metrics were the number of sessions, modules, or lessons completed. Other measures include app usage frequency, number of messages exchanged with therapists, and days to program discontinuation.

Engagement levels in comparative studies varied substantially. One study found participants completed only 19% of lessons, on average,[142] and another found that only half the participants even downloaded the app.[143] In other studies, most participants completed some of the program and about a quarter to a third of participants completed the entire program.[144, 145] A few studies demonstrated high engagement rates, with treatment completion rates ranging from 72–91%.[146–148] One study identified lower engagement among individuals with worse physical health, less education, and minority backgrounds.[149]

Notably, studies that examined digital content with the addition of coaching involvement resulted in moderate to high levels of engagement with greater than 50% completion of program sessions.[150–153] Additionally, one study found that patients who received content recommendations from a coach had higher sustained engagement over time than patients who just received notifications to engage.[154] Evidence that guided support boosts engagement was reinforced by a separate study comparing patient use of digital content with or without coaching or therapy. The study found that participating in any coaching or therapy sessions was associated with an 80% increase in the number of digital resources used.[155]

Studies consistently found that users with higher rates of engagement had better clinical outcomes.[156–162] Notably, older adult populations demonstrated particularly high engagement rates.[163, 164]

Importantly, engagement rates in study populations generally reflect best-case results and may not reflect real-world performance. While most studies in this assessment were short-term, if patterns are similar to other digital solutions, initial engagement tends to be high, followed by a substantial drop-off within weeks and months.

Although engagement may differ on the basis of how participants were identified and enrolled in the studies, there is no clear evidence that recruitment method or compensation substantially impacted engagement. Among the comparator studies reporting engagement data, 18 offered some form of compensation but did not have a consistent effect on engagement.

Satisfaction and Usability

User satisfaction and usability metrics help determine whether digital solutions meet user expectations and can be easily integrated into their lives. Twenty-six articles addressed satisfaction, usability, or similar metrics (e.g., helpfulness). Most studies reported high satisfaction with digital solutions, on par or sometimes better than traditional care models. In most studies, digital solutions also received high usability scores, with patients reporting that programs are easy to use, including among older adults.

Health Equity Outcomes

The few studies included in this review that examined solution impact on diverse populations suggested clinical outcomes for virtual solutions were relatively consistent across demographic groups. This suggests that digital solutions have the potential to be effective across diverse populations when users engage with them. However, actual engagement patterns vary widely across groups and warrant further efforts to reach and engage a more diverse set of users. The evidence supports the potential for these technologies to reduce disparities in mental healthcare access, particularly for rural and older populations, though more research is needed regarding socioeconomic disparities.

Gender: Importantly, study demographics reveal that these solutions are largely investigated in participant pools of younger, white females. Of the 124 articles from the systematic literature review, 67 (54%) included study samples with greater than 75% female participants. Several factors may contribute to the predominance of younger, white, female participants, such as gender differences in mental health help-seeking behaviors, greater likelihood to enroll in study programs, or recruitment and advertising methodologies via social media or online communities disproportionally populated by younger, white females.

Geography: Four studies reported baseline characteristics for geographic location,[165–168] with two examining primarily rural populations.[169, 170] These studies suggest that digital content is effective in reducing depression and anxiety symptoms for rural residents, where access to traditional mental health services may be limited.

Socioeconomic Status: Only one study examined the effects of virtual solutions across income levels.[171] While both low-income (<$30,000/year) and high-income (>$60,000/year) groups achieved symptom improvements, higher-income individuals reported better overall depression outcomes. Lower-income participants reported significantly greater depressive symptom severity throughout the study period.

Race and Ethnicity: Four studies examined clinical effectiveness across racial and ethnic groups with generally positive findings across groups.[172–175] Two studies found digital content improved depression and anxiety symptoms in African American and Hispanic patients slightly better or comparable to white patients, although engagement was lower in Hispanic patients.[176, 177] Interestingly, some African American patients saw symptom improvements despite no engagement with the solution, suggesting that just the availability of treatment could have a general effect on symptom improvement groups.[178] Only one study measured patient satisfaction with a virtual solution that found no meaningful differences across racial or ethnic groups.[179]

Age: Eight studies examining effectiveness by age consistently found positive results across groups. Two studies demonstrated comparable engagement levels and symptom improvements between older and younger adults using virtual solutions.[180, 181] Five studies showed virtual solutions were effective in improving depression symptoms in middle-aged and older populations, with high rates of engagement, usability, acceptability, and satisfaction.[182–186] One study found similar positive outcomes among young adults, with improvements in depressive symptoms and high levels of engagement and satisfaction.[187] These findings suggest digital solutions may be valuable across the age spectrum.

Category and Solution-Specific Analysis

This section evaluates the 15 specific virtual solutions for depression and anxiety included in this report. For each company, there is a description of the company's offerings and a review of the company's clinical evidence. Each solution has unique features, user engagement approaches, and staffing models.

Solutions can be broadly grouped into three main categories: **self-guided solutions, PDTs, and blended-care solutions.** Five companies (AbleTo, Headspace, Meru Health, Talkspace, and Teladoc) that sell blended-care solutions also sell their digital content as a stand-alone, self-guided product. Further details on solution-specific offerings and clinical evidence are summarized below.

Fourteen of the companies (all except Dario) included in this assessment engaged with PHTI during the evaluation process and 10 submitted evidence for review. Throughout the process, PHTI met with companies to better understand their solutions. Companies also had an opportunity to review company-related information in the report prior to publication. Confidential business information that was submitted to PHTI informed the assessment but is not detailed in this report. Clinical summaries are based on the full literature review, included company-submitted evidence. See **Appendix B-2** for a complete list of company-submitted clinical evidence that did not meet inclusion criteria for this analysis. Results for all included studies are captured in the detailed **online data supplement**.

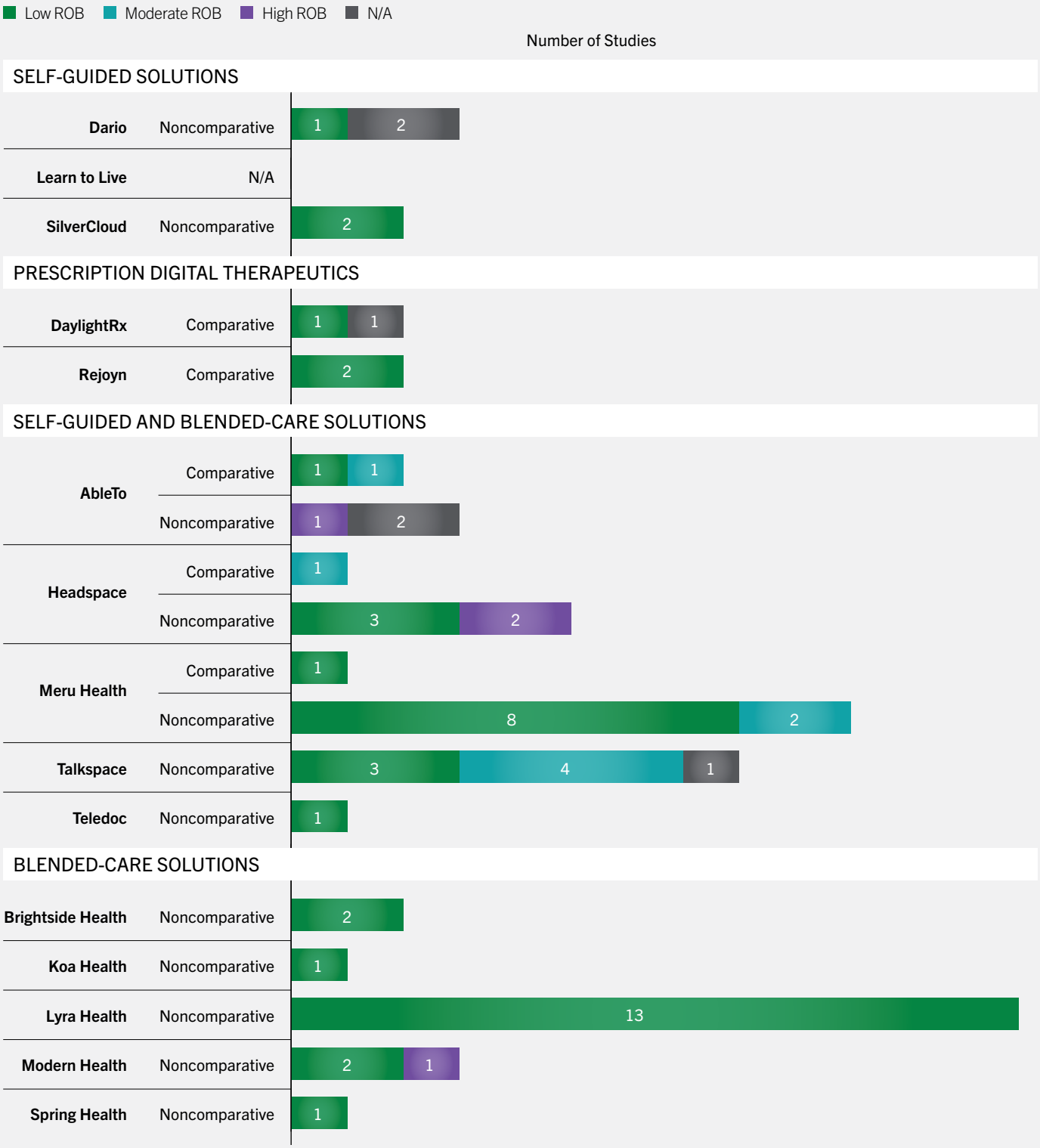
Company Evidence

Given the consistency in mechanism of action within similar categories, findings for one company may apply to solutions using a similar approach, but differences in design, user interface, and care model may produce meaningful variations in outcomes. There are different configurations of features available for each solution. For companies that offer both self-guided and blended-care solutions, those features are listed in the relevant features tables below.

All companies in this report—except for Learn to Live—produced at least one study about clinical effectiveness of their solutions (Exhibit 20). The two PDTs, as well as AbleTo, Headspace, and Meru Health were the only companies with comparative studies of their solutions versus controls. Lyra and Meru Health had a very large base of noncomparative studies that met inclusion criteria with low risk of bias.

Exhibit 20

RISK OF BIAS OF CLINICAL STUDIES, BY COMPANY



Notes: ROB = risk of bias. N/A = not applicable. One self-guided solution study assessed both SilverCloud and Headspace; this study is counted in both SilverCloud and Headspace's counts. For ease of interpretation across risk of bias ratings, "Low" refers to original ratings of "Low Risk of Bias" (RoB2) or "Good Study Quality" (NOS), "Moderate" refers to original ratings of "Some Risk of Bias" (RoB2) or "Fair Study Quality" (NOS), and "High" refers to original ratings of "High Risk of Bias" (RoB2) or "Poor Study Quality" (NOS).

Self-Guided Solutions

Eight of the companies sell self-guided solutions—which deliver CBT-based digital content, sometimes accompanied by coaching or features to increase engagement—were included in the assessment. Three companies (Dario, Learn to Live, and SilverCloud) offer only self-guided solutions. The other five companies (AbleTo, Headspace, Meru Health, Talkspace, and Teladoc) also sell more comprehensive, blended-care products. See Exhibit 21 for a summary of the self-guided product features.

As described in the primary outcomes section above, there is a robust body of evidence supporting the clinical benefits of digital content for depression and anxiety. However, most of the comparative clinical evidence comes from studies that do not include the solutions being evaluated in this assessment. Dario and SilverCloud produced solution-specific evidence that is summarized below.

DarioHealth

Dario provides a mental health solution as both a standalone offering and as part of its multicondition management programs. It combines CBT-based, self-guided interventions with digital and live coaching available as needed. Patients can engage with AI-chatbot coaching or certified health coaches who support stress and crisis management. In early 2025, Dario expanded its offering through a collaboration with Rula Health to include access to a provider network, though this expansion was not operational during the assessment period.[188] Dario sells to employers and health plans.

Data from Dario included one comparator study and two single-arm studies from the literature review, all showing that digital solutions led to reductions in depression and anxiety symptoms. These studies were conducted on a digital product that was subsequently acquired by Dario and may contain different features than the currently available solution.

Exhibit 21

CORE COMPONENTS OF VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY—SELF-GUIDED SOLUTIONS

● Standard Feature ○ Optional Feature

COMPONENT Feature	AbleTo (Self Care+ Coaching)	Dario[a]	Headspace (Core)[b]	Learn to Live	Meru Health (Coaching)	SilverCloud[c]	Talkspace (Talkspace Go)	Teladoc (Digital + Coaching)
CLINICIAN INVOLVED IN CARE Licensed therapist						○		
Psychiatrist								
PLATFORM Intake assessment	●	●	●	●	●	●	●	●
Coaches involved in goal-setting, motivation, and education	●	●	●	●	●	●		●
Self-guided care/CBT education modules and lessons/cognitive emotional training	●	●	●	●	●	●	●	●
Asynchronous psychotherapy messaging								
INTEGRATION Ability for providers to communicate within and outside the platform for coordinated care	●			●	●			●
DURATION Set timeline (X-week program)	●				●			

Source: Public information (websites, marketing materials, company-provided public information, etc.).

Notes: [a] Dario has both a human and AI-coach available when needed. [b] Headspace Core has an AI-companion available within their platform. [c] SilverCloud has a human coach within their platform and access to therapists within the Amwell network.

A retrospective study without a control arm compared two digital solutions with Happify (acquired by Dario) and found statistically significant improvements in well-being over 6 to 10 weeks.[189] Another study found that older adults who engaged with at least two activities per week experienced a statistically significant 20% improvement in anxiety scores, compared with 7% improvement for those with lower engagement.[190] A third study with a low risk of bias reported statistically significant reductions in PHQ-9 and GAD-7 scores over 16 weeks, with coaching engagement linked to reductions in depression symptoms and breathing exercises associated with reductions in anxiety symptoms.[191]

Learn to Live

Learn to Live provides digital mental health support through evidence-based CBT digital content and live coaching. All coaches are clinically trained in social work, psychology, or counseling. The platform adapts digital content based on ongoing standardized assessments and uses gamification to encourage engagement. Learn to Live sells to health systems, health plans, and employers.

Learn to Live did not submit any data, nor did the systematic literature review identify any relevant studies.

SilverCloud

SilverCloud offers an automated, digital, mental health platform with on-demand and self-guided structured CBT-based programs. The platform uses interactive self-guided content, videos, and asynchronous coaching support. Licensed therapists and psychiatrists are available through Amwell's provider network. SilverCloud sells to health plans, health systems, and employers.

Two clinical studies met inclusion criteria. A single-arm observational study with low risk of bias assessed SilverCloud's digital program over two years, finding that participants with at least moderate depression experienced a statistically significant three-point decrease in PHQ-9 scores, while those with moderate anxiety demonstrated a statistically significant four-point reduction in GAD-7 scores.[192] One study with a low risk of bias compared SilverCloud's digital content with Headspace and enhanced personalized feedback interventions. The study found both SilverCloud's enhanced personalized feedback and digital content arms showed statistically significant reductions in depressive symptoms from baseline to six weeks (PHQ-9 change from baseline: −2.1 to −2.5), with no statistically significant differences between intervention types.[193]

Other Companies Offering Self-Guided Solutions

Five companies sell stand-alone, self-guided solutions in addition to blended-care solutions, three of which (AbleTo, Headspace, and Teladoc) produced studies examining the digital components of their offerings. Comparative studies from AbleTo and Headspace found that digital content improved primary outcomes significantly more than control groups. An older, single-arm study of a digital content solution acquired by Teladoc found only small, not clinically meaningful incremental improvements in depression and anxiety from baseline. Further details on these companies and their clinical evidence are included in the blended-care section.

Prescription Digital Therapeutics (PDTs)

Two PDTs—which are FDA-cleared, CBT-based, digital content solutions prescribed by a mental health provider—are included in the assessment. Features of DaylightRx, for anxiety, and Rejoyn, for depression, are included below (see Exhibit 22).

Exhibit 22

CORE COMPONENTS OF VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY—PDTS

● Standard Feature ○ Optional Feature

COMPONENT Feature	DaylightRx	Rejoyn[a]
CLINICIAN INVOLVED IN CARE[b] Licensed therapist	●	●
Psychiatrist	●	●
PLATFORM Intake assessment		
Coaches involved in goal-setting, motivation, and education		○
Self-guided care/CBT education module and lessons	●	●
Cognitive emotional training		●
Asynchronous psychotherapy messaging		●
INTEGRATION Ability for providers to communicate within and outside the platform for coordinated care	●	
DURATION Set timeline (X-week program)	●	●

Source: Public information (websites, marketing materials, company-provided public information, etc.).

Notes: [a] Some patients are connected to nurses who provide education and treatment support. [b] Primary care providers and other mid-level practitioners are able to prescribe these solutions.

The clinical evidence about PDTs includes three well-designed, comparative company studies that reported results using PHQ-9 and GAD-7 scores. These studies showed PDTs deliver larger average improvements in depression (5.9 points on PHQ-9) and anxiety (5.6 points on GAD-7) symptoms, relative to the rest of the evidence about digital content for people receiving usual care (4.6 on PHQ-9 and 3.5 on GAD-7). PDTs achieved clinically meaningful improvements from baseline for depression in one of the two studies and in anxiety in two of the three studies.

PDTs are approved to be used as an adjunct to clinician-managed outpatient care. As a result, the total population likely to use PDTs is smaller, since PDTs are not likely to be used to expand access to care. However, the companies produced economic evidence that assumes that some clinicians may prescribe PDTs as an alternative to either therapy or medication, which warrants further study. The section below summarizes the two PDT offerings and their clinical evidence. Both of the companies offering PDTs engaged with PHTI as part of the evaluation.

DaylightRx

Big Health offers DaylightRx, a PDT intended to treat GAD in patients aged 22 years and older as an adjunct to usual care.

DaylightRx provides digital cognitive behavioral treatment that is fully automated and tailored to the individual. The program guides patients through interactive lessons and exercises that address anxiety symptoms and tracks progress with regular standardized assessment. DaylightRx is sold to health systems and providers and reimbursed by a growing number of payers.

Two DaylightRx studies met inclusion criteria. An RCT with low risk of bias evaluated DaylightRx[§] and found greater reductions in GAD-7 scores compared with waitlist controls (3.2-point between-group difference) and clinically meaningful improvements from baseline (6.1 points). Improvements in depressive symptoms were also favorable for the intervention group.[194] Another article from the same study compared DaylightRx with a waitlist control group and found significant between-group differences in social functioning with smaller improvements in work and family-life domains.[195] The other study, submitted as part of Daylight's 510(k) premarket notification, compared Daylight to online psychoeducational content for adults with anxiety. At 10 weeks, participants using Daylight experienced a statistically significant reduction in GAD-7 scores from baseline (7.7).[196]

[§] Product was named Daylight during the study period.

Rejoyn

Rejoyn is a PDT commercialized by Otsuka Precision Health, Inc., that augments depression treatment for adults 22 years of age and older who are on an antidepressant medication. The six-week structured program is based on a brain-training exercise designed to improve cognitive control of emotion and reduce depression symptoms. The treatment also includes brief animated videos featuring CBT-based therapy lessons. Patients typically engage with the platform 3–6 times per week, supported by automated motivational text messaging and nurse calls as needed. Rejoyn sells directly to patients, employers, providers, and health systems.

Two studies met inclusion criteria. Data from one study focused on adults with depression was used as part of Rejoyn's 510k submission and as part of four company-submitted posters. An RCT with low risk of bias evaluated the EFMT—a digital, cognitive-emotional, training intervention—in adults with depression. The study reported continued improvements in depression symptoms, with the EFMT participants showing statistically significant reductions in depression symptoms and 36% of participants reaching a clinical response, compared with 17% in the active control group.[197] An RCT with low risk of bias found Rejoyn users had greater reductions in PHQ-9 scores relative to a sham app (1.6-point between-group difference) and statistically significant and clinically meaningful improvements from baseline (6.7).[198] Additional posters found that higher engagement was associated with stronger clinical benefits[199] and that 85% of participants completed at least 12 of 18 sessions.[200]

Blended-Care Solutions

Ten companies offer **blended-care solutions,** which combine the digital content included in the **self-guided care solutions** (with and without coaches) with live or asynchronous therapeutic services delivered by therapists and psychiatrists—AbleTo, Brightside, Headspace, Koa Health, Lyra, Meru Health, Modern Health, Spring Health, Talkspace, and Teladoc. A comparison of features across the blended-care solutions are included below.

Exhibit 23

CORE COMPONENTS OF VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY – BLENDED-CARE SOLUTIONS

● Standard Feature ○ Optional Feature

COMPONENT Feature	AbleTo (Therapy +360)[a]	Brightside	Headspace (Care/EAP)[b]	Koa Health[c]	Lyra	Meru Health (Therapy)[d]	Modern Health	Spring Health	Talkspace	Teladoc (Integrated Mental Health Program)
CLINICIAN INVOLVED IN CARE Licensed therapist	●	●	●	○	●	●	●	●	●	●
Psychiatrist	○	●	●		●	○	●	●	●	●
PLATFORM Intake assessment	●	●	●	●	●	●	●	●	●	●
Coaches involved in goal-setting, motivation, and education	●		●		●		●	●		●
Self-guided care/CBT education modules and lessons/cognitive emotional training	●	●	●	●	●	●	●	●	●	●
Asynchronous psychotherapy messaging		●			●	●	●	●	●	
INTEGRATION Ability for providers to communicate within and outside the platform for coordinated care	●	●	●		●	●	●	●	●	●
DURATION Set timeline (X-week program)	●	●				●				

Source: Public information (websites, marketing materials, company-provided public information, etc.).

Notes: [a] AbleTo has the ability to refer out to psychiatrists. [b] Headspace Care/EAP has both a human and AI-coach within their platforms. [c] Koa Health refers their patients stepped up to therapy to an outside network of therapists. [d] Meru Health psychiatrists cannot prescribe medications to patients.

Blended-care solutions combine two interventions—digital content and virtual therapy—that have each been well-studied independently. For people who are not receiving psychotherapy, the evidence suggests a blended-care solution that combines digital content with live-therapy providers produces better outcomes than self-guided tools alone. People who are receiving usual care may also benefit from blended-care solutions, which may make it easier to access therapists and also enables therapists to refer patients to digital tools within the product.

The comparative evidence base about the combined effects of blended-care solutions is limited, with only two studies. There are, however, 27 single-arm studies that examine the impact of these solutions on depression and anxiety symptoms over time (i.e., relative to baseline).

The two comparative studies assessed patients using blended-care solutions versus patients receiving usual care, both showing clinically meaningful improvements in depression and anxiety symptoms. In a 12-week RCT with a low risk of bias, patients with moderately severe depression who used a blended-care solution demonstrated substantial clinical benefit, improving PHQ-9 scores by 4.5 points more than the control group, and only those users in the digital solution arm achieved MCID (improving by 6.4 points from baseline).[201] For anxiety outcomes, the digital solution arm improved by a statistically significant 4.1 points more than the control arm, with the digital solution arm meeting MCID (improving 5.1 points from baseline) while the usual care arm did not.

In another RCT of patients with moderate-to-severe depression in a primary care setting, patients in the digital solution arm improved by 2.4 points more than the control arm. In this case, both patients in the control arm and the digital solution arm achieved clinically meaningful improvements in depression. For anxiety, the digital solution arm improved by 2.7 points more than the control arm, with only the digital solution arm meeting MCID (a 5.2-point reduction vs. 2.5 points in the control arm).[202]

Findings from a large volume of single-arm studies were consistent with these trends, showing relatively large and clinically meaningful before-after improvements in both PHQ-9 scores and GAD-7 scores for people using blended-care solutions—average improvement of 5.9 points for PHQ-9 and 5.5 points for GAD-7.** Seven single-arm studies examining blended-care solutions in populations not receiving psychotherapy at baseline had an average PHQ-9 improvement of 7.7 points, with five meeting MCID. Similarly, four single-arm studies reported anxiety outcomes and found average improvements in GAD-7 scores of 6.2 points (see **online data supplement**).

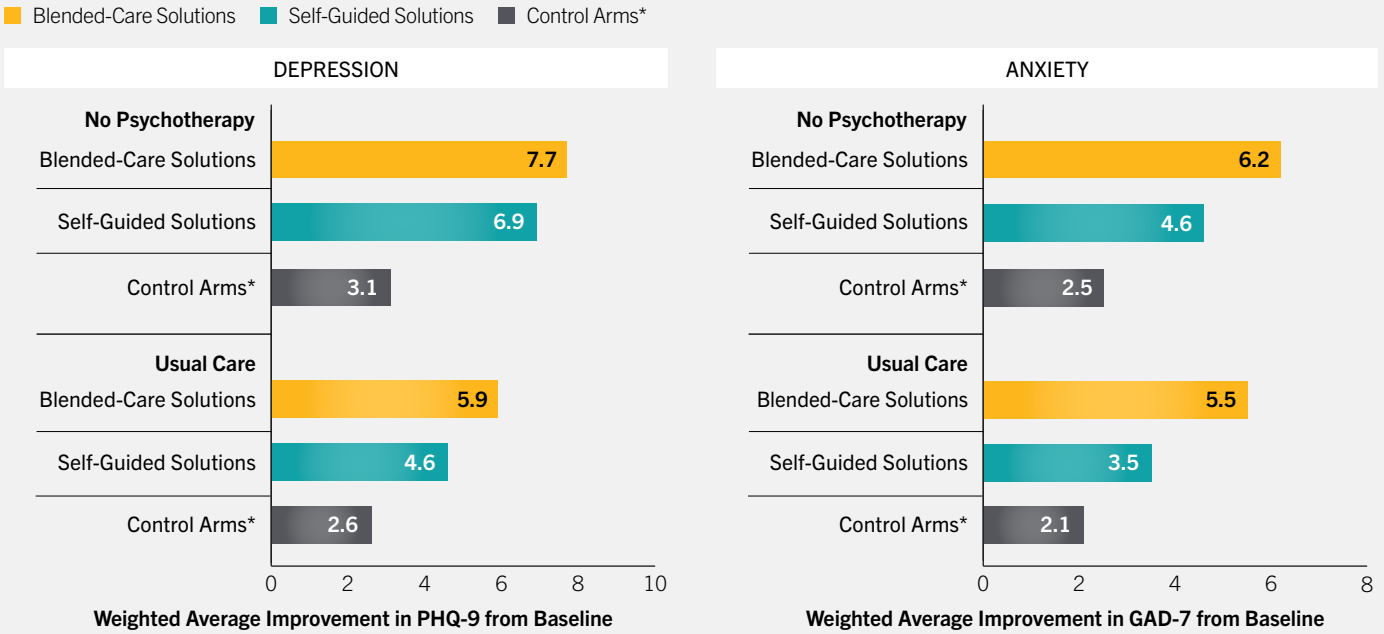
Exhibit 24 compares the results of these comparative and single-arm studies on blended-care solutions with the comparative results from self-guided solutions. The results suggest that blended-care solutions produce superior improvements in depression and anxiety symptoms—both for users receiving usual care and those not previously accessing psychotherapy. However, single-arm studies may overreport clinical improvements relative to well-designed RCTs and, thus, further comparative evidence is needed to strengthen confidence in the results.

Based on the combination of the two comparative studies and the large body of single-arm findings, blended-care solutions are likely to deliver meaningful improvements in both depression and anxiety. Using the ICER Evidence Rating Matrix, blended-care solutions receive a B+, with a higher certainty of incremental net health benefits.

** Seventeen single-arm studies report improvement in PHQ-9 scores, and thirteen report GAD-7 scores.

Exhibit 24

WEIGHTED AVERAGE IMPROVEMENTS FROM BASELINE FOR PHQ-9 AND GAD-7 IN BLENDED-CARE AND SELF-GUIDED SOLUTIONS



Notes: Weighted average improvement in PHQ-9 and GAD-7 score from baseline to last reported timepoint of the intervention period. The blended-care solution bars are a weighted average of two comparative studies and single-arm studies to provide a more comprehensive understanding. * The control arms bar is the weighted average of self-guided and blended-care solution control arms.

Stepped Care

A potential benefit of a comprehensive, blended-care solution is that patients can step up or down their treatment intensity on the basis of their changing needs. In theory, this could also improve efficiency by delivering clinical benefits using a combination of digital components and fewer hours of psychotherapy. Ideally, patients with higher-acuity needs could be escalated to psychotherapy, while patients with milder or more moderate symptoms could be treated with lower-cost digital options.

One study found that digital CBT with asynchronous therapist messaging was equally as effective as telephone CBT in reducing depressive symptoms and cut down patient time spent with a therapist and therapist costs by half.[203] Another study examined the effectiveness of a blended-care program as a stand-alone treatment versus in combination with in-person therapy, medication, or both.[204] All treatment groups showed similar symptom reduction over 12 weeks, but stand-alone digital treatments appear more effective for patients with mild to moderate depression and anxiety, while those with more severe symptoms self-selected into higher-intensity, combination treatments.

Engagement

Evidence suggests that blended-care solutions that include clinical navigation generally support higher engagement than self-guided solutions. Several studies that examined clinician-supported solutions demonstrated high rates of engagement, with greater than 70% program completion or completion of assigned lessons or modules.[205–208] Additionally, data shared by digital health companies suggests that employees are more likely to engage with blended-care solutions when more therapy and coaching sessions are covered as part of the offering. Findings suggest that users prefer blended-care solutions that include a range of care options and that users are more likely to engage when they believe their treatment needs will be met under the covered number of visits. Knowing that they will be able to maintain continuity of care without incurring additional out-of-pocket costs drives higher participation.

Company-Specific Evidence

All of the companies selling blended-care solutions produced clinical evidence that met inclusion criteria. Three companies had studies that specifically examined the digital content or self-guided portions of their solutions. Meru Health is the only company to produce clinical evidence comparing their blended-care solution to controls, as well as eight additional single-arm studies. Lyra Health also produced a large volume of single-arm studies examining the solution's impact on primary outcomes. Looking at individual solutions, Brightside, Lyra, and Meru have clinical evidence demonstrating more substantial improvements in symptoms.

AbleTo

AbleTo is a virtual therapy program for depression and anxiety that provides CBT-based treatment via self-guided resources, behavioral coaching, and one-on-one video or phone therapy. Treatment plans are individualized on the basis of regular assessments. Licensed therapists and psychiatric services are available through Optum's provider network. AbleTo sells to health plans and employers. AbleTo also offers stand-alone, self-guided solutions: Self Care+ and Coaching+.

Three comparator studies and two single-arm studies met inclusion criteria, with one single-arm assessing the features of AbleTo's blended-care offering. One RCT reported that patients using a self-guided, CBT-based, digital intervention had greater reductions in depression (PHQ-9, 6.1 points vs. 2.8 points) and anxiety (GAD-7, 5.0 points vs. 3.4 points) scores at eight weeks compared to the control arm, consistent with the category-level findings.[209] AbleTo users also had statistically significant higher remission rates for both conditions than the control group.[210] Another study evaluated a mood-based, activity-suggestion tool and showed modest improvements compared with control arm (PHQ-9, 1.8 points; GAD-7, 1.5 points) over four weeks.[211] A third comparator study that assessed two digital solutions without a control arm found similar PHQ-9 and GAD-7 improvements for users of a self-guided tool with or without coach support.[212] One single-arm study assessing AbleTo's digital content and coaching completion showed statistically significant improvements in depression and anxiety for users completing four or more modules.[213]

While AbleTo sells the studied components as standalone offerings, they are also integrated into their blended-care offering. One single-arm study evaluating their blended-care offering reported a 41% mean reduction in total work impairment and a 47% mean reduction in non-work activity impairment from baseline to final session after eight weeks of CBT app treatment use with a licensed therapist.[214]

Brightside

Brightside provides therapy via one-on-one video sessions or asynchronous messaging supported by digital interventions. Patients are provided with access to a collaborative care team of licensed therapists, psychologists, and psychiatrists, with triage and care plan design performed by a licensed therapist informed by a patient intake questionnaire. Brightside clinicians use AI-driven prescribing models and evidence-based guidelines to support treatment plan creation. Brightside sells to health systems and health plans but does not sell to employers. Brightside does not sell a stand-alone, self-guided solution.

Two single-arm studies met inclusion criteria, all with low risk of bias. A retrospective study comparing older (≥60) to younger adults found both groups had statistically significant reductions in PHQ-9 scores (8.3 and 9.7 points, respectively), with no significant differences between age groups.[215] Another observational study examining the impact of socioeconomic status found both higher- and lower-income patients showed statistically significant PHQ-9 and GAD-7 reductions, though lower-income patients had greater symptom severity at weeks 14 and 16.[216] Notably, Brightside's studies showed significant improvement in populations with severe starting symptoms.

Headspace

Headspace offers multiple product options that can include a mix of mindfulness exercises, self-guided CBT educational tools, mental health coaching, video therapy, and psychiatry. Headspace mental health coaches are required to have a master's or higher degree in a mental health–related field or to be certified by the National Board for Health & Wellness Coaching (NBHWC). Headspace providers coordinate care through a medical record system. Headspace sells to employers, health plans, and direct to consumers. Headspace also offers a stand-alone self-guided solution, Headspace Core, which does not include human-delivered clinical care.

A total of six studies met the inclusion criteria, with four studies from the literature review and two company-submitted studies. All studies that met the inclusion criteria examined Headspace's digital content programs only. One RCT with moderate risk of bias found users of the Headspace digital content demonstrated a clinically meaningful reduction in

anxiety symptoms (Beck Anxiety Inventory, 4.1 points) compared with the delayed-access control group at four weeks.[217] As described above, an RCT comparing Headspace's digital content with SilverCloud's reported that both Headspace arms—enhanced personalized feedback and digital content—delivered statistically significant between-group reductions in depressive symptoms from baseline at six weeks (PHQ-9 change from baseline: −2.7 to −2.9) , with no statistically significant differences between intervention types.[218]

Four single-arm observational studies of the blended-care option showed consistent symptom improvements[219–222] with one being a large, real-world study with low risk of bias that found that approximately 39% of users achieved a statistically significant full response in GAD-7 and PHQ-9 scores.[223]

Koa Health

Koa Health is a digital mental health platform that includes both digital tools rooted in CBT and access to therapists. Koa Health initially directs patients to prevention-focused digital tools and can connect patients to video sessions with certified therapists on the basis of clinical needs. Koa Health sells to health plans and health systems; Koa Health does not offer a stand-alone, self-guided solution.

One small, single-arm, observational study with low risk of bias met inclusion criteria. The study evaluated the Mindset for Depression app with therapist support among 28 participants with moderate-to-severe depression. PHQ-9 scores showed a statistically significant improvement, from an average of 15.1 at baseline to 7.1 at eight weeks, with improvements maintained at three months.[224]

Lyra

Lyra offers a full EAP replacement and health plan buy-up, which includes digital content; in-person and virtual care services spanning CBT coaching with coaches certified by the International Coaching Federation (ICF); therapy with licensed therapists and psychologists; and psychiatry. Provider-led practice sessions with asynchronous messaging support and digital tools between sessions are used to accelerate skill-building and practice. Lyra's EAP offering also includes crisis support and care navigation, workforce services, and leadership learning programs. Lyra sells to employers and health plans and does not offer a stand-alone self-guided solution.

Nine studies from the literature review and four company-submitted studies met inclusion criteria. All studies examined the Lyra blended-care program. One observational study with low risk of bias found that 82.1% of Lyra users recovered from clinical depression or anxiety symptoms.[225] Another retrospective study showed statistically significant and clinically meaningful reductions for those with clinical levels of depression and anxiety (7.1-point reduction in PHQ-9 and a 6.1-point reduction in GAD-7, respectively) at six weeks.[226]

Two studies focused on the impact of care models. One found that 86% of participants receiving live messaging–based coaching combined with Lyra's digital tools showed reliable improvement in anxiety symptoms.[227] Another study of Lyra's collaborative care medication management model resulted in statistically significant reductions in PHQ-9 of 7.2 points and in GAD-7 of 6.0 points at 24 weeks.[228] A study with a low risk of bias analyzed treatments for depression using a blended-care model and found that patients experienced a statistically significantly improvement in anxiety and depression and were able to sustain improvements over a 12-month period.[229] Additional studies examined therapeutic alliance with therapists, workplace impacts, and racial and ethnic differences in outcomes.[230, 231]

Six studies focused on engagement.[232–237] One found that each therapy session was associated with a statistically significant reduction of 1.0 point in PHQ-9 and 0.8 points in GAD-7 during the same week as treatment.[238] Another study found that more patient engagement with video therapy sessions and digital lessons was associated with statistically significant larger reductions in PHQ-9 and GAD-7.[239] One study found that median engagement included six live therapy sessions, six digital lessons, six exercises, and 16 direct messages per episode.[240]

Meru Health

Meru Health offers structured treatment programs for depression and anxiety using an integrated approach that combines CBT, mindfulness, behavioral activation, heart rate variability biofeedback, sleep education, exercise recommendations, and nutritional psychiatry. Meru offers both a digital program and a blended-care solution. The digital program is a structured eight-week program that uses health coaches to support patients and is designed for patients with mild depression and anxiety symptoms. The blended-care solution is a three-month program that includes scheduled

video sessions with licensed therapists or psychologists, between-session messaging, self-paced interactive practices, and anonymous community support. Meru also provides a heart rate variability biofeedback device for users as part of their program. Meru Health sells to health plans and employers; Meru sells the Meru Coaching digital content as a stand-alone solution.

Eleven studies met inclusion criteria, three comparative and nine single-arm, all of which examined the Meru blended-care solution. A RCT with low risk of bias assessed the Meru Health program and found the intervention group experienced statistically significant and clinically meaningful reductions in depressive symptoms relative to waitlist controls at 12 weeks (PHQ-9, 6.4 vs. 1.9), with 39.1% of Meru Health participants achieving MCID compared with 9.8% in the control group. Anxiety symptoms also declined significantly relative to controls (GAD-7, 5.1 vs. 1.0).[241]

A quasi-experimental study assessing two digital solutions without a control arm compared patients using Meru Health as a stand-alone intervention to those using Meru Health in tandem with in-person therapy and pharmacotherapy. No difference in depression and anxiety symptom improvement was reported between stand-alone Meru Health and those using Meru Health in conjunction with traditional modalities.[242] Another quasi-experimental study without a control arm evaluated the addition of heart rate–variability biofeedback to the Meru Health program, though a majority of study participants were from countries outside of the United States.[243]

Ten articles on single-arm, observational studies reported PHQ-9 and GAD-7 reductions with the use of Meru Health, with longer-term follow-up suggesting sustained benefits.[244–253] Articles from the same Meru Health study showed high completion rates, with one reporting 94% program completion[254] and another finding 90% of older adults completed their eight-week program.[255] One of the articles reported that engagement patterns varied by gender, with women completing more tasks than men.[256]

Modern Health

Modern Health offers full EAP replacement services, including mental health support through self-guided digital tools, structured and topic-focused coaching with ICF-certified and trained coaches, video and in-person therapy with licensed therapists and psychologists, psychiatry, and crisis services. The solution personalizes care recommendations by combining clinical assessments with individual preferences and leverages evidence-based approaches, such as CBT. Modern Health sells to employers and health plans; Modern Health does not sell a stand-alone self-guided solution.

Three single-arm, observational studies—all of which examined the blended-care solution—met inclusion criteria. Two studies assessed depression and anxiety symptom improvements in Modern Health users. One prospective study with low risk of bias showed statistically significant reductions of 5.2 points in PHQ-9 and 3.7 points in GAD-7.[257] A related article from the same study reported that 65.8% of Modern Health users exhibited statistically significant improvements in depressive symptoms and 59.2% showed statistically significant improvements in anxiety symptoms.[258] Another found superior outcomes for coaching or video therapy users than for those who utilized only psychological assessments to recommend patients to coaching or video therapy services.[259]

Engagement patterns were examined in a study reported across two studies. One study found that coaching and therapy users engaged more with self-guided resources,[260, 261] with 56% of users engaged with at least one service—44% of whom used both self-directed resources and one-on-one care.[262] The other study found that there were no significant symptom or engagement differences by racial or ethnic group, suggesting equitable effectiveness.[263, 264]

Spring Health

Spring Health offers a nationwide mental health capability as a full EAP replacement service, including mental health solutions that provide patients with varying levels of virtual and in-person care. Spring Health provides CBT-based treatment through on-demand, self-guided resources; ICF- or NBHWC-certified coaches; and in-person or virtual sessions with licensed therapists, psychologists, and psychiatrists. Spring Health uses an integrated electronic health record system to facilitate measurement-based care, provider collaboration, and patient recommendations, and to share progress and information with the patient's PCPs. Spring Health sells to health plans and employers; Spring Health does not sell a stand-alone self-guided solution.

One article from the literature review met inclusion criteria. This retrospective observational cohort study used mixed-effects models for workers using the Spring Health program, and found PHQ-9 and GAD-7 scores decreased by a statistically significant and clinically meaningful 6.3 points each, with approximately 69% of users showing reliable improvement for both depression and anxiety.[265]

Talkspace

Talkspace is a virtual, mental healthcare platform that offers self-guided support, texting and video therapy, and psychiatry. The Talkspace platform provides access to licensed providers, such as therapists and psychologists, through live video sessions; live audio; or asynchronous messaging via text, video, or audio messages. Patients can also engage in CBT-based treatments through on-demand, self-guided programs that include weekly therapist-led live classes. In addition to their clinical care platform, Talkspace also offers a stand-alone, self-guided solution, Talkspace Go. Talkspace sells to health plans and employers.

Three Talkspace comparative studies without control arms that assessed two digital solutions in their blended-care offering met inclusion criteria for this assessment. Two RCTs (one with low risk of bias and one with moderate risk) compared message-based therapy with video therapy and found both to be effective with no meaningful difference in clinical outcomes for depression and anxiety.[266, 267] Both message-based therapy and video therapy groups experienced statistically significant reductions in depression and anxiety symptoms from baseline.[268, 269] One of these studies found that people using message-based psychotherapy engaged for more weeks than those using video (7.8 weeks vs. 4.9 weeks).[270] Two studies reported on engagement and duration, finding that men were more likely to drop out of digital psychotherapy than women,[271] and that younger adults more frequently discontinued therapy because of cost concerns.[272]

Five single-arm, observational studies assessing their blended-care offering all demonstrated reductions in PHQ-9 and GAD-7 scores[273–277] with one study linking therapy use to reduced absenteeism and increased productivity[278] and another showing symptom improvement rates with approximately half of patients improving by at least 5 points on PHQ-9 or GAD-7 scales.[279]

One study found that users' engagement with blended-care solutions decreased over time, from 37% disengagement at six weeks to 92% disengagement at one year—showing benefits of technology-mediated therapy over a brief period of time.[280] One single-arm study identified flexible access, affordability, and reduced stigma as key factors driving engagement.[281]

Teladoc

Teladoc provides virtual mental health programs ranging from wellness to clinical treatment. The Mental Health Care platform offers on-demand, self-guided digital content; one-on-one live and asynchronous coaching; therapy with licensed therapists and psychologists; psychiatry with medication management; and crisis support. Teladoc also offers their digital content and coaching services as stand-alone offerings. Teladoc sells to health systems, health plans, and employers. Teladoc sells Mental Health Coaching and Mental Health Care as stand-alone self-guided solutions.

One single-arm, observational study met inclusion criteria. A retrospective study with low risk of bias evaluated the self-directed myStrength digital mental health program (acquired by Teladoc in 2019) and found only small improvements in outcomes, with PHQ-9 scores decreasing by 1.8 points on average at six months and GAD-7 scores decreasing by 1.2 points.[282] This study was conducted on solutions that have since been acquired by Teladoc and, thus, features of the offerings studied may vary in their current form.

Economic Impact

As rates of depression and anxiety increase and access to mental health services remains challenging, large employers and health plans are increasingly adopting virtual solutions to address unmet care needs. The price of these services can be expensive, however, so payers need to understand the budget impact associated with buying these solutions, as well as the cost savings and productivity benefits that result from improved mental health outcomes. Some research indicates that for every dollar spent on mental health support, employers realize a return of $4 through reduced medical expenses, lower absenteeism, and decreased disability costs.[283]

Virtual solutions can play an important role in providing access to mental healthcare for their workers and members, through both medical benefits and employee assistance programs. People with untreated depression and anxiety have higher overall healthcare spending, and studies show that people with more severe symptoms use more healthcare services.[284, 285] Virtual solutions can improve depression and anxiety outcomes, particularly for patients not previously receiving psychotherapy. Payers will want to understand how coverage of these solutions will impact total healthcare spending net of solution costs.

Budget Impact Model Methodology

The budget impact model seeks to estimate the expected one-year change in net healthcare spending that results from offering virtual solutions for depression and anxiety in commercial, Medicare, and Medicaid settings. Results are presented per digital solution users, PMPM across all plan members or employees, and in total for one million plan members. The model estimates the number of people eligible to use the virtual solution, the gross reduction in expected healthcare spending resulting from improved symptoms of depression and anxiety for patients enrolled in these programs, and the net impact on health system spending once such savings are offset by spending on the virtual solution. The model primarily considers direct healthcare costs; indirect impacts on worker productivity are estimated separately. Summary ratings are only based on the budget model results for the commercial market, where these solutions are predominantly deployed.

Based on the clinical effectiveness results above, the budget model estimates the impact of virtual solutions for depression and anxiety on healthcare spending across the three categories of solutions: self-guided solutions, PDTs, and blended-care solutions.

The primary components of the budget impact model are:

1. **Eligible population** – The total number of people eligible to use virtual solutions for depression and anxiety;
2. **Usual care costs** – The annual healthcare costs and spending on mental health services for people with depression and anxiety;
3. **Reduced costs from health improvements** – The changes in healthcare spending that result from improved symptoms of depression and anxiety;
4. **Technology price** – The price charged to a payer or provider for the virtual mental health solution, as well as any additional charges based on usage (e.g., additional charges for therapy sessions); and
5. **Participation rates** – The portion of health plan members that use the solution.

These components come together in an estimate of the net impact on healthcare spending per user of a virtual solution for depression and anxiety, and the overall PMPM impact of that spending across all enrollees in a hypothetical one-million-member plan. This section primarily describes results for the commercial market, where these virtual solutions are sold most often.

Eligible Population

The model estimates the number of U.S. adults with depression and anxiety who receive treatment across commercial insurance, Medicare, and Medicaid. Many people experience both depression and anxiety symptoms. In total, about 21% of adults in commercial insurance, 12% of Medicare beneficiaries, and 29% of adults in Medicaid have either anxiety or depression (Exhibit 25).[286,287]

Exhibit 25

ESTIMATING THE ELIGIBLE POPULATION FOR VIRTUAL DEPRESSION AND ANXIETY SOLUTIONS

	Commercial	Medicare	Medicaid
PROPORTION OF ENROLLEES WHO ARE ADULTS	78.9%	99.2%	48.7%
TOTAL PREVALENCE OF ANXIETY AND/OR DEPRESSION	21.4%	11.8%	29.0%
Prevalence of depression only	3.8%	3.1%	5.1%
Prevalence of anxiety only	7.5%	3.7%	10.2%
Prevalence of depression and anxiety	10.1%	5.0%	13.7%
USUAL CARE POPULATION: PROPORTION TREATED FOR ANXIETY AND/OR DEPRESSION[a]	9.5%	6.7%	8.0%
NO PSYCHOTHERAPY POPULATION: PROPORTION NOT OTHERWISE RECEIVING TREATMENT[b]	7.4%	5.0%	6.2%

Notes: [a] Calculated by applying condition-specific treatment rates to the prevalence of depression only, anxiety only, and co-occurring depression and anxiety. [b] Calculated by applying 100% minus the condition-specific treatment rates to the prevalence of depression only, anxiety only, and co-occurring depression and anxiety.

Not all people who experience symptoms receive treatment for their mental health needs. Treatment is received by approximately 61% of patients with depression,[288] 37% with anxiety,[289] and 69% with both depression and anxiety.[290]

Taken together, approximately 9.5% of all commercial enrollees, 6.7% of Medicare beneficiaries, and 8.0% of Medicaid beneficiaries receive treatment for their depression and anxiety symptoms. Another 7.4% of all commercial enrollees, 5.0% of Medicare beneficiaries, and 6.2% of Medicaid beneficiaries are not receiving treatment but might benefit from access to virtual solutions for depression and anxiety (Exhibit 25).

The model assumes that both treated and untreated people with depression and anxiety symptoms could use self-guided or blended-care solutions. The clinical benefits of these solutions will vary by the solution type and whether users were previously receiving usual care treatment. Because PDTs require a prescription from a clinician, users are assumed to be only those already receiving usual care.

Usual Care Costs

For people with depression and anxiety, annual healthcare spending increases with symptom severity. As described above, annual commercial healthcare spending ranges from $8,220 for people with minimal to mild depression to $12,433 for severe depression, and from $8,061 for people with mild to moderate anxiety to $11,067 for people with severe anxiety (Exhibit 4 and Exhibit 5). Total spending is lower in Medicare and Medicaid because of lower reimbursement rates.

For patients receiving usual care, the model estimates mental health service use on the basis of a typical CBT treatment episode, which includes an initial diagnostic evaluation and an average of 9.4 psychotherapy sessions across all plans.[291] The model assumes patients will have a single episode of care during the year, which may underestimate costs for patients who have recurring mental health needs. Clinical evidence about virtual solutions showed that within usual care groups, about half of patients are receiving psychotherapy at baseline. Thus, the

model assumes 4.7 sessions (50%) per person in usual care. For self-guided solution and PDT users, the model assumes the cost of usual care psychotherapy is added to the cost of the solution. Whereas all users of blended-care solutions are assumed to switch to receiving psychotherapy within the solution and no users would continue to receive outside psychotherapy sessions.

Reimbursement for the initial diagnostic evaluation (CPT code 90791) is assumed to be $172 and a 45-minute psychotherapy session (CPT code 90834) is assumed to be $103 per session, based on Medicare 2024 reimbursement rates.[292] Commercial mental health reimbursement rates are similar to Medicare; costs were converted for Medicaid rates on the basis of published literature.[293, 294] Total annual spending on therapy for people receiving usual care is estimated at $657 in Medicare and commercial plans, and $532 in Medicaid.

Reduced Costs from Health Improvements

The budget impact model uses published literature to estimate the decrease in expected healthcare spending due to improvements in depression and anxiety symptoms, as measured by PHQ-9 and GAD-7 scores. The model estimates the spending impact for individuals receiving usual care, those not engaged in psychotherapy, and those enrolled in a virtual solution program. The model assumes that the clinical improvements achieved by virtual solutions for depression and anxiety will be sustained for a full year, despite most studies having shorter follow-up periods. As a result, healthcare costs avoided from improved clinical outcomes may be over- or underestimated.

Real-world studies have examined annual healthcare spending for people with depression and anxiety by severity (Exhibit 4 and Exhibit 5). These estimates include direct medical costs for hospitalizations, provider visits, and emergency visits for both mental health and other needs.[295, 296] For instance, patients with severe anxiety have approximately $3,000 higher annual healthcare costs, on average, than people with mild to moderate symptoms (Exhibit 5). The model assumes a linear relationship between spending and PHQ-9 or GAD-7 scores within each level of severity. See **Appendix A** for detailed methodology.

The budget model uses results from the systematic literature review of primary outcomes and applies these spending estimates to the weighted average, within-group changes from baseline in PHQ-9 and GAD-7 scores, comparing improvements for people using virtual solutions with those in the control arm. Costs were inflated to 2024 U.S. dollars and converted to plan-specific values using published Medicare to Medicaid and Medicare to commercial cost ratios for outpatient services and do not include the cost of the intervention.[297–299]

By applying the average reduction in symptom scores from the clinical evidence, the model estimates the expected per person decrease in healthcare spending that results from improved mental health outcomes for those using virtual solutions (Exhibit 24). For instance, in the commercial market, people with depression and anxiety not previously receiving psychotherapy have estimated annual spending of $10,266. If those people engage with a self-guided solution, their PHQ-9 scores would be expected to decrease by 6.9 points (3.9 more than control) and their GAD-7 scores would be expected to decrease by 4.6 points (2.1 more than control). This improvement in mental health symptoms predicts that per user healthcare spending would decrease by $754 per year before accounting for solution costs (Exhibit 26). When comparing virtual solutions to usual

Exhibit 26

ANNUAL HEALTHCARE SAVINGS FROM IMPROVED HEALTH OUTCOMES

Treatment Arm	Commercial	Medicare	Medicaid
SELF-GUIDED SOLUTIONS			
No Psychotherapy	$754	$441	$289
Usual Care	$575	$324	$221
PRESCRIPTION DIGITAL THERAPEUTICS			
Usual Care	$643	$358	$247
BLENDED-CARE SOLUTIONS			
No Psychotherapy	$994	$574	$382
Usual Care	$961	$536	$369

Notes: Reflects avoided healthcare costs as a result of improved PHQ-9 and GAD-7 scores. Does not include solution and treatment costs for virtual solutions.

care, patients with commercial coverage who use self-guided solutions to augment their current treatment are estimated to spend $575 less than those receiving usual care.

For patients using PDTs to augment usual care, health improvements using just the comparative evidence available for PDTs are estimated to decrease per user healthcare spending by $643 (Exhibit 26).

Using the same methodology for blended-care solutions, health improvements for people not receiving psychotherapy are estimated to reduce spending by $994. For people who have usual care and begin using a blended-care solution, their annual spending is expected to decrease by $961. Because the clinical evidence suggests that blended-care solutions result in larger improvements in depression and anxiety symptoms, these solutions produce more potential for savings from health outcomes than self-guided solutions or PDTs (Exhibit 26).

These results demonstrate that virtual solutions—self-guided, PDT, and blended-care—have the potential to reduce healthcare utilization and spending. Benefits are greatest for patients who are not otherwise receiving psychotherapy but virtual solutions also reduced costs for patients receiving usual care. Importantly, these gross savings do not account for the added cost of the virtual solution, which is addressed below.

Technology Price

To estimate the net spending impact of virtual solutions for depression and anxiety, the model offsets the price of the virtual solution provided from the estimated healthcare savings.

Self-guided solutions for depression and anxiety are typically sold at a low price directly to employers as supplements to or replacements for elements of EAP programs, or to health plans through the medical benefit. Pricing information from a variety of sources (e.g., market analysis reports, vendor-supplied pricing, published economic studies, industry experts) estimated these solutions cost approximately $2 PMPM or less. The model assumes an average monthly solution price of $2 PMPM, or $24 per member per year, with no variation across plan type and covered for the entire one-million-member plan.

The reimbursement landscape for **PDTs** is evolving and varies across payers, influencing how providers access and integrate these treatments. Currently, PDTs are purchased by the consumers and—more recently due to expanded Medicare coverage as of January 2025—by providers. Because PDTs require a prescription, some providers are currently purchasing PDTs up-front and then billing health plans for reimbursement, though insurance coverage and reimbursement vary by payer. Medicare expanded coverage for select digital therapeutics for depression and anxiety in 2025;[300] however, commercial payers have varying coverage policies and Medicaid coverage remains limited in most states.[301]

Beginning January 1, 2025, Centers for Medicare & Medicaid Services (CMS) established three new payment codes that will enable reimbursement for FDA-cleared PDTs.[302] The initial code covers the supply of the device (i.e., software). Medicare contractors have not yet established reimbursement rates for PDTs; however, publicly available pricing for PDTs currently range between $200 and $400.[303, 304] The subsequent two codes will cover reimbursement to the provider for treatment-management services on a monthly basis. There are no limits on the number of times a provider can prescribe a PDT for an individual during a given year. Medicare administrative contractors, Medicare Advantage plans, and commercial plans may establish their own coverage policies regarding the frequency of coverage.

The model assumes the low end of the range at an annual reimbursement rate of $200 for the device supply and $40 per month for two months of billing of treatment management per user for a single treatment episode of depression and anxiety.[††] The cost impact of these solutions could be higher, however, if providers prescribe PDTs multiple times per year to the same patient.

Blended-care solutions for depression and anxiety may be sold as EAP packages to employers or as "buy up" to health plans as part of their medical benefit. The model estimates total healthcare spending, inclusive of medical benefit spending and EAP costs.

Blended-care solutions often charge a PMPM fee for all plan enrollees or employees to provide access to the platform. Pricing is structured as a higher bundled price that includes a limited number of therapy sessions and results in a predictable monthly fee for payers. Alternatively, pricing is based on engagement and usage with generally lower starting PMPM fees and an additional fee-for-service charge when members access coaching or therapy services.

Based on reviewed sources, PMPM prices average about $6 across the entire plan membership. Companies report that those who engage with the solution typically use 6–8 sessions,

[††] Rejoyn is prescribed for adults aged ≥22 with major depressive disorder on antidepressant medication. DaylightRx is prescribed as an adjunct to usual care in patients aged ≥22 with generalized anxiety disorder. The model assumes the use of a PDT to treat comorbid anxiety and depression.

Pricing Assumptions

Self-Guided Solutions:
$2 per member per month

Prescription Digital Therapeutics:
$200 for the device supply + $80 for treatment management per prescribed user per year

Blended-Care Solutions:
$6 per member per month + $792 per engaged user per year for therapy

including a mix of coaching and therapy. Prices for coaching sessions average $84 and therapy sessions average $143. Therefore, for blended-care solutions, the model assumes an average monthly solution price of $6 PMPM, or $72 per year, and an added cost of $792 per engaged user per year, based on an average utilization of seven sessions. Actual prices charged by specific solution vendors or negotiated by particular purchasers may vary and would impact these results.

Participation Rates

Participation rates for virtual solutions vary widely. Evidence suggests that blended-care solutions drive higher user participation, though engagement varies considerably across studies and solutions. The evidence shows that users are more likely to engage when they have access to more coaching and therapy sessions as part of their benefit.[305–308] As such, the model assumes differential participation rates between virtual solutions.

For **self-guided solutions,** the model assumes that 25% of people with symptoms of depression and anxiety could elect to use a virtual solution for their care. This means that one in four people receiving mental healthcare services might switch to using a virtual solution, if it was available to them. Further, a quarter of people who are experiencing mental health symptoms but not pursuing treatment could elect to engage with virtual solutions. Taken together, the model estimates a 4.2% total participation rate for the virtual solutions in a commercial plan, 3.0% in Medicare, and 3.5% in Medicaid.

PDTs require a prescription and will not be adopted by all providers. As a result, the model assumes that a maximum of 25% of people receiving usual care treatment for depression and anxiety could receive a PDT prescription through their provider.

For **blended-care solutions,** the model assumes a higher participation rate of 50% of people would elect to use a virtual solution for their care. Since most solutions include some therapy visits at no cost to the user, patients are more likely to engage in therapy as part of a blended-care solution. The other 50% of people receiving treatment for depression and anxiety may prefer to maintain care with their established provider outside of the virtual solution or may continue to not seek treatment for their condition. As a result, the total participation rates for a blended-care solution are 8.5% in commercial, 5.8% in Medicare, and 7.1% in Medicaid.

Because these solutions charge monthly access fees across all plan members, higher participation rates help reduce the net cost of these solutions by offsetting the virtual solution price with other healthcare savings.

Change in Overall Spending

The model estimates the change in overall health spending from using virtual solutions, including people who use virtual depression and anxiety solutions and other plan members who do not use the solutions or do not experience depression and anxiety symptoms. The model combines the solution price charged for all plan enrollees with the savings from users who experience lower healthcare spending resulting from improved depression and anxiety symptoms. For blended-care solutions, the model also includes estimated fees for users' coaching and therapy sessions and an assumption that users will begin receiving therapy through the app rather than through outside providers.

Per User Spending Results

In commercial coverage, users of **self-guided solutions** are estimated to have total net healthcare spending that is $629 lower than they would otherwise, including the price of the solution. For **PDTs** in a commercial plan, users of virtual solutions would have lower net healthcare spending of $363 per year. For **blended-care solutions** in a commercial plan, users of virtual solutions would have lower net healthcare spending of $482 per year (Exhibit 27).

Spending Results for All Plan Members

For **self-guided solutions** in a commercial plan, because the per-member solution prices are low ($2 PMPM), these solutions could save $0.30 PMPM across all enrollees, or $3.6M per million members (Exhibit 28).

Exhibit 27

NET CHANGE IN ANNUAL SPENDING PER VIRTUAL SOLUTION USER AT ESTIMATED PRICES

Per User Per Year	Commercial	Medicare	Medicaid
Self-Guided Solutions	–$629	–$350	–$227
Prescription Digital Therapeutics	–$363	–$78	+$33
Blended-Care Solutions	–$482	–$62	+$189

Note: Negative numbers represent healthcare savings and positive numbers represent healthcare spending.

Exhibit 28

ESTIMATED CHANGE IN ANNUAL HEALTHCARE SPENDING

	Commercial	Medicare	Medicaid
SELF-GUIDED SOLUTIONS			
Total Per 1M Members	–$3.6M	+$13.1M	+$15.1M
Per Member Per Month	–$0.30	+$1.09	+$1.26
PRESCRIPTION DIGITAL THERAPEUTICS			
Total Per 1M Members	–$8.7M	–$1.3M	+$0.6M
Per Member Per Month	–$0.72	–$0.11	+$0.05
BLENDED-CARE SOLUTIONS			
Total Per 1M Members	+$25.2M	+$64.1M	+$80.3M
Per Member Per Month	+$2.10	+$5.34	+$6.69

Note: Negative numbers represent healthcare savings and positive numbers represent healthcare spending.

For **PDTs** in a commercial plan, because the solution price is reimbursed per user, these solutions could save $0.72 PMPM across all enrollees, or $8.7M per million members. If payment rates were set higher at $400 per device, these solutions would still reduce net spending because the health benefits exceed the reimbursement rate (Exhibit 28).

For **blended-care solutions** in a commercial plan, even though solution users would experience lower spending, health plans would still face increased total spending because of the high PMPM charges for nonusers. In total, PMPM costs across the plan would increase by $2.10, or $25.2M per million members (Exhibit 28).

Self-guided solutions for depression and anxiety across all payers are expected to decrease total health spending on a per user basis but increase spending across Medicare and Medicaid enrollees. Because of lower annual healthcare costs in Medicare and Medicaid, the savings from health outcomes due to improved depression and anxiety symptoms are insufficient to offset the cost of the solution. **Blended-care solutions** for depression and anxiety are also shown to increase total health spending across all plan enrollees in Medicare and Medicaid. For **PDTs,** improved health outcomes are sufficient to offset the cost of the solution in Medicare, but not in Medicaid. If the Medicare reimbursement rate is less than $270 for the device supply, PDTs would yield net savings across all Medicare enrollees.

Scenario Analysis

While blended solutions demonstrate strong clinical effectiveness, these solutions increase net health spending across all payers; however, these solutions could achieve budget neutrality if three levers are effectively deployed:

1. **Reducing per-member prices** to limit the incremental cost of the solution for plan members who do not need mental health services;
2. **Increasing patient participation rates;** and
3. **Optimizing care management** by guiding patients to the most appropriate level of care and managing the duration of therapy.

In PHTI's analysis of the estimates, the primary cost driver of these solutions is their broad pricing model that charges for both users and nonusers. However, higher participation rates can contribute to improved clinical outcomes and can lead to greater savings in healthcare resource utilization, which could potentially offset the cost of the solution as more patients experience symptom improvement. Moreover, blended-care solutions may include integrated triage capabilities within their platform with the potential to ensure high-cost mental health services are reserved for individuals with the greatest need, while those with lower acuity are directed toward more cost-effective, self-guided, digital components of the solution. The scenario analyses below demonstrate the sensitivity to changing PMPM costs and use of coaching and therapy services.

Reducing PMPM Charges: Some blended-care solutions are sold as full EAP replacements that integrate mental health services with extensive workforce training, development, support, and resources. Traditional EAPs are typically priced at $2 PMPM.[309, 310] If an employer fully replaces an existing EAP with a blended-care solution, they could save about $2 PMPM (the typical price of a traditional EAP). This would reduce their net increase in PMPM spending to $4, plus additional charges for therapy among users. Assuming 50% of people would elect to use a virtual solution for their care, the net impact on total healthcare costs would be only $0.10 PMPM, or a net increase in spending of $1.2M per year per one million members.

Increasing Participation Rates: The base model assumes that blended-care solutions have higher participation rates than self-guided solutions. The higher the participation rates, the more economic benefit these solutions can deliver by helping users improve their health outcomes, which also helps offset some of the PMPM charges, which apply to all members regardless of use. Across all solutions, higher engagement rates will drive better economic impact for purchasers.

Managing Therapy Use: The base budget model assumes that all users of a blended-care solution will take advantage of access to therapy and will receive an average utilization of seven sessions through the platform. However, the benefit of a blended solution is that users can select among a range of care options, including self-guided digital content, coaching, and therapy. Providers in the app can also recommend less-intensive and lower-cost treatment options to users, if and when it is appropriate for them. For instance, users could begin receiving psychotherapy to address more acute depressive episodes and then, when their symptoms improve, they may transition to digital content for long-term management. Alternatively, some users may select digital-only content without therapy.

This scenario assumes that only half of the blended-care solution users will access therapy services through the solution, and the remaining users will engage with the digital content but continue to receive psychotherapy from outside providers. The model estimates the same average monthly solution price but a lower added session utilization cost of $396 per engaged user per year. By supporting users with more cost-efficient care, the net cost impact of blended solutions for commercial insurers would be a decrease of $0.68 PMPM, or a net decrease in spending of $8.2M per year per one million members.

Productivity Improvements

Symptom improvements for depression and anxiety from virtual solutions can result in additional savings for employers from improved productivity at work and lower absenteeism, presenteeism, and activity impairment. To estimate the indirect employer savings that could be achieved by using virtual solutions for depression and anxiety, the model combines literature-based estimates of productivity improvements, as measured by the Work Productivity and Activity Impairment—General Health Questionnaire (WPAI-GH), wage data from the Bureau of Labor Statistics, and assumes 85% of commercial enrollees are employed.[311, 312]

Using the same assumptions of clinical improvements as above, users of **self-guided solutions** could increase productivity by $825 per year for workers not receiving psychotherapy and $533 for workers who have usual care. Users of **PDTs** in a commercial plan also receiving usual care could similarly increase productivity by $565 per year. Users of **blended-care solutions** could increase productivity by $1,166 for workers not receiving psychotherapy and $976 for workers who have usual care (Exhibit 29).

Exhibit 29

ANNUAL INCREASES IN PRODUCTIVITY FROM IMPROVED HEALTH OUTCOMES

Treatment Arm	Commercial
SELF-GUIDED SOLUTIONS	
No Psychotherapy	$825
Usual Care	$533
PRESCRIPTION DIGITAL THERAPEUTICS	
Usual Care	$565
BLENDED-CARE SOLUTIONS	
No Psychotherapy	$1,166
Usual Care	$976

Patient Out-of-Pocket Costs

Patient out-of-pocket spending for mental health services can vary depending on provider participation in insurance networks and plan benefit design. For most patients, psychotherapy services often require significant out-of-pocket payment and remain inaccessible because of limited insurance acceptance among providers. Approximately one-third of private practice psychotherapists do not accept any form of insurance and, overall, only 64.9% of providers participate in insurance networks and 25% offer telehealth visits.[313] Patients pay on average $143 for psychotherapy sessions through cash-pay, making regular treatment financially challenging without adequate insurance coverage.

In many cases, virtual depression and anxiety solutions are offered to patients through EAPs, typically without cost-sharing requirements. These solutions can achieve broader access to mental healthcare by providing short-term counseling options, expanding insurance network participation and coverage options, and reducing financial strain on patients seeking mental health treatment. Therefore, PHTI's analysis found that while virtual depression and anxiety solutions may increase health plan budgets, they bridge potential access gaps that patients may experience from delayed care coverage, potentially contributing to improving mental health outcomes.

Solution-Specific Economic Analysis

Eight of the 13 companies assessed provided economic data that met the inclusion criteria (see **Appendix B-3**). The economic findings varied significantly in methodology, study design, and metrics reported, making direct comparisons challenging.

Several methodological factors should be considered when interpreting these economic findings:

1. **Savings attribution:** Companies reported different sources of savings, with some focusing on shifted mental health costs, others on broader medical utilization, and some including productivity improvements.
2. **Comparison groups:** Studies used various approaches to establish control groups, from waitlist controls to matched cohorts from claims databases, potentially affecting the validity of savings estimates.
3. **Engagement levels:** Several studies noted that economic benefits varied significantly on the basis of engagement level, with meaningfully engaged participants achieving substantially higher savings.
4. **Program costs:** Only four companies reported program costs, limiting the ability to calculate net savings and ROI across solutions.
5. **Study design:** Economic evidence ranged from financial models and ROI calculators to rigorous comparative claims analyses, with varying levels of methodological rigor.

For instance, a company may inaccurately claim healthcare savings because users' therapy costs shift from being covered under the medical benefit to being covered under the EAP or through the virtual solution. To accurately understand the aggregate net impact on total cost of care, payers must look at the total change in healthcare spending net of solution costs, across both medical and EAP benefits. Because of the heterogenous methods and potential bias in company analyses, PHTI relies on its budget impact model to determine the economic impact for its summary ratings.

None of the self-guided solutions provided economic data that met inclusion criteria, representing a significant evidence gap for this category. One company offering PDT solutions has published economic analyses. Blended-care solutions that integrate multiple levels of care and human support demonstrated more substantial economic evidence, with six companies providing data. The reported gross savings ranged widely, from $24 to $405 PMPM. However, direct comparisons between solutions were difficult given differences in study methodologies, population characteristics, and engagement levels.

DaylightRx's 2024 study compared "Daylight" to four alternative treatment options using a Markov model simulation, including comparing Daylight's digital program (priced at $400 per individual) to individual CBT (priced at $2,788 per individual). Over 12 months, Daylight was projected to deliver a net monetary benefit of $1,881 compared with individual CBT and to save $1,837 compared with people not receiving treatment.[314]

There are currently no publicly available studies on **Rejoyn's** cost impact. Rejoyn's website lists the price for the 6-week treatment at $200.[315]

Headspace provided a cost-impact analysis based on medical claims from a large employer that reported gross savings ranging from $24 to $53 PMPM. The claims analysis showed that meaningfully engaged participants and those receiving team-based care achieved higher savings than those with low engagement or coaching-only support.[316] Headspace offers performance guarantees on engagement, assessment, and symptom reduction measures.

Lyra's three matching cohort studies of employer data reported gross savings of $165–$345 per user per month at an annual price for the Lyra solution of $1,162 ($97 per user per month) with a reported ROI of 3.04.[317–319] Lyra offers performance guarantees on access to care, clinical outcomes, member engagement, member support, satisfaction, and return on investment.

Meru Health shared a white paper in which they performed a case-control analysis and found net savings of $21.69 PMPM. Another company white paper projected substantial healthcare cost reductions ($252 per user per month) for MDD patients. These findings were primarily based on modeling assumptions and the WPAI's self-reported outcomes.[320] Meru health offers performance guarantees on access to care, clinical outcomes, and member engagement.

Modern Health provided a single-arm study article evaluating subjective well-being and clinical improvements alongside cost analysis. The study reported median costs of $10 PMPM for telecoaching, $34 PMPM for teletherapy, and $47 PMPM for combined services. The odds of clinical improvement in depressive symptoms were significantly greater among those who utilized telecoaching, teletherapy, and both services, compared to those who only took the initial assessment. Telecoaching—while the least expensive option—demonstrated clinical improvements comparable to more intensive service types for specific population segments.[321] Modern Health offers performance guarantees on access, member support and satisfaction, utilization, outcomes, return on investment, and accuracy and timing of reporting.

Spring Health provided the most robust economic evidence, with five studies reporting gross savings of $164–$405 PMPM[322, 323] and ROI metrics from 1.9 to 2.4.[324, 325] A 2025 study in JAMA Open Network reported net savings of 13.5%, with program costs of approximately $89 PMPM.[326] A 2021 actuarial study of three employers found net savings of $693 per person per year.[327] Another study tied clinical results to workplace productivity, suggesting 0.32 fewer missed days from work per week and 0.64 fewer unproductive days per week.[328] The multiple study designs and consistent positive findings strengthen confidence in Spring Health's economic impact. Spring Health offers performance guarantees on outcomes, operations, and member experience.

Talkspace provided a Validation Institute report on their ROI calculator, which reported gross savings of $238 per engaged member per month and program costs of $182 per user per month—resulting in net savings of $56 per user per month and an ROI of 1.31. Notably, 67% of savings came from shifted mental health costs rather than reduced medical utilization.[329]

Teladoc's economic data related to the myStrength program (now integrated into Teladoc's platform), which showed gross savings of $35 per user per month and a ROI range of 1.90–6.95. This relatively high ROI was attributed to the program's low cost rather than large absolute savings.[330] Teladoc offers performance guarantees on clinical benefits, member satisfaction, access and availability, and member support.

Mental Health Parity Policy

The Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 generally prevents health insurance issuers from offering coverage of mental health and substance use services that is more restrictive than coverage for medical and surgical services. MHPAEA addresses both quantitative limitations, such as restrictions on the number of covered inpatient days or outpatient visits, as well as cost sharing, such as copays and coinsurance. It also applies to nonquantitative treatment limitations, such as prior authorization requirements, claim denial rates, and provider networks.

MHPAEA requires parity across most types of health coverage, including managed care Medicaid, CHIP, employer-sponsored health plans (insured and self-insured), and health insurance marketplace plans under the Affordable Care Act. MHPAEA does not apply to traditional Medicare, Medicare Advantage, or fee-for-service Medicaid.

Unfortunately, compliance with MHPAEA remains inconsistent despite statutorily specified protections. Disparities in coverage between mental health and substance use disorder benefits and medical and surgical services persist. A March 2024 Department of Health and Human Services (HHS) Office of Inspector General (OIG) audit of Medicaid managed care in eight states found that CMS had not ensured parity requirements were fully met. The July 2023 MHPAEA Comparative Analysis Report to Congress found many insurers did not compile a required comparative analysis to ensure their plans were designed to comply with parity.

In September 2024, new final parity rules were released by HHS and the departments of Labor and the Treasury to improve compliance with MHPAEA.

Summary Ratings

PHTI assigns summary ratings on the basis of its review of the clinical evidence and estimated economic impact from the budget model. Given the varying clinical outcomes for these solutions, depending on whether they are being used as a supplement to usual care or to expand access for people not receiving therapy, clinical ratings are assigned by solution category and user group.

Self-Guided Solutions: Based on PHTI's review of the evidence, self-guided solutions for depression and anxiety have strong potential to improve access to effective mental healthcare, particularly for people with moderate depression and anxiety who are not already receiving psychotherapy. For people receiving usual care, these solutions provide marginal improvements in depression outcomes and could provide alternative treatment options in lieu of ongoing therapy. Based on the ICER Evidence Rating Matrix, for people not receiving psychotherapy, self-guided solutions receive a B, with a high certainty of small net health benefits. When augmenting usual care, self-guided solutions receive a C+, with a high certainty of at least a comparable net health benefit.

At a low PMPM price point, the budget model suggests that self-guided solutions can also reduce net healthcare spending in the commercial market, but not in Medicare and Medicaid. As a result, self-guided solutions warrant broad adoption by employers and commercial health plans because they have been shown to modestly improve clinical outcomes and are anticipated to deliver small savings to payers.

Prescription Digital Therapeutics: Based on PHTI's review of the evidence, FDA-cleared PDTs—which are used in conjunction with usual care—offer clinically meaningful, incremental benefits for users in depression and anxiety symptoms. PDTs are most likely to improve outcomes for people receiving usual care. However, depending on provider adoption, PDTs could address some access gaps by enabling primary care doctors and other providers who are not mental health specialists to offer digital mental health treatment. Based on the ICER Evidence Rating Matrix, for people who are receiving usual care from a clinician, PDTs receive a B, with high certainty of a small net health benefit. Assuming device reimbursement rates are set at $200–$400 per episode, the budget model estimates that PDTs will reduce net health spending of commercial payers because the small clinical improvements are estimated to offset the cost of the product. Device reimbursement up to $270 is estimated to reduce net health spending in Medicare. PDTs could deliver additional savings if they were used as an alternative to therapy and were to reduce the average number of sessions per episode.

Blended-Care Solutions: Based on PHTI's review of the evidence, blended-care solutions are clinically effective and can reduce healthcare spending for people with depression and anxiety. Their clinical benefits appear to be superior to self-guided solutions but, given that most of the data comes from single-arm studies, findings should be confirmed with further evidence. Some companies, such as Brightside, Lyra, and Meru, have clinical evidence demonstrating more substantial improvements in symptoms. Blended-care solutions offer more treatment options to patients, which is likely to drive higher engagement and may be appropriate for people with moderate to severe symptoms. Based on the ICER Evidence Rating Matrix, for people not receiving psychotherapy, blended-care solutions receive a B+, with moderate certainty of substantial net health benefit. For people receiving usual care, blended-care solutions receive a C+, with moderate certainty of a small or comparable net health benefit.

Exhibit 30

PHTI RATINGS BY CATEGORY FOR VIRTUAL SOLUTIONS FOR DEPRESSION AND ANXIETY

● Positive ● Moderate ● Negative
● Higher Evidence Certainty ○ Lower Evidence Certainty

Category	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Self-Guided Solutions AbleTo,* Dario, Headspace,* Learn to Live, Meru Health,* SilverCloud, Talkspace,* Teladoc*	● **Results:** Clinically meaningful improvements in depression and anxiety symptoms for people not receiving psychotherapy **Evidence Certainty:** Higher	● Decreases net health spending for commercial payers	● **Evidence supports broader adoption for people not otherwise accessing therapy**
Prescription Digital Therapeutics DaylightRx, Rejoyn	● **Results:** Clinically meaningful improvements for depression and anxiety symptoms as part of usual care **Evidence Certainty:** Higher	● Decreases net health spending for commercial payers and Medicare at anticipated reimbursement rates	● **Evidence supports broader adoption due to improved efficacy of mental health treatment**
Blended-Care Solutions AbleTo,* Brightside, Headspace,* Koa Health, Lyra, Meru Health,* Modern Health, Spring Health, Talkspace,* Teladoc*	○ **Results:** Larger, clinically meaningful improvements for depression and anxiety symptoms for all users **Evidence Certainty:** Lower	● Increases net health spending for payers because savings from users' health improvements do not offset total solution costs	● **Positive clinical outcomes and net savings for users would support broader adoption, if prices were lower**

Source: PHTI, Virtual Solutions for Depression and Anxiety, May 2025. See PHTI.org for complete report, methods, and recommendations.

Notes: [a] Not all solutions have clinical data that meet the inclusion standards for this report. [b] Summary rating reflects the combination of clinical and economic results. * Companies offering both self-guided and blended-care solutions.

Based on PHTI's model, because of their high price point for all plan members or employees, blended-care solutions are estimated to increase total health spending in the commercial market. Improvements in worker productivity have the potential to offset these added costs for employers. As a result, PHTI's analysis finds blended-care solutions should be adopted cautiously. Purchasers have a number of options to manage the cost spending impact of these solutions, including:

- Integrate blended-care solutions as EAP replacements to help offset some of their added cost. Alternatively, negotiate lower prices (below $4 PMPM) to get close to break-even across a typical group of employees.
- Work with solution vendors to prioritize thoughtful patient triage by encouraging users to engage with self-directed components of the platform prior to stepping-up to live therapy.
- Ensure that solution vendors are focused on treating mental health episodes and stepping patients off of therapy when symptoms resolve, rather than paying for treatment continuously.
- Increase engagement with blended-care solutions to ensure workers who are experiencing depression and anxiety symptoms are getting the clinical benefits.

If purchasers are going to adopt blended-care solutions, they should look closely at solutions with lower PMPM costs, those with better evidence on clinical outcomes, and those with strong care-management plans to triage users to the most appropriate level of care.

Across all categories, there was a large body of well-designed, clinical evidence, but most studies had short durations and used recruitment methods (e.g., waitlist controls) that may bias the results. There were particularly well-designed comparative studies on the efficacy of digital content and the prescription digital therapeutics. However, the evidence for blended-care solutions is more limited and warrants further research. All solution categories would benefit from more research on diverse populations and patients with more mild symptoms.

Next Steps

Realizing Full Potential of Virtual Depression and Anxiety Solutions

Despite significant progress in mental health awareness and reductions in associated stigma, access to mental health treatment remains a challenge for many patients. In this context, digital mental health solutions have an important role to play in delivering flexible, timely access to quality mental healthcare treatment.

Used alongside or instead of traditional modes of mental health therapy, digital solutions have the potential to scale treatment options, given the limited workforce of mental health providers. However, to fully realize this opportunity, several areas require further attention:

1. **Improve evidence generation:** Develop more comparative evidence examining the performance of digital mental health solutions in key areas, such as access, durability, and patients with mild symptoms.
2. **Understand and enhance engagement:** Better understand opportunities to improve patient engagement, and design tools and systems that drive successful patient engagement across a heterogeneous population.
3. **Focus on efficient care delivery:** Identify clinically effective ways to deliver the lowest-cost treatment options that meets patients' needs.
4. **Align payment models with clinical benefits:** Take advantage of efficient and scalable digital solutions to improve outcomes and lower healthcare costs.

Improve Evidence Generation

While the evidence for virtual solutions in depression and anxiety is relatively robust, substantial questions remain—particularly in the areas of underserved populations, durability, and mild depression.

Access: One promise of virtual solutions is the expansion of access to treatment, particularly to underserved populations. However, within the body of evidence about virtual mental health solutions for depression and anxiety, users are disproportionately young, female, and white—groups that appear more likely to self-select into virtual care. Solution vendors and researchers need to focus on improved methods of engaging and deploying these solutions to a more diverse set of users.

Durability: Another area for further research is posttreatment durability of clinical effects. Most studies do not include longer-term follow-up to understand whether symptom improvements are sustained after the initial 6 to 12 weeks of the study. Further, only a few studies have examined the use of digital solutions to avoid symptom recurrence. This is a critical component of understanding how well these solutions work and for understanding potential economic savings.

Patients with Mild Symptoms: Average starting PHQ-9 and GAD-7 scores across the studies were generally in the moderate to moderate-severe range, and studies rarely broke out results by starting PHQ-9/GAD-7 levels. Because these solutions are often deployed across large populations with a variety of symptom acuity, more evidence is needed to understand treatment effects on people with milder symptoms. As access to care improves, patients with mild symptoms are the users who are most likely to newly engage in care. Additional research is critical to inform how any clinical benefits are balanced against treatment costs for this population.

Understand and Enhance Engagement

There is a strong and well-documented relationship between engagement and clinical and economic outcomes; however, the reviewed studies generally reported variable levels of engagement and program completion rates. Importantly, these reported rates may represent the best-case scenarios for solution engagement, as reported rates may be influenced by trial-specific conditions, such as engagement-based compensation.

Given the critical role engagement plays in driving clinical benefit and economic value, more research on how to best drive engagement is needed. This is true for all reviewed solution categories and may be particularly important for blended-care solutions, where variable rates by treatment type could impact intake and triage processes.

In addition, research is needed on factors that drive engagement with specific user types. Reviewed studies reported that patient demographics and the level of human involvement play a role in engagement rates, but more research is needed in this area.

Innovators must better understand engagement across users and then translate this research into new mechanisms and processes that help drive engagement across a heterogeneous health plan or employee population. Improvements in engagement will help increase purchaser confidence that the investment in these solutions will result in meaningful, population-level, clinical, and economic benefits.

Focus on Efficient Care Delivery

All the categories of virtual solutions demonstrated positive clinical outcomes and could be considered for purchase. However, the pricing of these solutions (particularly blended-care solutions), combined with the potential for significant utilization expansion, may be a barrier to broader adoption. This is particularly true if digital content is primarily used to augment other usual care or if the deployment of blended-care solutions results in higher utilization of costly therapy services.

Innovators should continue to explore ways to align individual care intensity to clinical needs through the development and improvement of care-matching systems and processes. Whenever clinically appropriate, providing lower-cost, digital services as first-line care can improve outcomes and may enable some patients to avoid more expensive therapy. Integrating stepped-care models that match patients to the most clinically appropriate level of care will also give purchasers more confidence when selecting a blended-care solution. Finally, solutions should be managing depression and anxiety symptoms as episodes of care, stepping patients off of therapy when clinically appropriate and using digital solutions to sustain long-term improvements.

Align Payment Models with Clinical Benefits

In parallel with the appropriate alignment of care intensity, variable pricing based on the type of care a patient is receiving will be critical for broad-scale adoption. Purchasers understand that these solutions may result in increases in engagement with mental health treatment (in fact, that is often an explicit goal). Innovators need to design variable pricing models that align clinical intensity with payments to ensure that purchasers are able to make these solutions broadly available.

Current pricing models often charge PMPM fees for all plan members or employees, rather than targeting only those users who engage with the solution. This creates a high price of entry for purchasers and means that blended-care solutions often increase total net spending.

Data suggests that adding mental health solutions may significantly increase the number of patients that access treatment. Given this, it is critical that purchasers work with virtual solution providers to create payment and contracting models that are tied to clinically meaningful outcomes. In addition, for stepped-care models, purchasers must create contracts that 1) give them confidence that patients are being appropriately triaged and 2) include differential payments for different levels of care. This includes prioritizing lower-cost and effective solutions for patients with mild symptoms or finding alternatives to therapy.

List of Appendices

Appendix A
Methodology Overview

Appendix B
SLR Studies, Company-Specific Clinical Citations and HCRU Data

Appendix C
Risk of Bias Ratings for SLR Studies

Appendix D
Key Comparator Studies with PHQ-9 Outcomes

Appendix E
Key Comparator Studies with GAD-7 Outcomes

To access all appendices, please visit https://phti.org/assessment/virtual-solutions-anxiety-depression/#appendices.

Online Data Supplement

Access the online data supplement at: https://phti.org/assessment/virtual-solutions-anxiety-depression/#data-supplement.

References

1 Substance Abuse and Mental Health Services Administration (SAMHSA), "Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020," 2014, Figure A.6. https://library.samhsa.gov/sites/default/files/sma14-4883.pdf

2 Terlizzi, Emily P., and Benjamin Zablotsky, "Symptoms of Anxiety and Depression Among Adults: United States, 2019 and 2022," *National Health Statistics Reports* 213 (2024): CS353885. https://www.cdc.gov/nchs/data/nhsr/nhsr213.pdf

3 Greenberg, Paul E., Andree-Anne Fournier, Tammy Sisitsky, et al., "The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)," *Pharmacoeconomics* 39, no. 6 (2021): 653–665. https://doi.org/10.1007/s40273-021-01019-4

4 SAMHSA, "Projections of National Expenditures," 2014.

5 Terlizzi, "Symptoms of Anxiety and Depression," CS353885.

6 Kalin, Ned H., "The Critical Relationship Between Anxiety and Depression," *American Journal of Psychiatry* 177, no. 5 (2020): 365–367. https://doi.org/10.1176/appi.ajp.2020.20030305

7 Brenan, Megan, "Depression Rates Reach New Highs in the U.S.," Gallup, June 15, 2023. https://news.gallup.com/poll/505745/depression-rates-reach-new-highs.aspx

8 Terlizzi, "Symptoms of Anxiety and Depression," CS353885.

9 Artiga, Samantha, Latoya Hill, and Nambi Ndugga, "Racial and Ethnic Disparities in Mental Health Care: Findings from the KFF Survey of Racism, Discrimination, and Health," KFF, May 23, 2023. https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-and-ethnic-disparities-in-mental-health-care-findings-from-the-kff-survey-of-racism-discrimination-and-health/

10 Brenan, "Depression Rates Reach New Highs."

11 Brenan, "Depression Rates Reach New Highs."

12 Terlizzi, "Symptoms of Anxiety and Depression," CS353885.

13 Terlizzi, "Symptoms of Anxiety and Depression," CS353885.

14 Mental Health America, "Co-Occurring Disorders and Depression," accessed April 7, 2025. https://mhanational.org/resources/co-occurring-disorders-and-depression/

15 Mayo Clinic, "Anxiety Disorders," accessed April 4, 2025. https://www.mayoclinic.org/diseases-conditions/anxiety/symptoms-causes/syc-20350961#:~:text=Complications,Suicide

16 SAMHSA, "Co-Occurring Disorders and Other Health Conditions," accessed April 7, 2025. https://www.samhsa.gov/substance-use/treatment/co-occurring-disorders

17 Barry, Michael J., Wanda K. Nicholson, Michael Silverstein, et al., "Screening for Depression and Suicide Risk in Adults: US Preventive Services Task Force Recommendation Statement," *JAMA* 329, no. 23 (2023): 2057–2067. https://doi.org/10.1001/jama.2023.9297

18 Bryan, Mark L., Andrew M. Bryce, and Jennifer Roberts, "The Effect of Mental and Physical Health Problems on Sickness Absence," *European Journal of Health Economics* 22, no. 9 (2021): 1519–1533. https://doi.org/10.1007/s10198-021-01379-w

19 American Psychological Association (APA), "Patient Health Questionnaire (PHQ-9 & PHQ-2)," accessed April 7, 2025. https://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/patient-health

20 APA, "Measurement-Based Care Suggested Measures," accessed April 7, 2025. https://www.apaservices.org/practice/measurement-based-care/suggested-measures

21 U.S. Preventive Services Task Force, "Screening for Depression and Suicide Risk in Adults: Preventive Medication Draft Recommendation Statement," January 9, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-depression-suicide-risk-adults

22 Mongelli, Francesca, Penelope Georgakopoulos, and Michele T. Pato, "Challenges and Opportunities to Meet the Mental Health Needs of Underserved and Disenfranchised Populations in the United States," *Focus* 18, no. 1 (2020): 16–24. https://doi.org/10.1176/appi.focus.20190028

23 National Institute of Mental Health (NIMH), "Major Depression," accessed April 7, 2025. https://www.nimh.nih.gov/health/statistics/major-depression

24 NIMH, "Psychotherapies," accessed April 7, 2025. https://www.nimh.nih.gov/health/topics/psychotherapies

25 NIMH, "Anxiety Disorders," accessed April 7, 2025. https://www.nimh.nih.gov/health/topics/anxiety-disorders

26 NIMH, "Depression," accessed April 7, 2025. https://www.nimh.nih.gov/health/topics/depression

27 Qaseem, Amir, Douglas K. Owens, Itziar Etxeandia-Ikobaltzeta, et al., "Nonpharmacologic and Pharmacologic Treatments of Adults in the Acute Phase of Major Depressive Disorder: A Living Clinical Guideline from the American College of Physicians," *Annals of Internal Medicine* 176, no. 2 (2023): 239–252. https://doi.org/10.7326/M22-2056

28 DeGeorge, Katharine C., Molly Grover, and Gregory S. Streeter, "Generalized Anxiety Disorder and Panic Disorder in Adults," *American Family Physician* 106, no. 2 (2022): 157–164. https://www.aafp.org/pubs/afp/issues/2022/0800/generalized-anxiety-disorder-panic-disorder.html

29 Qaseem, "Nonpharmacologic and Pharmacologic Treatments," 239–252.

30 DeGeorge, "Generalized Anxiety Disorder," 157–164.

31 APA, "What Is Psychiatry?" accessed April 7, 2025. https://www.psychiatry.org/patients-families/what-is-psychiatry

32 Anxiety & Depression Association of America (ADAA), "Different Types of Mental Health Therapies," accessed April 7, 2025. https://adaa.org/find-help/treatment-help/types-of-therapy

33 Curtiss, Joshua E., Daniella S. Levine, Ilana Ander, et al., "Cognitive-Behavioral Treatments for Anxiety and Stress-Related Disorders," *Focus* 19, no. 2 (2021): 184–189. https://doi.org/10.1176/appi.focus.20200045

34 Berg, Hannah, Elisabeth Akeman, Timothy J. McDermott, et al., "A Randomized Clinical Trial of Behavioral Activation and Exposure-Based Therapy for Adults with Generalized Anxiety Disorder," *Journal of Mood and Anxiety Disorders* 1 (2023): 100004. https://doi.org/10.1016/j.xjmad.2023.100004

35 Dimidjian, Sona, and David J. Weissman, "Chapter 12 —Behavioral Activation Treatments for Depression," In *The Clinician's Guide to Cognitive-Behavioral Therapy for Depression*, edited by Jesse H. Wright, Academic Press, 2017, pp. 221–237. https://www.sciencedirect.com/science/article/abs/pii/B978012803457600012X

36 Curtiss, "Cognitive-Behavioral Treatments," 184–189.

37 Beck, Judith S., *Cognitive Behavior Therapy: Basics and Beyond*. Guilford Publications, 2020.

38 Wiles, Nicola, Laura Thomas, Anna Abel, et al., "Cognitive Behavioural Therapy as an Adjunct to Pharmacotherapy for Primary Care Based Patients with Treatment Resistant Depression: Results of the CoBalT Randomised Controlled Trial," *The Lancet* 381, no. 9864 (2013): 375–384. https://doi.org/10.1016/S0140-6736(12)61552-9

39 Levy, Hannah C., Emily M. O'Bryan, and David F. Tolin, "A Meta-Analysis of Relapse Rates in Cognitive-Behavioral Therapy for Anxiety Disorders," *Journal of Anxiety Disorders* 81 (2021): 102407. https://doi.org/10.1016/j.janxdis.2021.102407

40 NIMH, "Mental Health Medications," accessed April 7, 2025. https://www.nimh.nih.gov/health/topics/mental-health-medications

41 Cunningham, Peter J., "Beyond Parity: Primary Care Physicians' Perspectives on Access to Mental Health Care: More PCPs Have Trouble Obtaining Mental Health Services for Their Patients than Have Problems Getting Other Specialty Services," *Health Affairs* 28, Suppl. 1 (2009): w490–w501. https://doi.org/10.1377/hlthaff.28.3.w490

42 Barkil-Oteo, Andres, "Collaborative Care for Depression in Primary Care: How Psychiatry Could 'Troubleshoot' Current Treatments and Practices," *Yale Journal of Biology and Medicine* 86, no. 2 (2013): 139. https://pubmed.ncbi.nlm.nih.gov/23766735/

43 Golder, Su, Dominique Medaglio, Karen O'Connor, et al., "Reasons for Discontinuation or Change of Selective Serotonin Reuptake Inhibitors in Online Drug Reviews," *JAMA Network Open* 6, no. 7 (2023): e2323746. https://doi.org/10.1001/jamanetworkopen.2023.23746

44 Wiles et al., "Cognitive Behavioural Therapy," 375–384.

45 Cuijpers, Pim, Hisashi Noma, Eirini Karyotaki, et al., "A Network Meta-Analysis of the Effects of Psychotherapies, Pharmacotherapies and Their Combination in the Treatment of Adult Depression," *World Psychiatry* 19, no. 1 (2020): 92–107. https://doi.org/10.1002/wps.20701

46 Gartlehner, Gerald, Andreea Dobrescu, Andrea Chapman, et al., "Nonpharmacologic and Pharmacologic Treatments of Adult Patients with Major Depressive Disorder: A Systematic Review and Network Meta-Analysis for a Clinical Guideline by the American College of Physicians," *Annals of Internal Medicine* 176, no. 2 (2023): 196–211. https://doi.org/10.7326/M22-1845

47 Vittengl, Jeffrey R., Lee Anna Clark, Todd W. Dunn, et al., "Reducing Relapse and Recurrence in Unipolar Depression: A Comparative Meta-Analysis of Cognitive-Behavioral Therapy's Effects," *Journal of Consulting and Clinical Psychology* 75, no. 3 (2007): 475. https://doi.org/10.1037/0022-006X.75.3.475

48 Cuijpers, "A Network Meta-Analysis," 92–107.

49 Gartlehner, "Nonpharmacologic and Pharmacologic Treatments," 196–211.

[50] DeRubeis, Robert J., Steven D. Hollon, Jay D. Amsterdam, et al., "Cognitive Therapy vs Medications in the Treatment of Moderate to Severe Depression," *Archives of General Psychiatry* 62, no. 4 (2005): 409–416. https://doi.org/10.1001/archpsyc.62.4.409

[51] Cuijpers, "A Network Meta-Analysis," 92–107.

[52] Posternak, Michael A., and Ivan Miller, "Untreated Short-Term Course of Major Depression: A Meta-Analysis of Outcomes from Studies Using Wait-List Control Groups," *Journal of Affective Disorders* 66, no. 2–3 (2001): 139–146. https://doi.org/10.1016/S0165-0327(00)00304-9

[53] Stalujanis, Esther, Joel Neufeld, Martina Glaus Stalder, et al., "Induction of Efficacy Expectancies in an Ambulatory Smartphone-Based Digital Placebo Mental Health Intervention: Randomized Controlled Trial," *JMIR mHealth and uHealth* 9, no. 2 (2021): e20329. https://doi.org/10.2196/20329

[54] Linardon, Jake, Pim Cuijpers, Per Carlbring, et al., "The Efficacy of App-Supported Smartphone Interventions for Mental Health Problems: A Meta-Analysis of Randomized Controlled Trials," *World Psychiatry* 18, no. 3 (2019): 325–336. https://doi.org/10.1002/wps.20673

[55] Panchal, Nirmita, Rabah Kamal, Kendal Orgera, et al., "The Implications of COVID-19 for Mental Health and Substance Use," KFF, February 10, 2021. https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/

[56] Myers, Carole R., "Using Telehealth to Remediate Rural Mental Health and Healthcare Disparities," *Issues in Mental Health Nursing* 40, no. 3 (2019): 233–239. https://doi.org/10.1080/01612840.2018.1499157

[57] Andrilla, C. Holly A., Davis G. Patterson, Lisa A. Garberson, et al., "Geographic Variation in the Supply of Selected Behavioral Health Providers," *American Journal of Preventive Medicine* 54, no. 6 (2018): S199–S207. https://doi.org/10.1016/j.amepre.2018.01.004

[58] APA, "Psychologists Reaching Their Limits as Patients Present with Worsening Symptoms Year After Year: 2023 Practitioner Pulse Survey," no date. https://www.apa.org/pubs/reports/practitioner/2023-psychologist-reach-limits

[59] Sun, Ching-Fang, Christoph U. Correll, Robert L. Trestman, et al., "Low Availability, Long Wait Times, and High Geographic Disparity of Psychiatric Outpatient Care in the US," *General Hospital Psychiatry* 84 (2023): 12–17. https://doi.org/10.1016/j.genhosppsych.2023.05.012

[60] Sun, "Low Availability," 12–17.

[61] APA, "Mental Health Disparities: Diverse Populations," accessed April 7, 2025. https://www.psychiatry.org/psychiatrists/diversity/education/mental-health-facts

[62] APA, "Mental Health Disparities: Diverse Populations."

[63] Panchal, "The Implications of COVID-19."

[64] Panchal, "The Implications of COVID-19."

[65] Panchal, "The Implications of COVID-19."

[66] Ali, Hussain Y., and Krutika Amin, "Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic," KFF, March 15, 2023. https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/

[67] Panchal, "The Implications of COVID-19."

[68] Telehealth.HHS.gov, "Telehealth Policy Updates," accessed April 7, 2025. https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates

[69] SAMHSA, "Projections of National Expenditures," 2014.

[70] Harter, Jim, "The Economic Cost of Poor Employee Mental Health," Gallup, October 25, 2023. https://www.gallup.com/workplace/404174/economic-cost-poor-employee-mental-health.aspx

[71] Culpepper, Larry, Ashley Martin, Nadia Nabulsi, et al., "The Humanistic and Economic Burden Associated with Major Depressive Disorder: A Retrospective Cross-Sectional Analysis," *Advances in Therapy* 41, no. 5 (2024): 1860–1884. https://doi.org/10.1007/s12325-024-02817-w

[72] Kavelaars, RuthAnne, Haley Ward, Kushal M. Modi, et al., "The Burden of Anxiety Among a Nationally Representative US Adult Population," *Journal of Affective Disorders* 336 (2023): 81–91. https://doi.org/10.1016/j.jad.2023.04.069

[73] Melek, Sarah, Henry Harbin, and Dale Jarvis, "How Do Individuals with Behavioral Health Conditions Contribute to Physical and Total Healthcare Spending?" Milliman, January 2018. https://www.milliman.com/en/insight/How-do-individuals-with-behavioral-health-conditions-contribute-to-physical

[74] World Economic Forum, "How Science and Finance Can Combine to Transform Mental Health Treatments," January 10, 2025. https://www.weforum.org/stories/2025/01/science-and-finance-to-transform-mental-health-treatments/

75 Haque, M. D. Romael, and Sabirat Rubya, "An Overview of Chatbot-Based Mobile Mental Health Apps: Insights from App Description and User Reviews," *JMIR mHealth and uHealth* 11, no. 1 (2023): e44838. https://doi.org/10.2196/44838

76 Kim, Jiyeong, Michael L. Chen, Shawheen J. Rezaei, et al., "Perspectives on Artificial Intelligence–Generated Responses to Patient Messages," *JAMA Network Open* 7, no. 10 (2024): e2438535. https://doi.org/10.1001/jamanetworkopen.2024.38535

77 Heinz, Michael V., Daniel M. Mackin, Brianna M. Trudeau, et al., "Randomized Trial of a Generative AI Chatbot for Mental Health Treatment," *NEJM AI* 2, no. 4 (2025). https://doi.org/10.1056/AIoa2400802

78 APA, "Digital Mental Health Technologies," accessed April 17, 2025. https://www.apa.org/practice/digital-therapeutics-mobile-health

79 Digital Therapeutics Alliance, "Understanding DTx," accessed April 17, 2025. https://dtxalliance.org/understanding-dtx/

80 Business Group on Health, "2022 Survey of Employer Approaches to Employee Assistance Programs," 2022. https://www.businessgrouphealth.org/-/media/bgh/documents/download-pdf/eap-survey-2022-ppt---final.pdf

81 Patterson, Beth, Michael H. Boyle, Michelle Kivlenieks, et al., "The Use of Waitlists as Control Conditions in Anxiety Disorders Research," *Journal of Psychiatric Research* 83 (2016): 112–120. https://www.sciencedirect.com/science/article/abs/pii/S0022395616302448

82 Furukawa, Toshi A., Hisashi Noma, Deborah M. Caldwell, et al., "Waiting List May Be a Nocebo Condition in Psychotherapy Trials: A Contribution from Network Meta-Analysis," *Acta Psychiatrica Scandinavica* 130, no. 3 (2014): 181–192.

83 APA, "Patient Health Questionnaire (PHQ-9 & PHQ-2)."

84 APA, "Measurement-Based Care Suggested Measures."

85 Kroenke, Kurt, Robert L. Spitzer, and Janet B. W. Williams, "The PHQ-9: Validity of a Brief Depression Severity Measure," *Journal of General Internal Medicine* 16, no. 9 (2001): 606–613. https://doi.org/10.1046/j.1525-1497.2001.016009606.x

86 Cuijpers, "A Network Meta-Analysis," 92–107.

87 Sugarman, Dawn E., and Alisa B. Busch, "Telemental Health for Clinical Assessment and Treatment," *BMJ* 380 (2023): e072398. https://doi.org/10.1136/bmj-2022-072398

88 Meyerhoff, Jonah, Miranda Beltzer, Sarah Popowski, et al., "Small Steps Over Time: A Longitudinal Usability Test of an Automated Interactive Text Messaging Intervention to Support Self-Management of Depression and Anxiety Symptoms," *Journal of Affective Disorders* 345 (2024): 122–130. https://doi.org/10.1016/j.jad.2023.10.119

89 Segal, Zindel V., Sona Dimidjian, Arne Beck, et al., "Outcomes of Online Mindfulness-Based Cognitive Therapy for Patients with Residual Depressive Symptoms: A Randomized Clinical Trial," *JAMA Psychiatry* 77, no. 6 (2020): 563–573. https://doi.org/10.1001/jamapsychiatry.2019.4693

90 Wilhelm, Sabine, Emily E. Bernstein, Kate H. Bentley, et al., "Feasibility, Acceptability, and Preliminary Efficacy of a Smartphone App–Led Cognitive Behavioral Therapy for Depression Under Therapist Supervision: Open Trial," *JMIR Mental Health* 11, no. 1 (2024): e53998. https://doi.org/10.2196/53998

91 Cochran, Jeffrey, Huan Jiang, Hossain Saboonchi, et al., "CT-152, a Prescription Digital Therapeutic for Major Depressive Disorder: A Real-World Analysis," poster presented at Psych Congress 2024 Annual Meeting, Boston, MA, October 29–November 2, 2024.

92 Stuart, Roderick, Heidi Fischer, Arthur S. Leitzke, et al., "The Effectiveness of Internet-Based Cognitive Behavioral Therapy for the Treatment of Depression in a Large Real-World Primary Care Practice: A Randomized Trial," *Permanente Journal* 26, no. 3 (2022): 53. https://doi.org/10.7812/tpp/21.183

93 Hall, Shana, Eileen Y. Wong, Dani Bradley, et al., "Efficacy and Safety of a Scalable App-Based Depression Program in Adults," poster presented at ADAA Annual Conference, Boston, MA, April 11–14, 2024.

94 Schure, Mark B., Janet C. Lindow, John H. Greist, et al., "Use of a Fully Automated Internet-Based Cognitive Behavior Therapy Intervention in a Community Population of Adults with Depression Symptoms: Randomized Controlled Trial," *Journal of Medical Internet Research* 21, no. 11 (2019): e14754. https://doi.org/10.2196/14754

95 Rothman, Brian, Mary Slomkowski, Austin Speier, et al., "A Prescription Digital Therapeutic, CT-152, for Treating Major Depressive Disorder: Future Research Will Focus on the Real-World Adherence and Engagement of CT-152 and Further Explore the Role of This Treatment Modality in Various Patient Populations," poster presented at Psych Congress 2024 Annual Meeting, Boston, MA, October 29–November 2, 2024.

96 Rothman, "A Prescription Digital."

[97] McCallum, Meaghan, Matthew Baldwin, Paige Thompson, et al., "Long-Term Efficacy of a Mobile Mental Wellness Program: Prospective Single-Arm Study," *JMIR mHealth and uHealth* 12 (2024): e54634. https://doi.org/10.2196/54634

[98] Mehta, Ashish, Andrea Nicole Niles, Jose Hamilton Vargas, et al., "Acceptability and Effectiveness of Artificial Intelligence Therapy for Anxiety and Depression (Youper): Longitudinal Observational Study," *Journal of Medical Internet Research* 23, no. 6 (2021): e26771. https://doi.org/10.2196/26771

[99] Schure, Mark, Bernadette McCrory, Kathryn Tuchscherer Franklin, et al., "Twelve-Month Follow-Up to a Fully Automated Internet-Based Cognitive Behavior Therapy Intervention for Rural Adults with Depression Symptoms: Single-Arm Longitudinal Study," *Journal of Medical Internet Research* 22, no. 10 (2020): e21336. https://doi.org/10.2196/21336

[100] Ferguson, IreLee, Grace George, Kevin O. Narine, et al., "Acceptability and Engagement of a Smartphone-Delivered Interpretation Bias Intervention in a Sample of Black and Latinx Adults: Open Trial," *JMIR Mental Health* 11 (2024): e56758. https://doi.org/10.2196/56758

[101] Xiang, Xiaoling, Skyla Turner, Sofia Ruiz-Sierra, et al., "Older Adults' Experience with a Layperson-Supported Digital Mental Health Intervention for Depression: Qualitative Insights on Engagement," *Clinical Gerontologist* (2024): 1–12. https://doi.org/10.1080/07317115.2024.2395890

[102] Dzubur, Eldin, Jessica Yu, Julia Hoffman, et al., "The Effect of a Digital Mental Health Program on Anxiety and Depression Symptoms: Retrospective Analysis of Clinical Severity," *JMIR Formative Research* 7, no. 1 (2023): e36596. https://doi.org/10.2196/36596

[103] Ezawa, Iony D., Steven D. Hollon, and Noah Robinson, "Examining Predictors of Depression and Anxiety Symptom Change in Cognitive Behavioral Immersion: Observational Study," *JMIR Mental Health* 10, no. 1 (2023): e42377. https://doi.org/10.2196/42377

[104] Sharif-Sidi, Zakariyah, Christine Shen, William Wong, et al., "Addressing Depression and Behavioral Health Needs Through a Digital Program at Scale," *Healthcare* 9, no. 2 (2021): 100521. https://doi.org/10.1016/j.hjdsi.2021.100521

[105] Chiauzzi, Emil, Andre Williams, Timothy Y. Mariano, et al., "Demographic and Clinical Characteristics Associated with Anxiety and Depressive Symptom Outcomes in Users of a Digital Mental Health Intervention Incorporating a Relational Agent," *BMC Psychiatry* 24, no. 1 (2024): 79. https://doi.org/10.1186/s12888-024-05532-6

[106] Schure, "Twelve-Month Follow-Up," e21336.

[107] Chiauzzi, "Demographic and Clinical," 79.

[108] Iacoviello, Brian M., James W. Murrough, Megan M. Hoch, et al., "A Randomized, Controlled Pilot Trial of the Emotional Faces Memory Task: A Digital Therapeutic for Depression," *NPJ Digital Medicine* 1, no. 1 (2018): 21. https://doi.org/10.1038/s41746-018-0025-5

[109] Santopetro, Nicholas, Danielle Jones, Andrew Garron, et al., "Examining a Fully Automated Mobile-Based Behavioral Activation Intervention in Depression: Randomized Controlled Trial," *JMIR Mental Health* 11 (2024): e54252. https://doi.org/10.2196/54252

[110] Shah, Avani, Martin Morthland, Forrest Scogin, et al., "Audio and Computer Cognitive Behavioral Therapy for Depressive Symptoms in Older Adults: A Pilot Randomized Controlled Trial," *Behavior Therapy* 49, no. 6 (2018): 904–916. https://doi.org/10.1016/j.beth.2018.06.002

[111] Mullarkey, Michael C., Aliza T. Stein, Rahel Pearson, et al., "Network Analyses Reveal Which Symptoms Improve (or Not) Following an Internet Intervention (Deprexis) for Depression," *Depression and Anxiety* 37, no. 2 (2020): 115–124. https://doi.org/10.1002/da.22972

[112] Dahne, Jennifer, C. W. Lejuez, Vanessa A. Diaz, et al., "Pilot Randomized Trial of a Self-Help Behavioral Activation Mobile App for Utilization in Primary Care," *Behavior Therapy* 50, no. 4 (2019): 817–827. https://doi.org/10.1016/j.beth.2018.12.003

[113] McCallum, "Long-Term Efficacy," e54634.

[114] Chiauzzi, "Demographic and Clinical," 79.

[115] Santopetro, "Examining Fully," e54252.

[116] Abbott, Deah, Caleb W. Lack, and Page Anderson. "Does Using a Mindfulness App Reduce Anxiety and Worry? A Randomized-Controlled Trial," *Journal of Cognitive Psychotherapy* 37, no. 1 (2023): 26–42. https://doi.org/10.1891/jcpsy-d-20-00058

[117] Forand, Nicholas R., Jeffrey G. Barnett, Daniel R. Strunk, et al., "Efficacy of Guided iCBT for Depression and Mediation of Change by Cognitive Skill Acquisition," *Behavior Therapy* 49, no. 2 (2018): 295–307. https://doi.org/10.1016/j.beth.2017.04.004

[118] Stiles-Shields, Colleen, Enid Montague, Mary J. Kwasny, et al., "Behavioral and Cognitive Intervention Strategies Delivered via Coached Apps for Depression: Pilot Trial," *Psychological Services* 16, no. 2 (2019): 233. https://doi.org/10.1037/ser0000261

[119] Wu, Monica S., Shih-Yin Chen, Robert E. Wickham, et al., "Outcomes of a Blended Care Coaching Program for Clients Presenting with Moderate Levels of Anxiety and Depression: Pragmatic Retrospective Study," *JMIR Mental Health* 8, no. 10 (2021): e32100. https://doi.org/10.2196/32100

[120] Mason, Michael J., J. Douglas Coatsworth, Nikola Zaharakis, et al., "Testing Mechanisms of Change for Text Message–Delivered Cognitive Behavioral Therapy: Randomized Clinical Trial for Young Adult Depression," *JMIR mHealth and uHealth* 11 (2023): e45186. https://doi.org/10.2196/45186

[121] Kannampallil, Thomas, Olusola A. Ajilore, Nan Lv, et al., "Effects of a Virtual Voice-Based Coach Delivering Problem-Solving Treatment on Emotional Distress and Brain Function: A Pilot RCT in Depression and Anxiety," *Translational Psychiatry* 13, no. 1 (2023): 166. https://doi.org/10.1038/s41398-023-02462-x

[122] Jonassaint, Charles R., Bea Herbeck Belnap, Yan Huang, et al., "Racial Differences in the Effectiveness of Internet-Delivered Mental Health Care," *Journal of General Internal Medicine* 35 (2020): 490–497. https://doi.org/10.1007/s11606-019-05542-1

[123] Dahne, Jennifer, Anahi Collado, C. W. Lejuez, et al., "Pilot Randomized Controlled Trial of a Spanish-Language Behavioral Activation Mobile App (¡Aptívate!) for the Treatment of Depressive Symptoms Among United States Latinx Adults with Limited English Proficiency," *Journal of Affective Disorders* 250 (2019): 210–217. https://doi.org/10.1016/j.jad.2019.03.009

[124] Graham, Andrea K., Carolyn J. Greene, Mary J. Kwasny, et al., "Coached Mobile App Platform for the Treatment of Depression and Anxiety Among Primary Care Patients: A Randomized Clinical Trial," *JAMA Psychiatry* 77, no. 9 (2020): 906–914. https://doi.org/10.1001/jamapsychiatry.2020.1011

[125] Renn, Brenna N., Teresa J. Walker, Brian Edds, et al., "Naturalistic Use of a Digital Mental Health Intervention for Depression and Anxiety: A Randomized Clinical Trial," *Journal of Affective Disorders* 368 (2025): 429–438. https://doi.org/10.1016/j.jad.2024.09.104

[126] Owusu, Jocelynn T., Pam Wang, Robert E. Wickham, et al., "Outcomes of a Live Messaging, Blended Care Coaching Program Among Adults with Symptoms of Anxiety: Pragmatic Retrospective Cohort Study," *JMIR Formative Research* 7 (2023): e44138. https://doi.org/10.2196/44138

[127] Wu, "Outcomes of a Blended Care," e32100.

[128] Jonassaint, "Racial Differences in," 490–497.

[129] Kannampallil, "Effects of a Virtual," 166.

[130] Horwitz, Adam G., Elizabeth D. Mills, Srijan Sen, et al., "Comparative Effectiveness of Three Digital Interventions for Adults Seeking Psychiatric Services: A Randomized Clinical Trial," *JAMA Network Open* 7, no. 7 (2024): e2422115. https://doi.org/10.1001/jamanetworkopen.2024.22115

[131] Mohr, David C., Stephen M. Schueller, Kathryn Noth Tomasino, et al., "Comparison of the Effects of Coaching and Receipt of App Recommendations on Depression, Anxiety, and Engagement in the IntelliCare Platform: Factorial Randomized Controlled Trial," *Journal of Medical Internet Research* 21, no. 8 (2019): e13609. https://doi.org/10.2196/13609

[132] Pratap, Abhishek, Brenna N. Renn, Joshua Volponi, et al., "Using Mobile Apps to Assess and Treat Depression in Hispanic and Latino Populations: Fully Remote Randomized Clinical Trial," *Journal of Medical Internet Research* 20, no. 8 (2018): e10130. https://doi.org/10.2196/10130

[133] Areán, Patricia A., Michael D. Pullmann, Isabell R. Griffith Fillipo, et al., "Randomized Trial of the Effectiveness of Videoconferencing-Based Versus Message-Based Psychotherapy on Depression," *Psychiatric Services* 75, no. 12 (2024): 1184–1191. https://doi.org/10.1176/appi.ps.20230176

[134] Song, Jiyoung, Boris Litvin, Ryan Allred, et al., "Comparing Message-Based Psychotherapy to Once-Weekly, Video-Based Psychotherapy for Moderate Depression: Randomized Controlled Trial," *Journal of Medical Internet Research* 25 (2023): e46052. https://doi.org/10.2196/46052

[135] Segal, Outcomes of Online," 563–573.

[136] Jonassaint, "Racial Differences in," 490–497.

[137] Areán, "Randomized Trial of," 1184–1191.

[138] Pratap, "Using Mobile Apps," e10130.

[139] Forman-Hoffman, Valerie L., Megan Flom, Robert Montgomery, et al., "Improvements in Work Productivity and Activity Impairment Among Adults with Anxiety or Depressive Symptoms Participating in a Relational Agent-Delivered Digital Mental Health Intervention," *Journal of Occupational and Environmental Medicine* 66, no. 3 (2023): e99–e105. https://doi.org/10.1097/jom.0000000000003038

[140] Anton, P. Margaret, "Prevalence and Change in Work Productivity and Activity Impairment Among Employed U.S. Adults Completing a Cognitive Behavioral Telehealth Treatment for Depression and Anxiety." In Proceedings of the Anxiety and Depression Conference, Denver, CO, 2022.

[141] Forman-Hoffman, Valerie L., Samuel Sihvonen, Joseph Wielgosz, et al., "Therapist-Supported Digital Mental Health Intervention for Depressive Symptoms: A Randomized Clinical Trial," *Journal of Affective Disorders* 349 (2024): 494–501. https://doi.org/10.1016/j.jad.2024.01.057

[142] Stuart, "The Effectiveness of Internet-Based," 53.

[143] Oser, Megan, Meredith L. Wallace, Francis Solano, et al., "Guided Digital Cognitive Behavioral Program for Anxiety in Primary Care: Propensity-Matched Controlled Trial," *JMIR Mental Health* 6, no. 4 (2019): e11981. https://doi.org/10.2196/11981

[144] Segal, "Outcomes of Online," 563–573.

[145] Davis, Carter H., Marissa L. Donahue, Brandon A. Gaudiano, et al., "Adding Online Storytelling-Based Acceptance and Commitment Therapy to Antidepressant Treatment for Primary Care Patients: A Randomized Clinical Trial," *Cognitive Behaviour Therapy* 53, no. 1 (2024): 48–69. https://doi.org/10.1080/16506073.2023.2265560

[146] Kannampallil, "Effects of a Virtual," 166.

[147] Wright, Jesse H., Jesse Owen, Tracy D. Eells, et al., "Effect of Computer-Assisted Cognitive Behavior Therapy vs Usual Care on Depression Among Adults in Primary Care: A Randomized Clinical Trial," *JAMA Network Open* 5, no. 2 (2022): e2146716. https://doi.org/10.1001/jamanetworkopen.2021.46716

[148] Thase, Michael E., Jesse H. Wright, Tracy D. Eells, et al., "Improving the Efficiency of Psychotherapy for Depression: Computer-Assisted Versus Standard CBT," *American Journal of Psychiatry* 175, no. 3 (2018): 242–250. https://doi.org/10.1176/appi.ajp.2017.17010089

[149] Rotondi, Armando J., Bea Herbeck Belnap, Scott Rothenberger, et al., "Predictors of Use and Drop Out from a Web-Based Cognitive Behavioral Therapy Program and Health Community for Depression and Anxiety in Primary Care Patients: Secondary Analysis of a Randomized Controlled Trial," *JMIR Mental Health* 11 (2024): e52197. https://doi.org/10.2196/52197

[150] Xiang, Xiaoling, Jay Kayser, Skyla Turner, et al., "Layperson-Supported, Web-Delivered Cognitive Behavioral Therapy for Depression in Older Adults: Randomized Controlled Trial," *Journal of Medical Internet Research* 26, no. 1 (2024): e53001. https://doi.org/10.2196/53001

[151] Kannampallil, "Effects of a Virtual," 166.

[152] Forand, "Efficacy of Guided," 295–307.

[153] Jonassaint, "Racial Differences in," 490–497.

[154] Camacho, Erica, Sarah M. Chang, Danielle Currey, et al., "The Impact of Guided Versus Supportive Coaching on Mental Health App Engagement and Clinical Outcomes," *Health Informatics Journal* 29, no. 4 (2023). https://doi.org/10.1177/14604582231215872

[155] Nowels, Molly Aideen, Meghan McDarby, Lilla Brody, et al., "Predictors of Engagement in Multiple Modalities of Digital Mental Health Treatments: Longitudinal Study," *Journal of Medical Internet Research* 26 (2024): e48696. https://doi.org/10.2196/48696

[156] Iacoviello, "A Randomized Controlled," 21.

[157] Wright, "Effect of Computer-Assisted," e2146716.

[158] Owusu, Jocelynn T., Pam Wang, Robert E. Wickham, et al., "Blended Care Therapy for Depression and Anxiety: Outcomes Across Diverse Racial and Ethnic Groups," *Journal of Racial and Ethnic Health Disparities* 10, no. 6 (2023): 2731–2743. https://doi.org/10.1007/s40615-022-01450-z

[159] Wu, Monica S., Robert E. Wickham, Shih-Yin Chen, et al., "Examining the Impact of Digital Components Across Different Phases of Treatment in a Blended Care Cognitive Behavioral Therapy Intervention for Depression and Anxiety: Pragmatic Retrospective Study," *JMIR Formative Research* 5, no. 12 (2021): e33452. https://doi.org/10.2196/33452

[160] Wu, "Outcomes of a Blended Care," e32100.

[161] Owusu, Jocelynn T., Pam Wang, Robert E. Wickham, et al., "Real-World Evaluation of a Large-Scale Blended Care-Cognitive Behavioral Therapy Program for Symptoms of Anxiety and Depression," *Telemedicine and E-Health* (2022): 1412–1420. https://doi.org/10.1089/tmj.2021.0590

[162] Geramita, Emily M., Bea Herbeck Belnap, Kaleab Z. Abebe, et al., "The Association Between Increased Levels of Patient Engagement with an Internet Support Group and Improved Mental Health Outcomes at 6-Month Follow-Up: Post-Hoc Analyses from a Randomized Controlled Trial," *Journal of Medical Internet Research* 20, no. 7 (2018): e10402. https://doi.org/10.2196/10402

[163] Shah, "Audio and Computer," 904–916.

[164] Xiang, "Older Adults' Experience," 1–12.

[165] Schure, "Use of a Fully Automated," e14754.

[166] Schure, "Twelve-Month Follow-Up," e21336.

[167] Wilhelm, "Feasibility, Acceptability, and," e53998.

[168] Nitzburg, George C., and Barry A. Farber. "Patterns of Utilization and a Case Illustration of an Interactive Text-Based Psychotherapy Delivery System," *Journal of Clinical Psychology* 75, no. 2 (2019): 247–259. https://doi.org/10.1002/jclp.22718

[169] Schure, "Use of a Fully Automated," e14754.

[170] Schure, "Twelve-Month Follow-Up," e21336.

[171] Belanger, Heather G., and Mirène Winsberg. "Exploring Social Determinants of Health: Comparing Lower and Higher Income Individuals Participating in Telepsychiatric Care for Depression," *Frontiers in Psychiatry* 13 (2023): 1026361. https://doi.org/10.3389/fpsyt.2022.1026361

[172] Jonassaint, "Racial Differences in," 490–497.

[173] Owusu, "Blended Care Therapy," 2731–2743.

[174] Pratap, "Using Mobile Apps," e10130.

[175] Sagui Henson, Sara J., Camille E. Welcome Chamberlain, Brooke J. Smith, et al., "Utilization, Satisfaction, and Clinical Outcomes of People of Color and White Adults Using an Employer-Sponsored Digital Mental Health Platform," *International Journal of Environmental Research and Public Health* 21, no. 12 (2024): 1660. https://doi.org/10.3390/ijerph21121660

[176] Jonassaint, "Racial Differences in," 490–497.

[177] Pratap, "Using Mobile Apps," e10130.

[178] Jonassaint, "Racial Differences in," 490–497

[179] Stoeckl, S. E., R. Henry, and E. M. Boucher, "Race-Based Differences in Engagement and Outcomes in a Digital Mental Health Intervention," poster presented at the Anxiety and Depression Association of America Annual Conference, Washington, DC, April 13–16, 2023.

[180] Raue, Patrick J., Nicole Fridling, Jiyoung Song, et al., "Message-Based Psychotherapy for Older Adults: A Cohort Comparison Study," *Frontiers in Psychiatry* 13 (2022): 951354. https://doi.org/10.3389/fpsyt.2022.951354

[181] Belanger, Heather G., and Mirène Winsberg, "Do Older Adults Benefit from Telepsychiatric Care: Comparison to Younger Adults," *Frontiers in Psychiatry* 13 (2022): 998401. https://doi.org/10.3389/fpsyt.2022.998401

[182] Alfaro, Ana J., Joseph Wielgosz, Eric Kuhn, et al., "Determinants and Outcome Correlates of Engagement with a Mobile Mental Health Intervention for Depression and Anxiety in Middle-Aged and Older Adults," *Journal of Clinical Psychology* 80, no. 3 (2024): 509–521. https://doi.org/10.1002/jclp.23636

[183] Gould, Christine E., Chalise Carlson, Flora Ma, et al., "Effects of Mobile App–Based Intervention for Depression in Middle-Aged and Older Adults: Mixed Methods Feasibility Study," *JMIR Formative Research* 5, no. 6 (2021): e25808. https://doi.org/10.2196/25808

[184] Gould, Christine E., Chalise Carlson, Ana Jessica Alfaro, et al., "Changes in Quality of Life and Loneliness Among Middle-Aged and Older Adults Participating in Therapist-Guided Digital Mental Health Intervention," *Frontiers in Public Health* 9 (2021): 746904. https://doi.org/10.3389/fpubh.2021.746904

[185] Xiang, "Older Adults' Experience," 1–12.

[186] Xiang, "Layperson-Supported, Web-Delivered," e53001.

[187] Mason, "Testing Mechanisms of Change," e45186.

[188] DarioHealth, "Dario Expands Behavioral Health Offerings to Include a Provider Network Through Strategic Arrangement with Rula," March 7, 2025. https://dariohealth.investorroom.com/2025-03-07-Dario-Expands-Behavioral-Health-Offerings-to-Include-a-Provider-Network-Through-Strategic-Arrangement-with-Rula

[189] Stoeckl, "Race-Based Differences," 13–16.

[190] Ward, B. Haley, "Assessing the Effects of a Digital Mental Health Intervention in Older Adults with Real-World User Data." In Proceedings of the Anxiety and Depression Conference, Denver, CO, 2022.

[191] Fundoiano-Hershcovitz, Yifat, Inbar Breuer Asher, Marilyn D. Ritholz, et al., "Specifying the Efficacy of Digital Therapeutic Tools for Depression and Anxiety: Retrospective, 2-Cohort, Real-World Analysis," *Journal of Medical Internet Research* 25 (2023): e47350. https://doi.org/10.2196/47350

[192] Sharif-Sidi, "Addressing Depression and," 100521.

[193] Horwitz, "Comparative Effectiveness of," e2422115.

[194] Carl, Jenna R., Christopher B. Miller, Alasdair L. Henry, et al., "Efficacy of Digital Cognitive Behavioral Therapy for Moderate-to-Severe Symptoms of Generalized Anxiety Disorder: A Randomized Controlled Trial," *Depression and Anxiety* 37, no. 12 (2020): 1168–1178. https://doi.org/10.1002/da.23079

[195] Wong, Eileen Y., Nishat Bhuiyan, Alasdair L. Henry, et al., "Domains of Impairment in GAD: Improvements in Patient Generated Concerns After Digital CBT," poster presented at the Society for Digital Mental Health Annual Meeting, virtual, June 20–21, 2023.

[196] FDA, K233872, (Daylight, Big Health), U.S Food & Drug Administration letter of response to Big Health, Inc. 510(k) premarket notification of intent for Daylight, August 1, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233872.pdf

[197] Iacoviello, "A Randomized Controlled," 21.

[198] Rothman, "A Prescription Digital."

[199] Cochran, "CT-152, a Prescription Digital Therapeutic."

[200] Cochran, Jeffrey, Jessica Ash, Zhen Zhang, et al., "Emotional Faces Memory Task Performance and Clinical Outcomes for the Novel Prescription Digital Therapeutic, CT-152," poster presented at Psych Congress Annual Meeting, Boston, MA, October 29–November 2, 2024.

[201] Forman-Hoffman, "Therapist-Supported Digital," 494–501.

[202] Wright, "Effect of Computer-Assisted," e2146716.

[203] Mohr, David C., Emily G. Lattie, Kathryn Noth Tomasino, et al., "A Randomized Noninferiority Trial Evaluating Remotely-Delivered Stepped Care for Depression Using Internet Cognitive Behavioral Therapy (CBT) and Telephone CBT," *Behaviour Research and Therapy* 123 (2019): 103485. https://doi.org/10.1016/j.brat.2019.103485

[204] Nelson, Benjamin W., Nicholas C. Peiper, and Valerie L. Forman-Hoffman, "Digital Mental Health Interventions as Stand-Alone vs. Augmented Treatment as Usual," *BMC Public Health* 24, no. 1 (2024): 969. https://doi.org/10.1186/s12889-024-18412-1

[205] Alfaro, "Determinants and Outcome," 509–521.

[206] Espel-Huynh, Hallie M., Lu Wang, Emily G. Lattie, et al., "Clinical Effects of Asynchronous Provider-Guided Practice Sessions During Blended Care Therapy for Anxiety and Depression: Pragmatic Retrospective Cohort Study," *Journal of Medical Internet Research* 26 (2024): e60502. https://doi.org/10.2196/60502

[207] Gould, "Effects of Mobile," e25808.

[208] Wright, "Effect of Computer-Assisted," e2146716.

[209] Renn, "Naturalistic Use of," 429–438.

[210] Renn, "Naturalistic Use of," 429–438.

[211] Moberg, Christine, Andrea Niles, and Dale Beermann, "Guided Self-Help Works: Randomized Waitlist Controlled Trial of Pacifica, a Mobile App Integrating Cognitive Behavioral Therapy and Mindfulness for Stress, Anxiety, and Depression," *Journal of Medical Internet Research* 21, no. 6 (2019): e12556. https://doi.org/10.2196/12556

[212] Renn, Brenna, Teresa Walker, Matthew Schurr, et al., "Preliminary Testing of a Digital Mental Health Intervention for Depression and Anxiety," poster presented at the ADAA Annual Conference, Denver, CO, March 17–20, 2022.

[213] Anton, Margaret T., Heidi Mochari Greenberger, Evie Andreopoulos, et al., "Evaluation of a Commercial Mobile Health App for Depression and Anxiety (AbleTo Digital+): Retrospective Cohort Study," *JMIR Formative Research* 5, no. 9 (2021): e27570. https://doi.org/10.2196/27570

[214] Anton, P. Margaret, "Prevalence and Change in Work Productivity and Activity Impairment among Employed U.S. Adults Completing A Cognitive Behavioral Telehealth Treatment for Depression and Anxiety." In Proceedings of the Anxiety and Depression Conference, Denver, CO, 2022.

[215] Belanger, "Do Older Adults," 998401.

[216] Belanger, "Exploring Social Determinants," 1026361.

[217] Abbott, "Does Using a," 26–42.

[218] Horwitz, "Comparative Effectiveness of," e2422115.

[219] Kunkle, Sarah, Manny Yip, and Justin Hunt, "Evaluation of an On-Demand Mental Health System for Depression Symptoms: Retrospective Observational Study," *Journal of Medical Internet Research* 22, no. 6 (2020): e17902. https://doi.org/10.2196/17902

[220] Kunkle, Sarah, Manny Yip, Justin Hunt, et al., "Association Between Care Utilization and Anxiety Outcomes in an On-Demand Mental Health System: Retrospective Observational Study," *JMIR Formative Research* 5, no. 1 (2021): e24662. https://doi.org/10.2196/24662

[221] Shih, Emily, Brandon S. Aylward, Sarah Kunkle, et al., "Health-Related Quality of Life Among Members Using an On-Demand Behavioral Health Platform: Pilot Observational Study," *JMIR Formative Research* 6, no. 7 (2022): e35352. https://doi.org/10.2196/35352

[222] Shih, Emily, Brandon S. Aylward, Sarah Kunkle, et al., "Association Between Care Modality and Use with Treatment Response Among Members Accessing Virtual Mental Health Services: Real-World Observational Study," *JMIR Formative Research* 6, no. 7 (2022): e36956. https://doi.org/10.2196/36956

[223] Shih, "Association Between Care," e36956.

[224] Wilhelm, "Feasibility, Acceptability, and," e53998.

[225] Owusu, "Real-World Evaluation," 1412–1420.

[226] Lungu, Anita, Janie Jihee Jun, Okhtay Azarmanesh, et al., "Blended Care-Cognitive Behavioral Therapy for Depression and Anxiety in Real-World Settings: Pragmatic Retrospective Study," *Journal of Medical Internet Research* 22, no. 7 (2020): e18723. https://doi.org/10.2196/18723

[227] Owusu, "Outcomes of a Live Messaging," e44138.

[228] Das, Smita, Jane Wang, Shih-Yin Chen, et al., "Telemental Health Collaborative Care Medication Management: Implementation and Outcomes," *Telemedicine and e-Health* 28, no. 7 (2022): 1035–1043. https://doi.org/10.1089/tmj.2021.0401

[229] Lee, "Clinical Outcomes from," 100798.

[230] Wu, Monica S., Robert E. Wickham, Shih-Yin Chen, et al., "A Large-Scale Evaluation of Therapeutic Alliance and Symptom Trajectories of Depression and Anxiety in Blended Care Therapy," *PLOS One* 19, no. 11 (2024): e0313112. https://doi.org/10.1371/journal.pone.0313112

[231] Owusu, "Blended Care Therapy," 2731–2743.

[232] Lungu, Anita, Robert E. Wickham, Shih-Yin Chen, et al., "Component Analysis of a Synchronous and Asynchronous Blended Care CBT Intervention for Symptoms of Depression and Anxiety: Pragmatic Retrospective Study," *Internet Interventions* 28 (2022): 100536. https://doi.org/10.1016/j.invent.2022.100536

[233] Espel-Huynh, "Clinical Effects of," e60502.

[234] Wu, "Outcomes of a Blended Care," e32100.

[235] Wu, Monica S., Shih-Yin Chen, Robert E. Wickham, et al., "Predicting Non-Initiation of Care and Dropout in a Blended Care CBT Intervention: Impact of Early Digital Engagement, Sociodemographic, and Clinical Factors," *Digital Health* 8 (2022). https://doi.org/10.1177/20552076221133760

[236] Wu, "Examining the Impact," e33452.

[237] Grasso, "Examining Changes in," 253–266.

[238] Lungu, "Component Analysis of," 100536.

[239] Espel-Huynh, "Clinical Effects of," e60502.

[240] Espel-Huynh, "Clinical Effects of," e60502.

[241] Forman-Hoffman, "Therapist-Supported Digital," 494–501.

[242] Nelson, "Digital Mental Health," 969.

[243] Economides, Marcos, Paul Lehrer, Kristian Ranta, et al., "Feasibility and Efficacy of the Addition of Heart Rate Variability Biofeedback to a Remote Digital Health Intervention for Depression," *Applied Psychophysiology and Biofeedback* 45 (2020): 75–86. https://doi.org/10.1007/s10484-020-09458-z

[244] Alfaro, "Determinants and Outcome," 509–521

[245] Aschbacher, Kirstin, Luisa M. Rivera, Silvan Hornstein, et al., "Longitudinal Patterns of Engagement and Clinical Outcomes: Results from a Therapist-Supported Digital Mental Health Intervention," *Psychosomatic Medicine* 85, no. 7 (2023): 651–658. https://doi.org/10.1097/psy.0000000000001230

[246] Economides, Marcos, Kristian Ranta, Albert Nazander, et al., "Long-Term Outcomes of a Therapist-Supported, Smartphone-Based Intervention for Elevated Symptoms of Depression and Anxiety: Quasiexperimental, Pre-Postintervention Study," *JMIR mHealth and uHealth* 7, no. 8 (2019): e14284. https://doi.org/10.2196/14284

[247] Nelson, Benjamin W., Nicholas C. Peiper, Kirstin Aschbacher, et al., "Evidence-Based Therapist-Supported Digital Mental Health Intervention for Patients Experiencing Medical Multimorbidity: A Retrospective Cohort Intent-to-Treat Study," *Psychosomatic Medicine* 86, no. 6 (2024): 547–554. https://doi.org/10.1097/psy.0000000000001319

[248] Peiper, Nicholas C., Benjamin W. Nelson, Kirstin Aschbacher, et al., "Trajectories of Depression Symptoms in a Therapist-Supported Digital Mental Health Intervention: A Repeated Measures Latent Profile Analysis," *Social Psychiatry and Psychiatric Epidemiology* 58, no. 8 (2023): 1237–1246. https://doi.org/10.1007/s00127-022-02402-y

[249] Forman-Hoffman, Valerie L., Benjamin W. Nelson, Kristian Ranta, et al., "Significant Reduction in Depressive Symptoms Among Patients with Moderately-Severe to Severe Depressive Symptoms After Participation in a Therapist-Supported, Evidence-Based Mobile Health Program Delivered via a Smartphone App," *Internet Interventions* 25 (2021): 100408. https://doi.org/10.1016/j.invent.2021.100408

[250] Gould, "Effects of Mobile," e25808.

[251] Gould, "Changes in Quality," 746904.

[252] Hornstein, Silvan, Valerie Forman-Hoffman, Albert Nazander, et al., "Predicting Therapy Outcome in a Digital Mental Health Intervention for Depression and Anxiety: A Machine Learning Approach," *Digital Health* 7 (2021): 20552076211060659. https://doi.org/10.1177/20552076211060659

[253] Pettitt, Adam K., Benjamin W. Nelson, Valerie L. Forman-Hoffman, et al., "Longitudinal Outcomes of a Therapist-Supported Digital Mental Health Intervention for Depression and Anxiety Symptoms: A Retrospective Cohort Study," *Psychology and Psychotherapy: Theory, Research and Practice* 97, no. 2 (2024): 288–300. https://doi.org/10.1111/papt.12517

[254] Alfaro, "Determinants and Outcome," 509–521.

[255] Gould, "Effects of Mobile," e25808.

[256] Alfaro, "Determinants and Outcome," 509–521.

[257] Roos, Lydia G., Sara J. Sagui-Henson, Cynthia Castro Sweet, et al., "Improvement and Maintenance of Clinical Outcomes in a Digital Mental Health Platform: Findings from a Longitudinal Observational Real-World Study," *JMIR mHealth and uHealth* 12 (2024): e48298. https://doi.org/10.2196/48298

[258] Roos, L., S. Sagui-Henson, C. Castro Sweet, et al., "Review of Engagement and Clinical Outcomes of a Digital Mental Health Benefit," *Psychosomatic Medicine* 85, no. 4 (2023): A153.

[259] Prescott, Maximo R., Sara J. Sagui-Henson, Camille E. Welcome Chamberlain, et al., "Real World Effectiveness of Digital Mental Health Services During the COVID-19 Pandemic," *PLOS One* 17, no. 8 (2022): e0272162. https://doi.org/10.1371/journal.pone.0272162

[260] Nowels, "Predictors of Engagement," e48696.

[261] Nowels, Molly, Danielle H. Llaneza, Lilla Brody, et al., "Engaging with One-on-One Modalities Increases Digital mHealth Resource Engagement: A Prospective Longitudinal Study," presentation at the Society for Digital Mental Health Annual Meeting, virtual, June 20–21, 2023.

[262] Nowels, "Predictors of Engagement," e48696.

[263] Sagui Henson, "Utilization, Satisfaction, and Clinical," 1660.

[264] Sagui-Henson, Sara J., Welcome Chamberlain, Camille E., Smith, Brooke J., et al., "Equity in Digital Mental Health Services: Race and Ethnic Comparisons of Engagement and Effectiveness," presentation at the 44th Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine, Phoenix, AZ, April 26–29, 2023.

[265] Bondar, Julia, Cecina Babich Morrow, Ralitza Gueorguieva, et al., "Clinical and Financial Outcomes Associated with a Workplace Mental Health Program Before and During the COVID-19 Pandemic," *JAMA Network Open* 5, no. 6 (2022): e2216349. https://doi.org/10.1001/jamanetworkopen.2022.16349

[266] Song, "Comparing Message-Based," e46052.

[267] Areán, "Randomized Trial of," 1184–1191.

[268] Song, "Comparing Message-Based," e46052.

[269] Areán, "Randomized Trial of," 1184–1191.

[270] Areán, "Randomized Trial of," 1184–1191.

[271] Griffith Fillipo, Isabell R., Michael D. Pullmann, Thomas D. Hull, et al., "Participant Retention in a Fully Remote Trial of Digital Psychotherapy: Comparison of Incentive Types," *Frontiers in Digital Health* 4 (2022): 963741. https://doi.org/10.3389/fdgth.2022.963741

[272] Raue, "Message-Based Psychotherapy," 951354.

[273] DellaCrosse, Meghan, Kush Mahan, and Thomas D. Hull, "The Effect of Messaging Therapy for Depression and Anxiety on Employee Productivity," *Journal of Technology in Behavioral Science* 4 (2019): 1–5. https://doi.org/10.1007/s41347-018-0064-4

[274] Nitzburg, "Patterns of Utilization," 247–259.

[275] Choudhary, Varun, "Is Everyone Really Anxious and Depressed?: A Closer Look at Managing Mental Health," *Journal of General Internal Medicine* 38 (2023): S682. https://doi.org/10.1007/s11606-023-08226-z

[276] Hull, Thomas D., Matteo Malgaroli, Philippa S. Connolly, et al., "Two-Way Messaging Therapy for Depression and Anxiety: Longitudinal Response Trajectories." *BMC Psychiatry* 20 (2020): 1–12. https://doi.org/10.1186/s12888-020-02721-x

[277] Darnell, Doyanne, Michael D. Pullmann, Thomas D. Hull, et al., "Predictors of Disengagement and Symptom Improvement Among Adults with Depression Enrolled in Talkspace, a Technology-Mediated Psychotherapy Platform: Naturalistic Observational Study," *JMIR Formative Research* 6, no. 6 (2022): e36521. https://doi.org/10.2196/36521

[278] DellaCrosse, "The Effect of Messaging," 1–5.

[279] Hull, "Two-Way Messaging," 1–12.

[280] Darnell, "Predictors of Disengagement," e36521.

[281] Nitzburg, "Patterns of Utilization," 247–259.

[282] Dzubur, "The Effect of a Digital," e36596.

[283] NORC, "National Safety Council and NORC at the University of Chicago Announce Results from Mental Health in the Workplace Poll," May 31, 2023. https://www.norc.org/research/library/national-safety-council-and-norc-at-the-university-of-chicago-an.html

[284] Claxton, Gary, Krutika Amin, and Cynthia Cox, "Privately Insured People with Depression and Anxiety Face High Out-of-Pocket Costs," Peterson-KFF Health System Tracker, March 4, 2024. https://www.healthsystemtracker.org/brief/privately-insured-people-with-depression-and-anxiety-face-high-out-of-pocket-costs/

[285] Claxton, "Privately Insured People."

[286] U.S. Census Bureau, "Age and Sex Composition in the United States: 2022," accessed April 7, 2025. https://www.census.gov/data/tables/2022/demo/age-and-sex/2022-age-sex-composition.html

[287] Centers for Disease Control and Prevention, "Mental Health—Household Pulse Survey," accessed April 7, 2025. https://www.cdc.gov/nchs/covid19/pulse/mental-health.htm

[288] ADAA, "What is Depression?" accessed April 7, 2025. https://adaa.org/understanding-anxiety/depression

[289] ADAA, "Anxiety Disorder Facts & Statistics," accessed April 7, 2025. https://adaa.org/understanding-anxiety/facts-statistics

[290] Weisberg, Risa B., Courtney Beard, Ethan Moitra, et al., "Adequacy of Treatment Received by Primary Care Patients with Anxiety Disorders," *Depression and Anxiety* 31, no. 5 (2014): 443–450. https://doi.org/10.1002/da.22209

[291] Schneider, Renee A., Joseph R. Grasso, Shih Yin Chen, et al., "Beyond the Lab: Empirically Supported Treatments in the Real World," *Frontiers in Psychology* 11 (2020): 1969. https://doi.org/10.3389/fpsyg.2020.01969

[292] Centers for Medicare & Medicaid Services (CMS), "Physician Fee Schedule Search," accessed April 7, 2024. https://www.cms.gov/medicare/physician-fee-schedule/search

[293] Zhu, Jane M., Stephanie Renfro, Kelsey Watson, et al., "Medicaid Reimbursement for Psychiatric Services: Comparisons Across States and with Medicare," *Health Affairs* 42, no. 4 (2023): 556–565. https://doi.org/10.1377/hlthaff.2022.00805

[294] Pelech, Daria, and Tamara Hayford, "Medicare Advantage and Commercial Prices for Mental Health Services," *Health Affairs* 38, no. 2 (2019): 262–267. https://doi.org/10.1377/hlthaff.2018.05226

[295] Culpepper, "The Humanistic and Economic," 1860–1884.

[296] Kavelaars, "The Burden of Anxiety," 81–91.

[297] Federal Reserve Bank of St. Louis, "Consumer Price Index for All Urban Consumers: Medical Care in U.S. City Average," accessed February 2025. https://fred.stlouisfed.org/series/CUUS0000SAM

[298] Congressional Budget Office, "The Prices that Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services," accessed April 7, 2025. https://www.cbo.gov/publication/57778

[299] Commonwealth Fund, "COVID-19's Impact on Older Workers: Employment, Income, and Medicare Spending," accessed April 7, 2025. https://www.commonwealthfund.org/sites/default/files/2020-10/Jacobson_COVID_impact_older_workers_ib_v3.pdf

[300] CMS, "HHS Proposes Physician Payment Rule to Drive Whole-Person Care and Improve Health Quality for All Individuals with Medicare," accessed April 7, 2025. https://www.cms.gov/newsroom/press-releases/hhs-proposes-physician-payment-rule-drive-whole-person-care-and-improve-health-quality-all

[301] Salsabili, Mahsa, Mark Tesell, Matthew Alcusky, et al., "Prescription Digital Therapeutics: Applying Medicaid Experience to Value Assessment and Formulary Management," *Journal of Managed Care & Specialty Pharmacy* 29, no. 6 (2023): 685–691. https://doi.org/10.18553/jmcp.2023.29.6.685

[302] Federal Register, "Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments," accessed April 7, 2025. https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other

[303] Rejoyn, "Frequently Asked Questions," accessed April 7, 2025. https://www.rejoyn.com/faqs

[304] Big Health, "Try Daylight," accessed April 7, 2025. https://www.bighealth.com/trydaylight

[305] Alfaro, "Determinants and Outcome," 509–521.

[306] Espel-Huynh et al., "Clinical Effects of," e60502.

[307] Gould, "Effects of Mobile," e25808.

[308] Wright, "Effect of Computer-Assisted," e2146716.

[309] Attridge, Mark, "Workplace Outcome Suite© (WOS) EAP Industry Global Report No. 6: Use and Effectiveness for Over 140,000 Counseling Cases from 2010 to 2022." TELUS Health & Employee Assistance Professionals Association, August 1, 2024. https://www.researchgate.net/publication/381879302_Workplace_Outcome_SuiteC_WOS_EAP_Industry_Global_Report_No_6_Use_and_Effectiveness_for_Over_140000_Counseling_Cases_from_2010_to_2022

[310] SHRM, "Companies Seek to Boost Low Usage of Employee Assistance Programs," accessed April 17, 2025. https://www.shrm.org/topics-tools/news/hr-magazine/companies-seek-to-boost-low-usage-employee-assistance-programs#:~:text=EAPs%20have%20remained%20in%20employers,can%20go%20up%20to%20%242

[311] Culpepper, "The Humanistic and Economic," 1860–1884.

[312] Kavelaars, "The Burden of Anxiety," 81–91.

[313] Zhu, Jane M., Aine Huntington, Simon Haeder, et al., "Insurance Acceptance and Cash Pay Rates for Psychotherapy in the US," *Health Affairs Scholar* 2, no. 9 (2024): qxae110. https://doi.org/10.1093/haschl/qxae110

[314] Darden, Michael, Jenna R. Carl, Jasper A.J. Smits, et al., "Cost-Effectiveness of Automated Digital CBT (Daylight) for Generalized Anxiety Disorder: A Markov Simulation Model in the United States," *PLOS Mental Health* 1, no. 3 (2024): e0000116. https://doi.org/10.1371/journal.pmen.0000116

[315] Rejoyn, "Frequently Asked Questions."

[316] Accorded, "Headspace Care Cost Impact Report," 2022. https://5327495.fs1.hubspotusercontent-na1.net/hubfs/5327495/Headspace-Care-Cost-Impact-Analysis.pdf

[317] Aon, "Lyra Health Cost Efficiency Analysis: The Impact of Lyra EAP Services on Employer Medical Plan Spend in 2018 and 2019," September 2021.

[318] Aon, "Lyra Health Claims Behavioral Cost Impact of Behavioral Health Services 2021 Cost Efficiency Measurement," July 2024. https://cdn.intelligencebank.com/us/share/d23K/AE0L1/OBWJ3/original/Aon-Report-Claims-Cost-Impact-of-Behavioral-Health Services?mkt_tok=MzU5LUdRUi01MDIAAAGZAKWAqMaNCK Gh-R4akFSqaiu8E-qygEgwDGxeNq8A7E4Z_tVfPg0il1oAen4Kt98yx TTbEuGc6hfEXSQQV-GAS6u9bZZWfETQ-96BWl74BqK3eg

[319] Aon, "Lyra Health Claims Cost Impact of Behavioral Health Services 2018–2021 Cost Efficiency Measurement," May 2024. https://cdn.intelligencebank.com/us/share/d23K/AE0L1/RYpOW/original/MDC-6160-Aon-Report?mkt_tok=MzU5LUdRUi01MDI AAAGZAKR2QfdRT7SNhvAV80vFkhQs_u1icJ8G3LPD_McNxLk UnAFfBvgmS26KWLvjuXj4S1WkGRdRTUenvjmhdW3oMovyuqo HYkjx4HzsGRMgfmaUA

[320] Meru Health, "Meru Health Works with Stanford and Harvard to Provide Significant Clinical Results and Cost Savings," June 15, 2020. https://get.meruhealth.com/wp-content/uploads/2022/10/MeruHealthCostSavingsWhitepaper.pdf

[321] Prescott, "Real World Effectiveness," e0272162.

[322] Hawrilenko, Matt, Casey Smolka, Emily Ward, et al., "Return on Investment of Enhanced Behavioral Health Services," *JAMA Network Open* 8, no. 2 (2025): e2457834. https://doi.org/10.1001/jamanetworkopen.2024.57834

[323] Validation Institute, "2023 Validation Report Review for: Spring Health," 2023. https://8056012.fs1.hubspotusercontent-na1.net/hubfs/8056012/Spring_Health_Savings_Final_2023.pdf

[324] Hawrilenko, "Return on Investment," e2457834.

[325] Validation Institute, "2024 Validation Institute Review for: Spring Health," 2024.

[326] Hawrilenko, "Return on Investment," e2457834.

[327] Santa Barbara Actuaries, "Analysis of Spring Health's Impact on Health Plan Claims Costs," June 2022. https://lp.springhealth.com/hubfs/SBA-Spring%20White%20Paper%20Claims%20Costs%20FINAL%20JUN%2010%202022%20(3).pdf

[328] Bondar, "Clinical and Financial," e2216349.

[329] Validation Institute, "2024 Validation Report Review for: Talkspace," 2024. https://b2b.talkspace.com/hubfs/Content/Reports/Talkspace%20ROI%20Calculator%20-%20Certified%20by%20the%20Validation%20Institute.pdf?hsCtaTracking=dd4dbee5-d71d-4ae4-92e6-20a2ee67a3a3%7C2a5d1e07-baf0-4c11-8ba8-7e688dff9e98

[330] Abhulimen, Sese, and Abigail Hirsch, "Quantifying the Economic Impact of a Digital Self-Care Behavioral Health Platform on Missouri Medicaid Expenditures," *Journal of Medical Economics* 21, no. 11 (2018): 1084–1090. https://doi.org/10.1080/13696998.2018.1510834

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