Woebot Health is the single most mentioned digital therapeutics company in the peer-reviewed scientific literature today.
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Peer-reviewed scientific publications

Chatbot-Delivered Cognitive Behavioral Therapy in Adolescents With Depression and Anxiety During the COVID-19 Pandemic: Feasibility and Acceptability Study

Collaborator: Washington University (WashU)

Key points:
- This paper reports on the results of a pilot study investigating the acceptability and effectiveness of W-GenZD + standard of care, compared to standard of care alone.

Synopsis: Depression, anxiety and related suicidal ideation and self-harm are common among adolescents, and have increased in prevalence and severity during the pandemic to crisis levels, exacerbated by the long-standing workforce shortage of child mental health professionals. As a result, primary care providers are often called on to provide first-line care for these youth. Digital health interventions extend mental health specialty care to youth with moderately severe symptoms, but few are evidence-based. This manuscript evaluated the feasibility of delivering the W-GenZD to adolescents (N=17) ages 13-17 years with moderate depressive symptoms treated in ambulatory pediatric primary care clinical settings between October 2020 and October 2021. In addition to obtaining preliminary estimates of acceptability, effectiveness and use of the app. The study demonstrated the feasibility, acceptability, usability and safety of using a CBT-based chatbot for adolescents presenting with moderate depressive symptoms in a network of PBRN-based primary care clinics. Given the small nature of the pilot study, effectiveness could not be established but results suggest further study in a larger pediatric population is warranted. Future studies should encompass diverse clinical environments, such as those located in rural, socio-economically disadvantaged and underrepresented communities.

Disclaimer: W-GenZD is not yet available and has not yet been cleared/approved or evaluated by FDA

Anatomy of a Woebot® (WB001): Agent Guided CBT for Women with Postpartum Depression

Key points:

- This is the first description of a CBT-based digital therapeutic in the Expert Review of Medical Devices describing the scientific and clinical rationale behind Woebot for postpartum depression.
- Woebot leverages clinical experience, user-centered design practices and artificial intelligence (AI) to create a product one reviewer called a potential watershed moment in how psychological interventions are delivered.

Synopsis: This report is the first description of a CBT-based digital therapeutic in the Expert Review of Medical Devices and describes the scientific and clinical rationale behind how Woebot approaches postpartum depression (PPD). The Expert Opinion details the challenges faced by women experiencing PPD who face a lack of screening, support or therapy at one of the most challenging times in their lives. Woebots agent-guided CBT leverages the experience of a team of clinical psychologists, psychiatrists, and licensed therapists, and combines that with user-centered design practices and artificial intelligence (AI) to create a product that one peer reviewer felt could be a watershed moment in how psychological interventions are delivered.

Disclaimer: WB001 is not yet available and has not yet been cleared/approved or evaluated by FDA


Associations Between Substance Use Problems and Stress During COVID-19

Collaborator: Stanford University School of Medicine

Key points:

- Data from a Randomized Controlled Trial of Woebot for Substance Use Disorder (W-SUD) (N=180; % women) indicated that worsened mental health symptoms during the Covid-19 pandemic were associated with more substance use as well as depression and anxiety symptoms.

Synopsis: The COVID-19 pandemic has produced major life disruptions and increased stress. This manuscript explored the associations between pandemic-related stress and substance use problems among a sample of individuals participating in an RCT evaluating Woebot for Substance Use Disorders.
Participants who struggled with responsibilities at home, had greater mental health impacts, greater personal growth, and frequented bars or large gatherings had higher scores on the Short Inventory of Problems for Alcohol and Drugs scores (all p-values <.05). Participants who struggled with responsibilities at home, had difficulty getting necessities, had greater mental health impacts, and worried more about their children had higher GAD-7 and PHQ-8 scores (all p-values <.05). Additionally, participants who lost a job or income during the pandemic had higher PHQ-8 scores (p-values <.015). In multivariable analyses, greater mental health impacts were associated with higher SIP-AD, PHQ-8 and GAD-scores (all p-values <.0). The study concluded that experiencing worsened mental health symptoms during COVID-19 was associated with more substance use problems and depression & anxiety symptoms. Pandemic disruptions may exacerbate pre-existing substance use problems.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA

Citation: Vogel EA, Chieng AC, Robinson A, Pajarito S, Prochaska JI. (2021). Associations Between Substance Use Problems and Stress During COVID-19. Journal of Studies on Alcohol and Drugs

A Randomized Controlled Trial of a Therapeutic Relational Agent for Reducing Substance Misuse during the COVID-19 Pandemic

Collaborator: Stanford University School of Medicine

Key points:
- In a randomized clinical trial, use of Woebot-SUD (W-SUD) for 8 weeks resulted in significant reductions in substance use compared with waitlist control.
- Reduction in substance use was associated with better outcomes, including improved mental health.
- Participants who completed high school had the highest overall satisfaction scores and scores on the WAI-SR total scale as compared to participants with college degrees.

Synopsis: This randomized trial compared Woebot-SUDs (W-SUDs) to a waitlist control, for reducing problematic substance use during the pandemic. US adults (N=180, age M=40, 65% female, 68% non-Hispanic white) who screened positive for substance use (CAGE-AID>1) participated. Relative to the waitlist control, the treatment group significantly reduced past-month substance use occasions (p <.05) and increased confidence in navigating high-risk situations (p <.05). Treatment group improvements in substance use, confidence and cravings were correlated with improvements in substance-related problems and depressive symptoms. Satisfaction with WB-SUD was high, with 96% of lessons rated positively, and 82% of participants indicating that they would recommend W-SUDs.

Disclaimer: W-SUD is not yet available and has not been cleared/approved or evaluated by FDA
Evidence of Human-level Bond Established with a Digital Conversational Agent: An Observational Study

Key points:

- The bond that Woebot formed with users, who ranged in age from 18-78 years old, appeared to be non-inferior to the bond created between human therapists & patients.
- The bond is established quickly, in just 3-5 days.
- The bond does not appear to diminish over time.

Synopsis: This cross-sectional, retrospective study of 36,070 users who self-referred to Woebot investigated whether the conversational agent resulted in similar levels of working alliance or bond as other CBT modalities. Bond was measured by the Working Alliance Inventory-Short Revised (WAI-SR), and depression was assessed using the 2-item Patient Health Questionnaire (PHQ-2). WAI-SR scores were compared to scientific literature abstracted from recent reviews. Participants ranged in age from 18 to 78 years and 57% reported female gender. Mean PHQ-2 score was 3.03 (SD 1.79) with 55% scoring over the cutoff score of 3 for depression screening. Within 5 days of initial app use, mean WAI-SR score was 3.36 (SD 0.8) with a mean Bond subscale score of 3.8 (SD 1.0) comparing favorably with recent studies from the literature of traditional outpatient individual CBT and group CBT (mean Bond subscale 4 and 3.8, respectively). PHQ-2 scores at baseline were negatively correlated with bond ($r = -0.04$, $p < 0.001$) however, this difference was minimal, with mean scores for all groups above the threshold for high (3.45). Often presumed to be the exclusive domain of human therapeutic relationships, the findings challenge the notion that digital therapeutics are incapable of establishing a therapeutic bond with users. Future research will investigate the role of therapeutic bond as a mediator of clinical outcomes, since boosting engagement and efficacy of digital therapeutics could have major public health benefits.

Disclaimer: This version of Woebot is a non-prescription product that is not meant to diagnose, treat, or prevent any disease. It is regulated under enforcement discretion which means that the FDA does not evaluate, clear or approve these products.

Citation: Darcy, A, Daniels, J, Salinger, D, Wicks, P, Robinson, A. Evidence of Human-level Bond Established with a Digital Conversational Agent: An Observational Study. Journal of Medical Internet Research: Formative Research. Doi: 10.2196/27868
A Therapeutic Relational Agent for Reducing Problematic Substance Use (Woebot): Development and Usability Study

Collaborator: Stanford University School of Medicine

Key points:

- During the 8 week study, substance use occasions were reduced by 30% cravings decreased by 50% and confidence to resist urges to use a substance increased 36%.
- Study participants also reported a 21% reduction in symptoms of depression and a 23% reduction in anxiety symptoms.
- Participants demonstrated high scores for Bond on a scale of therapeutic alliance, suggesting that it may mediate outcomes.

Synopsis: This study evaluated the feasibility, acceptability and preliminary efficacy of Woebot adapted for Substance use Disorders (W-SUDs). These adaptations included tracking craving, mood and new content informed by Motivational Interviewing and Dialectical Behavior Therapy. In a single group pre/post design, 101 participants with an average age of 36.8 years, engaged with W-SUDs for 8 weeks. Participants were predominantly female (75%), non-Hispanic white (78%) and employed (72%). About 94% of completed modules were rated positively. Study attrition was relatively high, with about half of participants completing the post-treatment assessment. From pre- to post treatment, confidence to resist urges to use substances significantly increased (mean score change +16.9, SD 21.4; p<.001), whereas past month substance use occasions (mean change -9.3, SD 14.1 p<.001) and scores on the Alcohol Use Disorders Identification Test-Concise (mean change -1.3, SD 21.4; p<.001), 10-item Drug Abuse Screening Test (mean change 1.2, SD 2.0 p<.001), Patient Health Questionnaire-8 item (mean change 2.1, SD 5.2 p=.005), Generalized Anxiety Disorder-7 (mean change 2.3, SD 4.7 p<.001), and cravings scale (68.6% vs 47.1% moderate to extreme p=.01) all significantly decreased. Future research will evaluate W-SUDs in a randomized controlled trial with a more diverse sample and with the use of greater study retention strategies.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA

Delivering Cognitive Behavior Therapy to Young Adults With Symptoms of Depression and Anxiety Using a Fully Automated Conversational Agent (Woebot): A Randomized Controlled Trial

Collaborator: Stanford University School of Medicine, Dept Psychiatry & Behavioral Sciences

Key points:
- Woebot led to a significant reduction in depression symptoms in 2 weeks compared to an active control group.
- The intervention was highly engaging: participants talked to Woebot almost every day.
- Participants appreciated the process (empathy, accountability, etc.) as well as the content (psychoeducation) of the intervention.

Synopsis: This study evaluated the feasibility, acceptability, and preliminary efficacy of Woebot for college students with symptoms of anxiety and depression. 70 participants aged 18-28 (average of 22.2 years old) were randomized to receive either Cognitive Behavioral Therapy delivered through Woebot, a text-based conversational agent (n=34) or to an information-only control group that received an ebook on depression in college students published by the National Institute of Mental Health (n=36). All participants completed standardized measures of Depression (Patient Health Questionnaire PHQ-9), and Anxiety (Generalized Anxiety Disorder GAD-7) at baseline and 2-3 weeks later. The majority of participants were female (67%), non-Hispanic (93%) and Caucasian (79%). There were no significant differences between the groups at baseline, and 83% of participants provided follow-up data. Those in the Woebot group significantly reduced their symptoms of depression as measured by the PHQ-9, while those in the information-only control group did not (F=6.47; p=.01). Participants in both groups significantly reduced anxiety as measured by the GAD-7 (F= 9.24; p=.004). This study demonstrated that Woebot is a feasible, engaging, and effective way to deliver CBT.

Disclaimer: This version of Woebot is a non-prescription product that is not meant to diagnose, treat, or prevent any disease. It is regulated under enforcement discretion which means that the FDA does not evaluate, clear or approve these products.

Citation: Fitzpatrick KK, Darcy A, Vierhile M. Delivering Cognitive Behavior Therapy to Young Adults With Symptoms of Depression and Anxiety Using a Fully Automated Conversational Agent (Woebot): A Randomized Controlled Trial. (2017) JMIR Mental Health 4(2). doi: 10.2196/mental.7785.
A Relational Agent Intervention for Adolescents Seeking Mental Health Treatment: Protocol for a Randomized Controlled Feasibility Study

**Collaborator:** Children’s Hospital of The King’s Daughters (CHKD)

**Key points:**

- This manuscript describes the protocol for a randomized controlled trial evaluating the feasibility and acceptability of an investigational device, Woebot for Adolescents (W-GenZD), within an outpatient MH clinic for youth presenting with depression and/or anxiety.

**Synopsis:** Unmet pediatric mental health (MH) needs are growing as rates of pediatric depression and anxiety dramatically increase. Access to care is limited by multiple factors, including a shortage of clinicians trained in developmentally specific, evidence-based services. Novel approaches to MH care delivery, including technology-leveraged and readily accessible options, need to be evaluated in service of expanding evidence-based services to youths and their families. Preliminary evidence supports the use of Woebot, a relational agent that digitally delivers guided cognitive behavioral therapy (CBT) through a mobile app, for adults with MH concerns. However, no studies have evaluated the feasibility and acceptability of such app-delivered relational agents specifically for adolescents with depression and/or anxiety within an outpatient MH clinic, nor compared them to other MH support services. This paper describes the protocol for a randomized controlled trial evaluating the feasibility and acceptability of an investigational device, Woebot for Adolescents (W-GenZD), within an outpatient MH clinic for youths presenting with depression and/or anxiety. The study’s secondary aim will compare the clinical outcomes of self-reported depressive symptoms with W-GenZD and a telehealth-delivered CBT-based skills group (CBT-group). Tertiary aims will evaluate additional clinical outcomes and therapeutic alliance between adolescents in W-GenZD and the CBT-group.

**Disclaimer:** W-GenZD is not yet available and has not yet been cleared/approved or evaluated by FDA

**Citation:** Chiauzzi E, Robinson A, Martin K, Petersen C, Wells N, Williams A, Gleason M M. Manuscript accepted for publication in JMIR Research Protocols
A Relational Agent for Treating Substance Use in Adults: Protocol for a Randomized Controlled Trial with a Psychoeducational Comparator

Synopsis: This paper describes the protocol for a randomized controlled trial investigating the efficacy of W-SUDs relative to a psychoeducation comparator. The study will recruit 400 adults reporting problematic substance use. Following baseline assessment, participants will be randomized to 8 weeks of W-SUDs or a psychoeducational control. Assessments will take place at weeks 4, 8 (EOT), and 12 (1-month post-treatment). Primary outcome is past-month number of substance use occasions, summed across all substances. Secondary outcomes are number of heavy drinking days, the percent of days abstinent from all substances, substance use problems, thoughts about abstinence, cravings, confidence to resist substance use, symptoms of depression and anxiety, and work productivity. If significant group differences are found, we will explore moderators and mediators of treatment effects. The study will build upon emerging evidence of a digital therapeutic for reducing problematic substance use by examining sustained effects and testing against a psychoeducational control condition. If efficacious, the findings have implications for scalable mobile health interventions for reducing problematic substance use.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA


Common Practices for Demographics Data Collection in App-based Psychological Intervention Research: A Scoping Review

Synopsis: The objective of this scoping review is to determine the common practices for collection of demographic information in clinical trials involving app-based psychological interventions. The recent proliferation of app-based psychological intervention research offers hope for improving service accessibility. However, standardization of demographic data collection methods and widely disseminated best practices have lagged behind. This scoping review aims to formally characterize the state of demographic data collection practices in app-based psychological intervention research. A self-published non-peer reviewed pre-registration.

Presentations

Oral Presentations

**Acceptability of Postpartum Mood Management Through a Smartphone-based Automated Conversational Agent**

**Collaborator:** Lucile Packard Children’s Hospital, Stanford University Hospital & Clinics

**Key points:**
- This study evaluated the acceptability of Woebot in a large sample of women who had recently given birth.
- Participants reported high levels of satisfaction and acceptability with the 6-week program.

**Synopsis:** This randomized clinical trial evaluated acceptability and satisfaction with a CBT-based automated conversational agent, Woebot, as a postpartum mood management tool. Women (N=192) were recruited and randomized to the chatbot intervention or treatment as usual during their delivery hospitalization. 60% of women indicated child-bearing women face stigma if they seek anxiety or depression services and 93% reported that anxiety and depression are important to monitor during pregnancy and postpartum. 91% of participants reported satisfaction with the 6-week Woebot program. Such programs should be further examined as a postpartum mental health resource.

**Disclaimer:** This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA


**Feasibility, Acceptability, and Preliminary Efficacy of an Automated Conversational Agent for Reducing Problematic Substance Use**

**Collaborator:** Stanford University School of Medicine

**Key points:**
- Use of Woebot for Substance Use Disorders (W-SUDS), resulted in significant reductions in alcohol use, substance use, depression and anxiety
The majority of users rated the program as helpful and would recommend it to a friend.

Synopsis: This study evaluated a therapeutic relational agent designed to reduce problematic substance use. The 8-week program draws upon evidence-based psychotherapies and provides tracking mood and craving, accessing psychoeducational stories, and learning psychotherapeutic skills. Participants demonstrated significant reductions in alcohol use (AUDIT-C, 7.6±2.1 to 5.6±3.5), drug use, DAST-10 (5.4±1.5 to 3.2±2.6), number of substance use occasions (30±14 to 21±18), and scores on measures of depression (PHQ-8, 10.7±5.4 to 9.0±5.4) and anxiety (GAD-7, 10.4±5.7 to 8.0±5.5). 85% of users rated the program as beneficial and 75% said they would recommend it to a friend. With these encouraging findings, future research will evaluate W-SUDs in an RCT with a more diverse sample and greater study retention strategies.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA

improvements in substance use, confidence and cravings were correlated with improvements in substance-related problems and depressive symptoms.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA


Poster Presentations

Effect of an Automated Conversational Agent on Postpartum Mental Health: A Randomized, Controlled Trial

Collaborator: Department of Obstetrics and Gynecology, Stanford University Hospital & Clinics and Lucille Packards Childrens Hospital

Key points:
- 192 women were randomized to Woebot or treatment-as-usual within 2 hours of giving birth.
- On average, the sample had subclinical scores on baseline measures of postnatal depression.
- Those who had elevated scores demonstrated greater decreases in depression when receiving Woebot relative to treatment-as-usual.

Synopsis: Barriers to postpartum mental health resources include stigma, and limited provider availability and cost. Automated conversational agents can deliver CBT content through text-based conversations, reducing depression and anxiety symptoms in select populations. This randomized clinical trial sought to examine the effect of a mental health chatbot, Woebot, on mood in a general postpartum population. The self-selected sample of 192 women yielded sub-clinical baseline scores, assessed within 72 hours of giving birth, on both the Patient Health Questionnaire and Edinburgh Postnatal Depression Scale. However, among the women with elevated baseline depression scores, trends indicated greater drops in the intervention as compared to the treatment-as-usual group.

Disclaimer: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA
**Associations between COVID-19 Pandemic-Related Stress & Substance Use Problems**

**Collaborator:** Stanford University

**Key points:**
- The COVID-19 pandemic has produced major life disruptions and increased stress.
- Experiencing worsened mental health symptoms during COVID-19 was associated with more substance use problems and depression and anxiety symptoms.
- Pandemic disruptions may exacerbate pre-existing substance use problems.

**Synopsis:** Stress is associated with both substance use and relapse in Substance Use Disorders (SUDs). By understanding how individuals in recovery cope with stress, we can better understand the recovery process and inform treatments for SUDs. Delay discounting is associated with substance use, relapse, and treatment outcomes. Associations between coping and delay discounting have yet to be assessed in individuals in recovery from SUDs.

Disclaimer: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA.


**Feasibility, Acceptability, & Preliminary Efficacy of a Therapeutic Relational Agent for Reducing Substance Misuse**

**Collaborator:** Stanford University

**Key points:**
- In a randomized trial, we tested a tailored digital health solution, Woebot-SUDs (W-SUDs), for reducing problematic substance use during the pandemic.
- W-SUDs was associated with significant reductions in substance use occasions.
- Reduced substance use occasions were associated with improvements in mental health W-SUDs satisfaction was high.
Synopsis: The COVID-19 pandemic disrupted access to treatment for substance use disorders (SUDs), while alcohol and cannabis sales increased. In a randomized trial, we tested a tailored digital health solution, Woebot-SUDs (W-SUDs), for reducing problematic substance use during the pandemic.

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA.


Panel Discussions

Reshaping the Future of Clinical Trials for Digital Therapeutics

Synopsis: Utilizing clinical trials to demonstrate clinical efficacy has been a mainstay within the therapeutic industry for years. However, with the introduction of new digital interventions, these trials are no longer efficient and optimal. This panel, led by the industry experts, will dive into the intricacies of adapting clinical trials specifically for digital therapeutics.

- What are the challenges with current clinical trials for digital therapeutics?
- Where can changes be made within the clinic to develop more efficient trials for DTx?
- An insight into decentralized clinical trials and why many digital therapeutics companies are adopting this as the new normal.
- How do decentralized clinical trials compare to traditional studies?
- What is the future of clinical trials for digital health interventions?

Symposia Presentations

The Potential of Machine Learning and Artificial Intelligence in the Delivery of Cognitive Behavioral Therapy

Synopsis: Machine learning and artificial intelligence are emerging technologies that are increasingly used to evaluate big datasets and collect additional knowledge about an individual's presentation and experience. Technology can quickly detect trends and nuances that might be overlooked by even highly experienced clinicians. Digital tools utilizing machine learning and artificial intelligence are particularly poised to deliver timely summaries of a client's mindset and offer tailored interventions, either facilitated by an expert or a machine. Sophisticated algorithms can help with conceptualizing, assessing, and providing a suite of programs for all levels of care. However, they raise important considerations, including the circumstances in which artificial intelligence can carry out behavioral healthcare tasks as well as or better than humans, implementation challenges that affect large-scale automation of certain aspects of behavioral healthcare, and human-machine interactions in behavioral interventions.

Citation: Darcy A, Daniels J, Salinger D, Wicks P, Robinson A. Digital Therapeutic Alliance: Is Bond with a Relational Conversational Agent Possible? Symposium presented at the annual meeting of the Association for Behavioral and Cognitive Therapies, New Orleans, 2021.
Diversity in Digital Mental Health Interventions

Key points:

- Digital mental health interventions may address the disparity and equity issues that traditionally plague mental health care access.
- An upcoming symposium presenting a collection of abstracts on diversity, equity, inclusion and belonging seeks to highlight the efforts aimed at broadening understanding of health equity research, an essential step in addressing ongoing disparities in mental health care.

Synopsis: Digital mental health interventions have the opportunity to address disparities in mental health care accessibility as well as improve inclusion of members of groups historically underrepresented in biomedical research. They also are poised to address the current state of emergency in mental health needs related to the COVID-19 pandemic, which has exacerbated pre-existing disparities in marginalized populations. This symposium presents a collection of abstracts showcasing research endeavors toward understanding and improving diversity, equity, inclusion and belonging (DEIB) in evidence-based digital mental health intervention research. The symposium will cover topics such as methodological considerations for assessment of participant demographics and self-identity characteristics; recruitment and randomization procedures to ensure participants from marginalized groups are included in study samples; higher baseline levels of clinical symptomatology among sexual and gender minority youth (SGMY) compared to their non-SGMY peers; considerations of evidence-based product content adaptations for marginalized populations; and efforts to teach the current and next generation of health equity researchers.

Health equity research is paramount to acknowledging and addressing ongoing disparities in mental health care. The symposium’s unique combination of clinicians and researchers from industry and academia will highlight diverse perspectives on current DEIB initiatives and future directions for advancing DEIB in the digital mental health field. Together these efforts also aim to address how digital mental health interventions can be used to address cognitive behavioral changes as well as increase resilience in a time highlighted by emergency and disaster.

Citation: Robinson A, Darcy A. Diversity in Digital Mental Health Interventions. Presented at the annual conference of the Association for Behavioral and Cognitive Therapies (ABCT), New York City, November 2022
**Synopsis:** Who are you? This seemingly mundane question may in fact be one of the most complex and nuanced questions asked in a research study. While the recent proliferation of mobile application (app) mental health intervention research has offered hope for reducing service inaccessibility, standardization of demographic data collection methods and widely disseminated best practices have lagged behind. There is the potential for certain under-served or at-risk groups to benefit from mental health apps, but such benefits will never be realized if the self-identity questions we ask at signup are poorly or insensitively worded or signal that the app is an unsafe space. Moreover, the ability to assess efficacy for underrepresented groups via individual trials as well as meta-analysis will be significantly hindered by lack of uniformity in demographic variables, further limiting accurate, reliable, and generalizable inferences.

Currently, few guidelines exist for the collection of such demographic data and no research has been published that assesses the field’s common practices in this area. Our team is performing a systematic literature review (SLR) intended to formally characterize the state of demographic and self-identity data collection in app-delivered mental health intervention research. The SLR will be completed in August 2022, with results ready for presentation in the proposed ABCT symposium.

The SLR search terms were optimized to capture all currently published clinical trial outcome manuscripts involving app-delivered mental health interventions. Following PRISMA guidelines, two independent coders will assess all retrieved citations against a pre-specified set of inclusion and exclusion criteria. Once the final set of included articles is identified, data extraction will be performed by two independent coders. Variables to be extracted were conceptualized with the intent of capturing the breadth of identity categories (e.g., race, ethnicity, gender, age, sexual orientation) that are currently being reported, the frequency each category is reported, common practices for answer choice options, and the degree to which open ended answers are permitted. Once synthesized, the project results will provide a much needed foundation for the future development of demographic data collection standards in app-delivered mental health intervention research.

**Citation:** Kirvin-Quamme A, Robinson A. Common Practices for Demographic and Self-Identity Data Collection in App-Delivered Mental Health Intervention Research: A Systematic Literature Review. Presented at the annual conference of the Association for Behavioral and Cognitive Therapies (ABCT), New York City, November 2022
**RCT of Woebot for Adolescent Depression compared to Digital Psychoeducation: The Headway Study**

**Synopsis:** Depression extends to virtually every facet of an adolescent’s life and, if left un- or undertreated, has profound impacts on current and future functioning. Depression symptoms doubled among youth globally during COVID-19. Sexual and gender minority youth are particularly at risk for depression and may be up to 3 times more likely to experience it compared to their heteronormative peers. Early, successful, and accessible intervention is crucial, yet up to 75% of young people will never get the care they need. Woebot for Adolescent Depression (W-GenZD), is a brief, self-guided intervention that addresses depressive symptoms and draws from cognitive behavioral therapy (CBT), interpersonal psychotherapy (IPT-A) and dialectical behavior therapy (DBT). Delivered through a smartphone application, W-GenZD guides the adolescent to develop emotion regulation skills in the context of their everyday life through brief “conversations” with Woebot, a relational conversational agent. A fully virtual RCT evaluated the efficacy of W-GenZD compared to a digital psychoeducational control group among (N=205) 16-17 year olds recruited within 6 weeks from social media. The sample was 60% women (26% men; 9% non-binary; 3% transgender man; 1% genderqueer, 1% reported another gender identity) and 60% white (15% Asian American; 11% Black/African American; 2% American Indian or Alaskan Native, 6% multiracial, 4% reported another race). Over 50% identified as LGBTQIA+ community members (42% heterosexual, 19% bisexual, 9% lesbian or gay, 9% queer, 8% questioning, 6% pansexual, 5% asexual, 1% reported another sexual orientation, 1% preferred not to answer). Overall, W-GenZD participants had significantly greater reductions in PHQ-8 measured depression at 4 weeks end-of-treatment (EOT) than did control group participants (t=3.1, p=.002; Cohen’s d = .44). Among those randomized to W-GenZD, LGBTQIA+ participants reported higher baseline depression than cisgender heterosexual participants (PHQ-8=12.4 and 10.5, respectively) which reduced to mild levels, on average, in both groups at EOT. Working Alliance with Woebot was consistent between LGBTIA+ and cisgender heterosexual participants; in both groups alliance was formed early (Day 3) and sustained through EOT. Results suggest that W-GenZD was feasible, acceptable, and potentially efficacious among a diverse sample of 16-17 year olds with depression. The relatively rapid recruitment rate suggests a potentially broad audience of teens interested in digitally delivered treatment for depressive symptoms.

**Disclaimer:** W-GenZD is not yet available and has not yet been cleared/approved or evaluated by FDA

**Citation:** Robinson A, Eaneff S, Darcy A. RCT of Woebot for Adolescent Depression compared to Digital Psychoeducation: The Headway Study. Presented at the annual conference of the Association for Behavioral and Cognitive Therapies (ABCT), New York City, November 2022
An Approach to Improving Diversity in Mental Health Research: The Connect Study

Ensuring individuals from diverse backgrounds are included in health research is critical to reducing health disparities and advancing health equity. Most groups historically underrepresented in health research suffer disproportionately from psychological distress and/or have less access to care. Low participation of these groups in research not only reduces the generalizability of findings but also impacts the development of effective interventions, further widening health inequalities. This presentation describes the Connect Study, an active research collaboration between Woebot Health (WH) and Scripps Research Translational Institute (SRTI), and its novel, multi-faceted approach to participant outreach and recruitment designed to ensure representation of groups historically underrepresented in health research.

Leveraging SRTI’s app-based research platform PowerMom, the Connect Study is a decentralized randomized controlled trial that will assess the feasibility and acceptability of WH’s CBT-based postpartum mental health app among a diverse sample of 450 postpartum people. Awareness of PowerMom is generated through multiple channels, many with national reach, and through community-based partners who provide services to Black/African American and Hispanic/Latina pregnant people.

Drawing from groups identified as historically underrepresented in biomedical research (UBR) by the National Institutes of Health (NIH) All of Us Research Program, the study aims to enroll at least 30% of participants identifying as members of racial or ethnic groups which are UBR, and at least 50% of participants identifying as any UBR category, including underrepresented racial and ethnic groups. Groups UBR prioritized in our study include racial and ethnic minorities identifying as Asian, Black or African American, Hispanic or Latina or Latinx, American Indian or Alaska Native, Native Hawaiian, or other Pacific Islander, those under the age of 18, residents of rural or non-metropolitan areas, those with annual household incomes at or below 200% of the federal poverty, and those with less than a high school education or equivalent. The Connect Study will manage its cohort diversity by recruiting from the broader diverse PowerMom cohort and waitlisting non-UBR participants when/if necessary.

Disclaimer: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA

Citation: Toluwalase A, Ramos E, Baca-Motes K, Robinson A, Durden E. An Approach to Improving Diversity in Mental Health Research: The Connect Study. Presented at the annual conference of the Association for Behavioral and Cognitive Therapies (ABCT), New York City, November 2022
Accepted manuscripts

A Randomized Clinical Trial Investigating the Feasibility and Acceptability of a Digital Therapeutic for PPD

Collaborator: Lucile Packard Children’s Hospital; Stanford Hospitals and Clinics

Key points:

- This paper reports on the results of the Randomized Clinical Trial investigating the feasibility and acceptability of Woebot for Postpartum depression (Woebot-PPD).
- 192 women who recently gave birth reported high satisfaction and acceptability with Woebot-PPD.

Synopsis: Postpartum depression (PPD) is the occurrence of a major depressive episode with onset during the third trimester of pregnancy or within the first four weeks following childbirth. The syndrome of PPD impacts approximately 10-20% of women worldwide, although more than 50% have some anxiety and depression symptoms (‘baby blues’) in the first year following childbirth. The PPD literature indicates that CBT and IPT are preferred psychotherapeutic approaches for women with mild to moderate PPD, yet significant barriers to such treatments limit access for women in need. This manuscript designed the protocol implementation of a randomized clinical trial investigating the feasibility and acceptability of digital therapeutic for PPD, delivered through a fully automated conversational agent, among N=192 women who had recently (within 72 hours) given birth. Participants reported high satisfaction with and acceptability of the 6-week program. Barriers and augment to participant recruitment within a Labor and Delivery Unit will be discussed. Such programs should be further examined as a postpartum mental health resource.

Disclaimer: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA

Citation: Suharwardy S, Ramachandran MK, Leonard SA, Gunaseelan A, Robinson A, Darcy A, Lyell D, Judy A. Manuscript accepted for publication in AJOG Global Reports.
Grant-funded research

Woebot for Substance Use Disorders

Collaborator: Stanford University School of Medicine

Funding agency: National Institutes of Drug Abuse, Small Business Innovation Research Award

Synopsis: Substance use disorder (SUD) manifests in continuous substance use in the face of significant substance related problems, including cognitive, behavioral as well as physiological symptoms. SUD prevalence is at public health epidemic levels and climbing, yet treatment seeking has plateaued given significant access barriers. Effective, accessible, and engaging intervention modalities for SUD are desperately needed. Woebot for Substance Use Disorders (W-SUDs) is a two-phase NIDA-funded SBIR. W-SUDs, a novel digital therapeutic, was developed and is presently being evaluated for feasibility and acceptability in the Phase I (N=104) non-controlled pilot. Phase II will investigate W-SUDs’s efficacy compared to an active control condition in a fully-powered randomized clinical trial (N=278). The noteworthy ecological validity of such mobile health initiatives makes the proposed research both warranted and timely with great potential to reach a traditionally underserved population in need of prompt attention.

Status: Phase I pilot was completed in July 2020. Phase II started September 2020. Phase I has yielded one conference abstract (Prochaska et al, Society of Behavioral Medicine) and one published paper (Prochaska et al., 2021 JMIR).

Disclaimer: W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA
**Woebot for Substance Use Disorders: COVID-19**

**Collaborator:** Stanford University School of Medicine

**Funding agency:** National Institutes of Drug Abuse, Covid-19 Administrative Supplement to the Parent Grant Small Business Innovation Research Award

**Synopsis:** Since the initial parent grant award of W-SUDs, and across mere months, Covid-19 became a global pandemic, and users worldwide came to Woebot to discuss it and seek help. The company responded by building and deploying Covid-19 specific programming (W-C19) in March 2020. W-C19 elements have been integrated into W-SUDs; we felt it was timely and appropriate to address users’ concerns about the pandemic and demonstrate that Woebot was ‘intelligent’ to the crisis. Experts expect Covid-19’s direct and indirect impact upon individuals with SUDs to be particularly heavy. These individuals often have physical vulnerabilities, which increase the relative risk of death from Covid-19, and face limited health care access fundamentally challenging given often comorbid mental illness. Moreover, high rates of housing insecurity hinders compliance with shelter-in-place and social distancing recommendations, thereby increasing contagion risk. This supplemental proposal to the parent grant award, with the timely addition of a randomized controlled trial comparing W-SUDs to a waitlist control (WL), expands understanding of W-SUDs’ efficacy whilst investigating Covid-19’s impact upon the SUD population. Secular trends of increased substance use are anticipated given Covid-19 stressors (e.g., shelter-in-place, disease concerns, economic strife, under-/unemployment). Hence, the WL condition is essential for testing W-SUDs’ efficacy in mitigating these Covid-19 related downstream effects. W-SUDs offers immediate access to a digital therapeutic in a resource constrained, socially distanced healthcare ecosystem for an already vulnerable and underserved population, likely faced with readily growing psychological challenges.

**Status:** Supplement awarded in June 2020 and was completed in October 2020. Supplement has yielded two conference abstracts, one manuscript in press, and one manuscript under active review.

**Disclaimer:** W-SUD is not yet available and has not yet been cleared/approved or evaluated by FDA
Determining Effectiveness of an mHealth Intervention to Provide Adolescent CBT

**Collaborator**: Washington University Department of Medicine and Pediatrics

**Funding agency**: Washington University Institute of Clinical and Translational Sciences

**Synopsis**: Adolescent depression is common and often debilitating. Many teens may be prescribed antidepressant medications, although families may express hesitancy around medication as a first line of treatment for their child. Research indicates that the optimal treatment typically includes a combination of antidepressant therapy (specifically selective serotonin reuptake inhibitors; SSRIs) plus psychotherapy. Woebot is a promising digital therapeutic intervention to deliver CBT to adolescents with depression in the context of primary care management. In collaboration with Washington University, Woebot Labs Inc. will be launching a RCT of Woebot for mild-moderate depression among adolescents in the summer of 2020, within approximately 11-13 participating pediatric clinics. This RCT will not only assess the preliminary feasibility and efficacy of the intervention itself, but will also gather valuable feedback qualitative from parents and pediatricians about the use of the digital therapeutic in this population. The goals of the feasibility and acceptability study are to establish the program’s utility and feasibility within the primary care ecosystem, as well as to test measurement strategies to inform a more rigorous, fully powered subsequent RCT to evaluate the effectiveness of the program in the primary care management of adolescent depression.

**Status**: Study completed. Manuscript in progress.

**Disclaimer**: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA.
Woebot for Postpartum Mood Management

Collaborator: Lucile Packard Children’s Hospital; Stanford Hospitals and Clinics

Funding agencies:
1. Stanford Society of Physician Scholars
2. Stanford MedScholars Grant
3. Stanford Maternal and Child Health Research Institute

Synopsis: Childbirth is a significant event, accompanied by definitive life changes, including physical, behavioral, psychological and emotional adjustments. Unfortunately, about half of all women report increased anxiety and depression symptoms during the postpartum period however only 20% report these symptoms to their doctors. Worldwide, about 10-20% of women develop the full clinical syndrome of peripartum depression. The American Psychiatric Association’s (APA) guidelines for the treatment of women with major depression who are pregnant or breastfeeding indicate psychotherapy without medication as a first line treatment. Cognitive behavioral therapy (CBT) and interpersonal psychotherapy (IPT) are evidence-supported and recommended psychotherapies for PPD. Research on evidence-based therapies translated into digital forms has demonstrated efficacy in reducing symptoms of depression, with enormous potential to scale up access. The purpose of this randomized controlled trial was to evaluate the feasibility and acceptability of a 6-week Woebot for postpartum mood management program among adult women recruited during their birth hospitalization.


Disclaimer: This version of Woebot is not yet available and has not yet been cleared/approved or evaluated by FDA
Other state of the art research*

**High-performance Medicine: The Convergence of Human and Artificial Intelligence**

**Theme:** AI and digital health

**Summary:** The use of artificial intelligence, and the deep-learning subtype in particular, has been enabled by the use of labeled big data, along with markedly enhanced computing power and cloud storage, across all sectors. In medicine, this is beginning to have an impact at three levels: for clinicians, predominantly via rapid, accurate image interpretation; for health systems, by improving workflow and the potential for reducing medical errors; and for patients, by enabling them to process their own data to promote health. The current limitations, including bias, privacy and security, and lack of transparency, along with the future directions of these applications will be discussed in this article. Over time, marked improvements in accuracy, productivity, and workflow will likely be actualized, but whether that will be used to improve the patient–doctor relationship or facilitate its erosion remains to be seen.

**Citation:** Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nat Med 25, 44–56 (2019). https://doi.org/10.1038/s41591-018-0300-7.

**It’s Only a Computer: Virtual Humans Increase Willingness to Disclose**

**Theme:** Relational Agents, Virtual Humans

**Summary:** Virtual humans (VHs) that can develop intimacy with people are now becoming reality. Researchers have successfully incorporated social skills (e.g., active listening, mimicry, gestures) into VH systems. When designed as supportive and “safe” interaction partners, VHs may improve clinical interviews by increasing willingness to disclose information. In health and mental health contexts, patients are often reluctant to respond honestly. This paper reports the results of a study in which participants interacted with a VH interviewer and were led to believe that the VH was controlled by either humans or automation. As predicted, compared to those who believed they were interacting with a human operator, participants who believed they were interacting with a computer reported lower fear of self-disclosure, lower impression management, displayed their sadness more intensely, and were rated by observers as more willing to disclose. These results suggest that automated VHs can help overcome a significant barrier to obtaining truthful patient information.

**Citation:** Lucas GM, Gratch J, King A, & Morency L-P. (2014). It’s only a computer: Virtual humans increase willingness to disclose. Computers in Human Behavior, 37(2014) 94-100.

*Other state of the art research is not funded by Woebot, nor does this research support Woebot directly.*
Psychological, Relational, and Emotional Effects of Self-Disclosure After Conversations With a Chatbot

Theme: Conversational AI, Chatbot, Human-machine communication

Summary: Disclosure can reduce stress arising from negative experiences, diminish anxiety, and increase negative affect in the short term, which ultimately results in long-term psychological improvement. Disclosure met with support can also improve relational outcomes, enhancing relational closeness and intimacy. A plethora of studies have found that people form perceptions of computerized agents and humans in the same way, even though people consciously know that computers are machines that do not have human personalities. This experiment examined downstream effects after emotional versus factual disclosures in conversations with a supposed chatbot or person. The effects of emotional disclosure were equivalent whether participants thought they were disclosing to a chatbot or to a person. This study advances current understanding of disclosure and whether its impact is altered by technology, providing support for media equivalency as a primary mechanism for the consequences of disclosing to a chatbot.


Conversational Agents and Mental Health: Theory-Informed Assessment of Language and Affect

Abstract: A study deployed the mental health Relational Frame Theory as grounding for an analysis of sentiment dynamics in human-language dialogs. The work takes a step towards enabling use of conversational agents in mental health settings. Sentiment tendencies and mirroring behaviors in 11k human-human dialogs were compared with behaviors when humans interacted with conversational agents in a similar-sized collection. The study finds that human sentiment-related interaction norms persist in human-agent dialogs, but that humans are twice as likely to respond negatively when faced with a negative utterance by a robot than in a comparable situation with humans. Similarly, inhibition towards use of obscenity is greatly reduced. We introduce a new Affective Neural Net implementation that specializes in analyzing sentiment in real time.

An Embodied Conversational Agent for Unguided Internet-based Cognitive Behavior Therapy in Preventative Mental Health: Feasibility and Acceptability Pilot Trial

**Background:** Recent years have seen an increase in the use of internet-based cognitive behavioral therapy in the area of mental health. Although lower effectiveness and higher dropout rates of unguided than those of guided internet-based cognitive behavioral therapy remain critical issues, not incurring ongoing human clinical resources makes it highly advantageous.

**Objective:** Current research in psychotherapy, which acknowledges the importance of therapeutic alliance, aims to evaluate the feasibility and acceptability, in terms of mental health, of an application that is embodied with a conversational agent. This application was enabled for use as an internet-based cognitive behavioral therapy preventative mental health measure.

**Methods:** Analysis of the data from the 191 participants of the experimental group with a mean age of 38.07 (SD 10.75) years and the 263 participants of the control group with a mean age of 38.05 (SD 13.45) years using a 2-way factorial analysis of variance (group × time) was performed.

**Results:** There was a significant main effect (P=.02) and interaction for time on the variable of positive mental health (P=.02), and for the treatment group, a significant simple main effect was also found (P=.002). In addition, there was a significant main effect (P=.02) and interaction for time on the variable of negative mental health (P=.005), and for the treatment group, a significant simple main effect was also found (P=.001).

**Conclusions:** This research can be seen to represent a certain level of evidence for the mental health application developed herein, indicating empirically that internet-based cognitive behavioral therapy with the embodied conversational agent can be used in mental health care. In the pilot trial, given the issues related to feasibility and acceptability, it is necessary to pursue higher quality evidence while continuing to further improve the application, based on the findings of the current research.
Advantages of Virtual Agents Over Clinical Psychologists During Comprehensive Mental Health Interviews Using a Mixed Methods Design

**Background:** The use of Virtual Agents (VAs) is currently a popular topic in mental health interviews. Advantages of VA over Real Expert (RE) in the interview were reported. However, the advantages of audio-visual VAs over REs during comprehensive mental health interviews remain unclear, and their clarification is important to promote the practical application of VAs in these settings.

**Methods:** To explore the advantages, we triangulated data using mixed methods design, aiming to show quantitative advantages of the VAs in their perceived rapport and eye movement, and to describe the qualitative advantages of the VAs in their disclosed mental symptoms during the interview. A total of 55 Japanese university students participated in comprehensive mental health interviews conducted by the VA and RE.

**Results:** Findings show that participants perceived rapport and moved their right eyes more often, along with disclosing numerous mental symptoms, with the RE than the VA. However, they disclosed more sex-related symptoms to the VA than the RE. The VA can be used most practically in sex-related health fields. The anonymity conditions in the VA setting might be relevant to patients’ self-disclosure of sex-related topics.
Embodied Conversational Agents in Clinical Psychology: A Scoping Review

**Background:** Embodied conversational agents (ECAs) are computer-generated characters that simulate key properties of human face-to-face conversation, such as verbal and nonverbal behavior. In Internet-based eHealth interventions, ECAs may be used for the delivery of automated human support factors.

**Objective:** We aim to provide an overview of the technological and clinical possibilities, as well as the evidence base for ECA applications in clinical psychology, to inform health professionals about the activity in this field of research.

**Methods:** Given the large variety of applied methodologies, types of applications, and scientific disciplines involved in ECA research, we conducted a systematic scoping review. Scoping reviews aim to map key concepts and types of evidence underlying an area of research, and answer less-specific questions than traditional systematic reviews. Systematic searches for ECA applications in the treatment of mood, anxiety, psychotic, autism spectrum, and substance use disorders were conducted in databases in the fields of psychology and computer science, as well as in interdisciplinary databases. Studies were included if they conveyed primary research findings on an ECA application that targeted one of the disorders. We mapped each study’s background information, how the different disorders were addressed, how ECAs and users could interact with one another, methodological aspects, and the study’s aims and outcomes.

**Results:** This study included N=54 publications (N=49 studies). More than half of the studies (n=26) focused on autism treatment, and ECAs were used most often for social skills training (n=23). Applications ranged from simple reinforcement of social behaviors through emotional expressions to sophisticated multimodal conversational systems. Most applications (n=43) were still in the development and piloting phase, that is, not yet ready for routine practice evaluation or application. Few studies conducted controlled research into clinical effects of ECAs, such as a reduction in symptom severity.

**Conclusions:** ECAs for mental disorders are emerging. State-of-the-art techniques, involving, for example, communication through natural language or nonverbal behavior, are increasingly being considered and adopted for psychotherapeutic interventions in ECA research with promising results. However, evidence on their clinical application remains scarce. At present, their value to clinical practice lies mostly in the experimental determination of critical human support factors. In the context of using ECAs as an adjunct to existing interventions with the aim of supporting users, important questions remain with regard to the personalization of ECAs’ interaction with users, and the optimal timing and manner of providing support. To increase the evidence base with regards to internet interventions, we propose an additional focus on low-tech ECA solutions that can be rapidly developed, tested, and applied in routine practice.
Computer-Controlled Virtual Humans in Patient-Facing Systems: Systematic Review and Meta-Analysis

**Background:** Virtual humans (VH) are computer-generated characters that appear humanlike and simulate face-to-face conversations using verbal and nonverbal cues. Unlike formless conversational agents, like smart speakers or chatbots, VH bring together the capabilities of both a conversational agent and an interactive avatar (computer-represented digital characters). Although their use in patient-facing systems has garnered substantial interest, it is unknown to what extent VH are effective in health applications.

**Objective:** The purpose of this review was to examine the effectiveness of VH in patient-facing systems. The design and implementation characteristics of these systems were also examined. Methods: Electronic bibliographic databases were searched for peer-reviewed articles with relevant key terms. Studies were included in the systematic review if they designed or evaluated VH in patient-facing systems. Of the included studies, studies that used a randomized controlled trial to evaluate VH were included in the meta-analysis; they were then summarized using the PICOTS framework (population, intervention, comparison group, outcomes, time frame, setting). Summary effect sizes, using random-effects models, were calculated, and the risk of bias was assessed.

**Results:** Among the 8,125 unique records identified, 53 articles describing 33 unique systems, were qualitatively, systematically reviewed. Two distinct design categories emerged — simple VH and VH augmented with health sensors and trackers. Of the 53 articles, 16 (26 studies) with 44 primary and 22 secondary outcomes were included in the meta-analysis. Meta-analysis of the 44 primary outcome measures revealed a significant difference between intervention and control conditions, favoring the VH intervention (SMD = .166, 95% CI .039-.292, P=.012), but with evidence of some heterogeneity, I²=49.3%. There were more cross-sectional (k=15) than longitudinal studies (k=11). The intervention was delivered using a personal computer in most studies (k=18), followed by a tablet (k=4), mobile kiosk (k=2), head-mounted display (k=1), and a desktop computer in a community center (k=1).

**Conclusions:** We offer evidence for the efficacy of VH in patient-facing systems. Considering that studies included different population and outcome types, more focused analysis is needed in the future. Future studies also need to identify what features of virtual human interventions contribute toward their effectiveness.
Embodied Conversational Agents for the Detection and Prevention of Suicidal Behaviour: Current Applications and Open Challenges

**Background:** Embodied conversational agents (ECAs) are advanced computational interactive interfaces designed with the aim to engage users in the continuous and long-term use of a background application. The advantages and benefits of these agents have been exploited in several e-health systems. One of the medical domains where ECAs are recently applied is to support the detection of symptoms, prevention and treatment of mental health disorders. As ECAs based applications are increasingly used in clinical psychology, and due that one fatal consequence of mental health problems is the commitment of suicide, it is necessary to analyse how current ECAs in this clinical domain support the early detection and prevention of risk situations associated with suicidality.

**Methods:** The present work provides and overview of the main features implemented in the ECAs to detect and prevent suicidal behaviours through two scenarios: ECAs acting as virtual counsellors to offer immediate help to individuals in risk; and ECAs acting as virtual patients for learning/training in the identification of suicide behaviours. A literature review was performed to identify relevant studies in this domain during the last decade, describing the main characteristics of the implemented ECAs and how they have been evaluated. A total of six studies were included in the review fulfilling the defined search criteria.

**Conclusions:** Most of the experimental studies indicate promising results, though these types of ECAs are not yet commonly used in routine practice. The identification of some open challenges for the further development of ECAs within this domain is also discussed.

The Personalization of Conversational Agents in Health Care: Systematic Review

**Background:** The personalization of conversational agents with natural language user interfaces is seeing increasing use in health care applications, shaping the content, structure, or purpose of the dialogue between humans and conversational agents. Objective: The goal of this systematic review was to understand the ways in which personalization has been used with conversational agents in health care and characterize the methods of its implementation.

**Methods:** We searched on PubMed, Embase, CINAHL, PsycInfo, and ACM Digital Library using a predefined search strategy. The studies were included if they: (1) were primary research studies that focused on consumers, caregivers, or health care professionals; (2) involved a conversational agent with an unconstrained natural language interface; (3) tested the system with human subjects; and (4) implemented personalization features.
Results: The search found 1958 publications. After abstract and full-text screening, 13 studies were included in the review. Common examples of personalized content included feedback, daily health reports, alerts, warnings, and recommendations. The personalization features were implemented without a theoretical framework of customization and with limited evaluation of its impact. While conversational agents with personalization features were reported to improve user satisfaction, user engagement and dialogue quality, the role of personalization in improving health outcomes was not assessed directly.

Conclusions: Most of the studies in our review implemented the personalization features without theoretical or evidence-based support for them and did not leverage the recent developments in other domains of personalization. Future research could incorporate personalization as a distinct design factor with a more careful consideration of its impact on health outcomes and its implications on patient safety, privacy, and decision-making.

Chatbots and Conversational Agents in Mental Health: A Review of the Psychiatric Landscape

Objective: The aim of this review was to explore the current evidence for conversational agents or chatbots in the field of psychiatry and their role in screening, diagnosis, and treatment of mental illnesses.

Methods: A systematic literature search in June 2018 was conducted in PubMed, EmBase, PsycINFO, Cochrane, Web of Science, and IEEE Xplore. Studies were included that involved a chatbot in a mental health setting focusing on populations with or at high risk of developing depression, anxiety, schizophrenia, bipolar, and substance abuse disorders.

Results: From the selected databases, 1466 records were retrieved and 8 studies met the inclusion criteria. Two additional studies were included from reference list screening for a total of 10 included studies. Overall, potential for conversational agents in psychiatric use was reported to be high across all studies. In particular, conversational agents showed potential for benefit in psychoeducation and self-adherence. In addition, the satisfaction rating of chatbots was high across all studies, suggesting that they would be an effective and enjoyable tool in psychiatric treatment.

Conclusion: Preliminary evidence for psychiatric use of chatbots is favorable. However, given the heterogeneity of the reviewed studies, further research with standardized outcomes reporting is required to more thoroughly examine the effectiveness of conversational agents. Regardless, early evidence shows that with the proper approach and research, the mental health field could use conversational agents in psychiatric treatment.
The Human Side of Human-chatbot Interaction: A Systematic Literature Review of Ten Years of Research on Text-based Chatbots

Over the last ten years there has been a growing interest around text-based chatbots, software applications interacting with humans using natural written language. However, despite the enthusiastic market predictions, 'conversing' with these kinds of agents seems to raise issues that go beyond their current technological limitations, directly involving the human side of interaction. By adopting a Human-Computer Interaction (HCI) lens, in this article we present a systematic literature review of 83 papers that focus on how users interact with text-based chatbots. We map the relevant themes that are recurrent in the last ten years of research, describing how people experience the chatbot in terms of satisfaction, engagement, and trust, whether and why they accept and use this technology, how they are emotionally involved, what kinds of downsides can be observed in human-chatbot conversations, and how the chatbot is perceived in terms of its humanness. On the basis of these findings, we highlight open issues in current research and propose a number of research opportunities that could be tackled in future years.

Thought leadership

Articles in peer-reviewed journals

Conversational Agents in Health Care (Letter to the Editor of JAMA)

Key points:

- Executive leadership from Woebot wrote a letter to the editor in response to an opinion piece calling for independent and additional regulation of conversational agents in health care.
- The authors argue that conversational agents do not need a separate regulatory mechanism because they should be considered in the context of their intended use, for which adequate regulatory mechanisms exist.
- The authors highlight and challenge the implicit suggestion that conversational agents should be considered through the lens of replacing human services, since many are not being used in this way.


Machine Learning and the Profession of Medicine (JAMA Viewpoint)

Key points:

- The world has entered a period of unprecedented innovation, bringing a wealth of possibilities to clinical medicine that amplifies the obligation of the medical profession to serve the human good. Ethical design thinking is essential at every stage of development and application of machine learning in advancing health.
- Physicians with integrity and sophistication should partner closely with computer and data scientists to reimagine clinical medicine. They must also be judicious in their approach to industry relationships so that technology may progress in a manner that upholds the ethical and social trust in medicine.
- Academic physicians must create opportunities for rigorous empirical validation of new innovations against clinical outcomes.
- Leaders throughout medicine must endeavor to create novel ethical approaches sufficient to address emerging dilemmas inherent to use of machine learning technologies in furthering health.


woebothealth.com
Articles in non peer-reviewed publications

**Why Generative AI Is Not Yet Ready for Mental Healthcare**

**Summary:** Amidst some extreme examples of badly behaving generative AIs, it's easy to dismiss the utility of all similar tech used in mental healthcare. However, more nuanced understanding is needed to prevent the erosion of public confidence in a key public health opportunity. As it stands today, AIs that are primarily rules-based are more suitable for healthcare than generative AIs for many reasons. Exacting work is required to build, test and regulate any new technology that may be used in a healthcare setting.

**Published:** March 1, 2023

**How to Evolve Artificial Intelligence Models Alongside Societal Needs**

**Summary:** As society becomes more open to and reliant on these tools, it is the responsibility of technology companies, especially those tasked with assisting people's mental health, to build and maintain artificial intelligence and machine learning models that adapt alongside societal needs. Our Vice President of Product, Joe Gallagher, explores how technology companies, especially those tasked with assisting people's mental health, can responsibly build, maintain and adapt AI and machine learning tools.

**Published:** October 16, 2022

**AI is Our Path to Holistic Mental Health Care**

**Summary:** AI is a critical tool to help accelerate innovation in mental health and augment the work of human therapists. No one makes a better case for a future where anyone, at any time of day, can access help for navigating challenging situations, moments or feelings than our Founder and President Alison Darcy, in this byline in MedCity News. "We need to move on from the idea that AI-powered services simply replicate what humans do. What AI can deliver is quite different—and therein lies the potential."

**Published:** February 10, 2022
**DTx and Cognitive Behavioral Therapy: Opportunities, Benefits, and Challenges of an Evolving Landscape**

**Summary:** Billions of people around the world have mobile devices, half of which are smartphones, so it’s not surprising that mobile technology has become a core component of digital therapeutics (DTx). Although care access is a key issue that digital solutions can improve, DTx also creates an opportunity for genuine innovation. In fact, DTx are not necessarily diluted versions of in-person psychotherapy. Rather, in some cases they give rise to a mechanism of action enabled by the digital medium itself. Innovations, however, are not good simply because they exist. Clinicians will need to carefully and thoughtfully consider different DTx offerings, their claimed mechanisms of action, evidence for their efficacy and ease of use, and other relative strengths and weaknesses.

**Published:** August 4, 2021

**Does Digital Mental Health Need to Rethink User Engagement?**

**Summary:** Gamification is being hailed as a promising tool within the digital mental health industry. But should the same tactics that are fueling our online addiction become the standard for driving engagement with solutions that are designed to improve our mental health? Our Founder and President Alison Darcy shares her opinion, calling for the field to consider what meaningful engagement means in a digital health context.

**Published:** February 26, 2021
Books that feature Woebot

Healing: Our Path from Mental Illness to Mental Health
*Thomas Insel, 2022, Penguin Press*

A bold, expert, and actionable map for the re-invention of America’s broken mental health care system.

Deep Medicine: How Artificial Intelligence Can Make Medicine Human Again
*Eric Topol, 2019 Basic Books*

A thoughtful and deep description from leading physician Eric Topol on the ways in which AI can truly unlock the potential of medicine, from deep learning techniques to identifying previously undiscovered tumor features to reinstating a meaningful patient-doctor relationship, to help make medicine better for all the humans.

Solomon’s Code: Humanity in a World of Thinking Machines
*Olaf Groth and Mark Nitzberg, 2018 Pegasus Books*

A thought-provoking examination of artificial intelligence and how it reshapes human values, trust, and power around the world.
Relationships 5.0: How AI, VR, and Robots Will Reshape Our Emotional Lives

*Elyakim Kislev, 2022 Oxford University Press*

Relationships 5.0 asks how recent technological developments cause us to think differently about our family lives, love affairs, and emotional needs.

Engaged: Designing for Behavior Change

*Amy Bucher, 2020 Rosenfeld Media*

A practical and science-based guide to the best psychological practices in use in digital product design, analyzing both the barriers and levers to achieving behavioral change.

Now for the Good News: To the Future with Love

*Ruby Wax, 2020 Generic*

How inspiring people spearheading the latest innovation are influencing a brighter future for humanity.

Left to Our Own Devices: Outsmarting Smart Technology to Reclaim Our Relationships, Health, and Focus

*Margaret E. Morris, with a foreword by Sherry Turkle, 2018 The MIT Press*

Unexpected ways that individuals adapt technology to reclaim what matters to them, from working through conflict with smart lights to celebrating gender transition with selfies.
Additional resources

Industry reports on our category

1. **One Mind PsyberGuide**
   **Publisher:** One Mind PsyberGuide
   **Synopsis:** One Mind is a nonprofit dedicated to helping people use technology to live mentally healthier. It independently evaluates technology, based on scientific evidence, the rigor of the development process, and the clarity of purpose to establish the most credible mental health apps available today. Woebot is the top rated “AI chatbot” in the One Mind PsyberGuide of mental health apps, with the only long standing, (5/5) perfect score for credibility. The score is based on the research supporting the technology and the credibility of the development process.

2. **Digital Health Assessment Framework (DHAF)**
   **Publisher:** ORCHA
   **Synopsis:** Woebot has passed the rigorous new Digital Health Assessment Framework (DHAF), a stringent framework for assessing safety, efficacy, privacy and security in digital health technologies. It was developed by the Organization for the Review of Care and Health Apps (ORCHA) to support the adoption of high-quality digital health technologies and to help healthcare professionals and patients make more informed decisions about which tools best suit their needs. The open framework includes components to assess privacy and security, clinical assurance and safety, and usability, and was crafted to support U.S.-specific guidelines, regulations and best practices for digital health technologies. The DHAF project has been led by the American College of Physicians (ACP) and the American Telemedicine Association (ATA), with ORCHA developing the framework itself. The DHAF allows the independent assessment of mobile apps and web-based tools used by healthcare providers and consumers.
3. Guide To Improving Wellness With Mobile (2021)

Publisher: Forrester Research

Synopsis: Consumers buy wearables, mobile app-based services, or subscriptions to help them to achieve their health or wellness objectives. However, too few services offer enough convenience to consumers to drive substantial, long-lasting changes in health outcomes. The shortcomings of consumer mobile technology aren’t the core issue. The services do mitigate friction — just not enough to overcome the difficult task of behavior change. This report focuses on how healthcare and service providers can best make use of today’s mobile technology.

4. Global Study: 82% of People Believe Robots Can Support Their Mental Health Better Than Humans (2020)

Publisher: Oracle (press release)

Synopsis: The COVID-19 pandemic has created the most stressful year in history and negatively affected the mental health of 78% of the global workforce. 85% of people say their mental health issues at work negatively affect their home. 68% of people would prefer to talk to a robot over their manager about stress and anxiety at work. 76% of people believe companies should be doing more to support the mental health of their workforce.


Publisher: Deloitte

Synopsis: This article talks about different kinds of digital therapeutic solutions, how they fit into the healthcare journey, potential benefits and challenges facing this industry, and decision making frameworks on putting digital therapeutics into action.
Papers on relational agents

1. Relational Agents in Clinical Psychiatry (2010)

**Theme:** Relational agents, Embodied Conversational Agent, Therapeutic alliance

**Abstract:** Relational agents are computational artifacts, such as animated screen-based characters or social robots, that are designed to establish a sense of rapport, trust, and even therapeutic alliance with patients, using ideal therapeutic relationships between human counselors and patients as role models. We describe the development and evaluation of several such agents designed for health counseling and behavior change interventions, in which a therapeutic alliance is established with patients in order to enhance the efficacy of the intervention. We also discuss the promise of using such agents as adjuncts to clinical psychiatry in a range of possible applications, and some of the challenges and ethical issues in developing and fielding them in psychiatric interventions, before speculating on possible directions for future research on relational agents in healthcare.

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