

Research Article

Bot to the Rescue? Effects of a Fully Automated Conversational Agent on Anxiety and Depression: A Randomized Controlled Trial

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Received: July 31, 2021; Accepted: August 17, 2021;

Published: August 24, 2021

Abstract

Web-based conversational agents powered by Artificial Intelligence (AI) and rooted in cognitive-behavioral therapy have been proven efficacious in alleviating the symptoms of anxiety and depression, when compared to passive controls. However, the benefits of a fully automated agent vs. active controls have not yet been examined. Furthermore, the potential impact of such interventions on the transdiagnostic factors underlying anxiety and depression is not known.

To elucidate this, 95 adults were randomized to receive (1) a 2-week intervention with an AI-powered chatbot (Woebot) (n=39) or (2) regular psychoeducational materials (n=54). In completers' analyses, significant main effects of time were obtained for one of the primary outcomes, anxiety, and for the secondary outcomes, transdiagnostic factors, with both groups showing decreased anxiety and intolerance of uncertainty and increased rumination, self-compassion, guilt and shame. No group by time interaction effects were found for either of the primary outcomes, depression and anxiety, or for the secondary outcomes. Intent-to-Treat analyses also revealed no significant effects of group on the primary or secondary outcomes. Our findings point to the necessity of further research to better understand the areas where chatbots might bring benefits superior to those obtained through simple and inexpensive strategies.

Keywords: Mobile mental health; mHealth; Depression; Anxiety; Transdiagnostic factors; Health apps

Abbreviations

AI: Artificial Intelligence; ANOVA: Analysis of Variance; CBT: Cognitive-Behavioral Therapy; ITT: Intention-to-Treat; M: Mean; RCT: Randomized Controlled Trial; SD: Standard Deviation

Introduction

Mental disorders, which affect up to 29% of people in their lifetime [1] and come with significant societal and personal costs [2], have increased in their prevalence and severity [3-6]. The onset period for several mental disorders, especially mood and anxiety disorders, is early 20's [4,7,8], with significantly higher rates of depression found in college students than in the general population [9]. Subclinical levels of depression and anxiety also lead to significant impairment [10,11].

While these realities point to the critical role of interventions in alleviating such symptoms, only 35.5-50.3 % of serious cases in developed countries and 76.3% - 85.4% in less developed countries end up receiving professional care [12]. The 2018 National Survey on Drug Use and Health reported that up to 56.7% of Americans with some form mental illness received no treatment, regardless of the form and severity of mental illness [13]. Tellingly, only 16.4% of students meeting the criteria for a mental illness receive adequate treatment for it [7].

Although the reasons for not receiving psychological care vary

across individuals, some of the reported barriers are: treatment not needed, lack of time, preference for self-management, and perceived stigma and embarrassment [14,15].

In addition to these obstacles, the current pandemic context brings forth additional limitations for conventional face-to-face psychological assistance, as social distancing, mask wearing, and surface disinfection are mandatory, pointing to the importance of exploring alternative means of providing psychological care, such as automated CBT interventions recommended by The National Institute for Health and Care Excellence, which can offer information and guidance similar to treatments delivered by standard methods [16].

Owing to the enormous recent increase in computing power, conversational agents (chatbots) powered by Artificial Intelligence (AI) (e.g., Replika, Shim, Woebot, Wysa) have emerged as a potentially useful therapeutic method in the recent years. Chatbots are cheap, easily accessible, and do not suffer from scale-up challenges. However, while the use of therapy bots has increased recently, the technology behind this kinds of interventions is still experimental in nature and the field lacks high-quality evidence derived from randomized controlled studies [17].

Given the fact that many such solutions may be marketed to vulnerable individuals, the necessity of rigorously validating their claims of mental health improvements with their use becomes

imperative. Some evidence for the benefits of the use of chatbots in psychiatry is positive, but there are concerns about the lack of higher quality evidence for any type of diagnosis and interventions in mental health research that uses them [18]. A systematic review on these types of interventions found that they can be effective in reducing depression, anxiety, stress, and substance use, but, out of the apps that were reviewed, only two were available for commercial use [19].

There is some evidence that web-based conversational agents rooted in cognitive-behavioral theory can be efficacious in alleviating the symptoms of some mental health conditions, such as anxiety and depression. For instance, a pilot randomized clinical trial on the effectiveness and adherence of an AI-powered smartphone app, delivering strategies used in positive psychology and CBT interventions using a conversational interface, reported no significant changes in the intervention group compared to a waitlist on any of the outcome measures. However, when the analysis included only the participants who adhered to the intervention, there was a significant group-by-time interaction effect on psychological well-being and perceived stress, with small to large effect sizes [20]. Likewise, another RCT on an AI-powered psychological intervention-Tess-showed significant reduction of self-reported symptoms of depression and anxiety in college students, compared to a control group who received informational materials [21].

Another AI-driven conversational agent-Woebot, a fully-automated CBT-driven chatbot – also showed promise in an RCT which compared it to a passive control group, in that it led to a higher decrease in depression and anxiety, although the control group's adherence to the intervention was not examined [22].

To date, to our knowledge, the research on the mediators and mechanisms of change in automated, computerized interventions has solely focused on symptom changes through specific therapeutic protocols for mental disorders. However, there is a growing body of evidence on the impact of transdiagnostic factors on mental health [23]. Transdiagnostic factors are vulnerability factors that overlap across several mental disorders [24]. Thus, treatments targeting key transdiagnostic factors (i.e., common vulnerability factors) could have a general impact across multiple disorders and prove efficacious in preventing declines in mental health [24].

For depression and anxiety, which tend to co-occur [25], the following major transdiagnostic factors have been identified: rumination, guilt, shame, intolerance of uncertainty (all associated with negative outcomes [23]), and self-compassion (associated with positive outcomes [26]).

Recent progress on the merits of AI-powered conversational agents notwithstanding, little is currently known about the potential impact of such chatbots on the transdiagnostic factors that underlie anxiety and depression.

To this end, the present study's objectives were twofold: (1) evaluate the efficacy in reducing anxiety and depression using a CBT-oriented conversational agent-Woebot-compared to an active control group, who received psychoeducational materials that they needed to show mastery of, and (2) to examine the role of this conversational agent in reducing the severity of the transdiagnostic factors associated with depression and anxiety.

Methods

Recruitment and procedure

Potential participants were recruited through announcements on social media websites such as Facebook and Instagram. The inclusionary criteria were: at least 18 years old; access to a computer/mobile phone/tablet and the Internet; and the ability to read and write in English (at least B2 level of English in the Common European Framework of Reference). The study was approved by the Ethics Committee of a large university in Europe.

After signing an informed consent, all participants were assigned a personal code and sent an online baseline evaluation. Confirmed participants (i.e., those who completed the baseline evaluation) were randomized to either the experimental (i.e., Woebot) or the control group. After approximately one week (T2), all enrolled participants were contacted to fill out an instrument assessing the transdiagnostic factors, and those in the experimental group were required to send a screenshot of their time spent on Woebot and their check-in diagram to check for treatment adherence. After two weeks (T3), the participants were contacted once again to complete the initial set of scales, and those in the experimental condition also sent screenshots of their check-in diagram and time spent within the app. The primary outcomes (anxiety and depression) were measured at pre-intervention and post-intervention, whereas rumination, intolerance of uncertainty, shame, guilt, and self-compassion were additionally assessed mid-intervention (after seven days), in order to test for their effects as mediators of treatment outcome. Participants who completed all three sets of evaluations were entered in a raffle for the opportunity to win the equivalent of US \$20.

Data collection was done exclusively online; the online instruments were created using Google Forms and QuestionPro.

Participants

An a priori power analysis was conducted with the G*Power [27], as informed by previous trials exploring the efficacy of fully automated conversational agents [22]. For a medium effect size of $f = .25$ (i.e., approximately equivalent to a partial η^2 of .06), at a statistical power of .80 and an alpha of .05, a total number of 38 participants (19 per trial arm) was deemed sufficient. However, to allow for attrition, a higher number of participants was recruited (Figure 1).

From the initial sample, 42 participants (20.8%) scored over the cut-off score for severe depression, 53 participants (26.8%) scored over the cut-off score for severe anxiety at pre-treatment.

A final sample of 95 adults (1 male, 94 female), from a non-clinical population, aged from 19 to 43 (Mean = 21.8, SD = 4.86) completed our trial.

Interventions

The experimental group (Woebot): Woebot is a fully automated, AI-powered conversational agent based on CBT principle, designed for non-clinical use. It provides users with daily conversations and mood tracking. Building upon users' replies to general questions about context and mood, the Woebot Health's Conversation Management System uses a modular approach to offer relevant psychoeducational materials and brief interventions, such as behavioral activation, mindfulness, cognitive restructuring, relaxation, gratitude journal

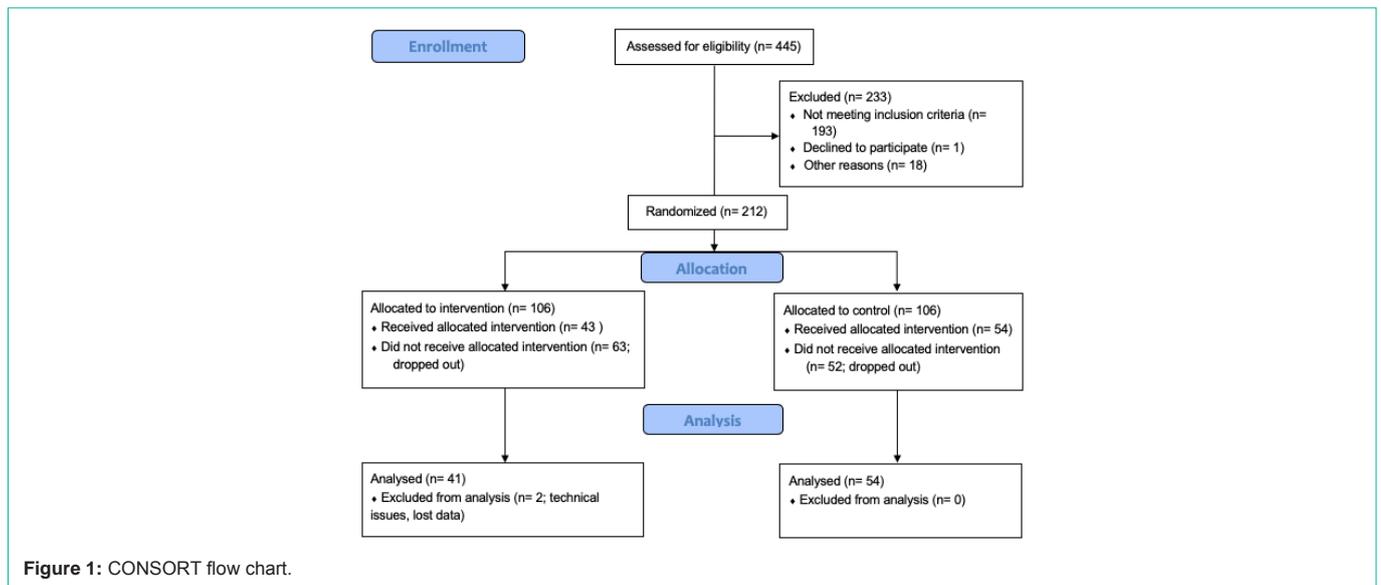


Figure 1: CONSORT flow chart.

and other. The app has been extensively described elsewhere [22,28].

Active control condition: In the active control condition, participants received a daily e-mail with a minimal psychoeducational intervention, consisting of mental health information sheets from the Centre for Clinical Interventions [29] and were asked to reply to questions (i.e., short pop-quizzes) from the materials provided. For example, on day 2, after reading the information sheet provided, participants were required to answer the following question: “What are the names of the evidence-based therapies mentioned in the Depression Information Sheet 03?”. They replied via e-mail and their response was logged if they provided the correct answer. The estimated daily time required for this task was 5 minutes.

Measures

The following demographic information was collected: age, gender, and educational level.

Anxiety and depression: To measure symptoms of anxiety and depression, the Depression, Anxiety and Stress Scales-DASS were used [30]. DASS is scored on a four-point scale (0 = never, 3 = very frequently). The Cronbach’s alpha for this study was .88 for depression and .82 for anxiety.

Transdiagnostic factors: Rumination was assessed with the Ruminative Responses Scale-RRS [31], a 22-item instrument using a four-point Likert scale (1 = almost never, 4 = almost always). The Cronbach’s alpha for this study was $\alpha = .93$.

Self-Compassion was assessed with the Self-Compassion Scale (SCS) [32], a 26-item instrument using a five-point Likert scale (1 = almost never, 5 = almost always). It assesses 6 components of self-compassion, with the following Cronbach’s alphas: Self-Kindness ($\alpha=.89$), Self-Judgment ($\alpha=.88$), Common Humanity ($\alpha=.84$), Isolation ($\alpha=.84$), Mindfulness ($\alpha=.84$) and Over-Identification ($\alpha=.81$).

Guilt and Shame were assessed using the 16-item Guilt and Shame Proneness Scale (GASP) [33]. GASP uses a 7-point Likert scale

(1 = very unlikely, 7 = very likely) and evaluates the following factors: Guilt-Negative-Behavior-Evaluation ($\alpha=.70$), Guilt-Repair ($\alpha=.51$), Shame-Negative-Self-Evaluation ($\alpha=.73$) and Shame-Withdraw ($\alpha=.46$). Lower reliability is expected in scenario-based measures as each item contains unique variance for the given scenario (e.g., [33-35]).

Intolerance of uncertainty was measured using the Intolerance of Uncertainty Scale (IUS) [36], a 12-item instrument using a five-point Likert (1 = not at all characteristic of me; 5 = entirely characteristic of me). The Cronbach’s alpha for this study was $\alpha = .91$.

Usability

The level of engagement in the intervention was assessed as follows: for the experimental condition (Woebot), the total number of interactions (i.e., moods recorded) with the bot over the 2-week period was recorded, as detailed earlier in 2.1. Recruitment and Procedure. For those in the control condition, the number of correct responses to the questions was recorded.

Statistical approach

To ensure that no pre-existing differences between the experimental groups could bias the results of the trial, independent samples t-tests were conducted for demographic variables, as well as the baseline levels of the primary and secondary outcomes were assessed with independent samples t-tests (i.e., for age, depression, anxiety, rumination, intolerance of uncertainty, self-compassion, guilt and shame) and chi-square analyses (i.e., for gender, engagement with an ongoing therapeutic process and the presence of a medical diagnosis, as assessed by a single self-report item). Differences between completers and drop-outs in terms of demographic variables and pre-treatment scores were also assessed using independent samples t-tests and chi-square tests.

To assess the interventions’ efficacy in reducing depression and anxiety - the primary outcomes of interest - 2 x 2 Repeated Measures ANOVAs were conducted on completers only, with time (i.e., pre-intervention vs. post-intervention) as a within-subject variable and

Table 1: Baseline characteristics.

	Group	Mean	SD	Percentage (Number)	χ^2 (df)	t (df)	p
Gender	Control	-	-	98.1% (53) female	.77 (1)	-	0.381
	Experimental	-	-	100% (41) female			
Engagement in therapy	Control	-	-	18.5% (10) yes	.25 (1)	-	0.616
	Experimental	-	-	14.6% (6) yes			
Medical diagnosis	Control	-	-	88.9% (48) no	2.80 (2)	-	0.247
	Experimental	-	-	97.6% (40) no			
Age	Control	22	5.19	-	-	.43 (93)	0.665
	Experimental	21.56	4.43	-			
Depression	Control	6.02	4.23	-	-	.32 (93)	0.748
	Experimental	5.71	5.18	-			
Anxiety	Control	5.33	4.46	-	-	-.09 (93)	0.993
	Experimental	5.34	4.31	-			
Rumination	Control	78.22	14.13	-	-	.19 (93)	0.845
	Experimental	77.59	17.55	-			
Intolerance of Uncertainty	Control	31.56	7.37	-	-	-.71 (68.34)	0.478
	Experimental	32.93	10.5	-			
Self-Compassion	Control	80.89	16.43	-	-	.42 (93)	0.671
	Experimental	79.39	17.65	-			
Guilt and Shame	Control	35.87	7.79	-	-	-.54 (93)	0.589
	Experimental	36.71	6.98	-			

group (i.e., Woebot *vs.* psychoeducation) as a between-subjects variable. Furthermore, to examine the effects of the Woebot app on the secondary outcomes, 3 x 2 Repeated Measures ANOVAs were conducted on completers only, with time (i.e., pre-intervention *vs.* mid-intervention *vs.* post-intervention) as a within-subject variable and group (i.e., Woebot *vs.* psychoeducation) as a between-subjects variables. Missing data were handled with the multiple imputation procedure [37], with data assumed to be missing at random. Consequently, intent-to-treat analyses were performed using ANCOVA on the post-treatment pooled scores for the primary and secondary outcomes with group as a factor and pre-treatment scores as covariates. Statistical corrections for homogeneity of variance and sphericity were applied where appropriate.

Results

Baseline measures and demographics

Independent samples t-tests showed that there were no significant differences at baseline between the group randomized to the experimental condition (Woebot) and the control condition, as detailed in Table 1.

Importantly, there was no significant difference in the number of participants dropping out of the experimental group *vs.* the control group (60 *vs.* 47), χ^2 (2) = 3.35, $p = .067$) although a trend favoring retention in the control group was observed.

Analyses indicated no differences between completers and non-completers on any of the variables (for the primary outcomes, i.e., depression and anxiety, and for the secondary outcomes, i.e., rumination, intolerance of uncertainty, self-compassion), with the

exception of gender, with males more likely to drop out (χ^2 (1) = 10.59, $p = .001$).

Primary outcomes

Completers' analyses revealed no significant interactions between group and time for the study's primary outcomes (Table 2). Additionally, no main effects of group were found for any of the primary outcomes: (a) depression, F (1, 93) = .61, $p = .435$; (b) anxiety, F (1, 93) = .02, $p = .874$. Main effects of time were also non-significant in the case of depression, F (1, 93) = .84, $p = .360$, but were significant for anxiety, F (1, 93) = 4.70, $p = .033$ partial $\eta^2 = .05$, revealing a decrease in time for both groups.

Secondary outcomes

No significant group by time interactions were found for the transdiagnostic factors (Table 2). There were no main effects for: (c) rumination, F (1, 93) = .15, $p = .696$; (d) intolerance of uncertainty, F (1, 93) = .51, $p = .473$; (e) self-compassion, F (1, 93) = .42, $p = .838$; (f) guilt and shame, F (1, 93) = .82, $p = .366$. Main effects of time were significant for (c) rumination, F (1.77, 165) = 3.22, $p = .048$, partial $\eta^2 = .03$; (d) intolerance of uncertainty, F (1.68, 156.50) = 10.22, $p < .001$, partial $\eta^2 = .10$; (e) self-compassion, F (1.63, 151.56) = 7.41, $p = .002$, partial $\eta^2 = .07$; (f) guilt and shame, F (1.60, 149.16) = 6.64, $p = .004$, partial $\eta^2 = .07$. These main effects of time revealed an increase in rumination and guilt and shame, but also in self-compassion, as well as a decrease in intolerance of uncertainty across the three time points (see Table 2 for means and standard deviations at post-intervention for the primary and secondary outcomes).

Intent to Treat (ITT)

ITT analyses revealed no significant effects of group on the

Table 2: Means and SDs at post-intervention and time X group interaction effects for primary and secondary outcomes in completers' analyses.

	Group	Mean	SD	95% CI	F	P
Depression	Control	5.96	5.31	4.58-7.33	0.65	0.423
	Experimental	4.88	4.76	3.30-6.45		
Anxiety	Control	4.5	4.24	3.34-5.65	0.09	0.767
	Experimental	4.24	4.3	2.92-5.56		
Rumination	Control	79.31	15.52	75.05-83.57	1.42	0.245
	Experimental	82.87	16.09	77.98-87.77		
Intolerance of Uncertainty	Control	28.98	8.4	26.44-31.52	0.13	0.977
	Experimental	30.2	10.56	27.28-33.10		
Self-Compassion	Control	83.27	17.49	78.66-87.89	1.45	0.238
	Experimental	85.78	16.49	80.48-91.07		
Guilt and Shame	Control	37.65	8.13	35.30-39.99	1.03	0.344
	Experimental	40.15	9.34	37.45-42.83		

Table 3: Means and standard error of means at post-intervention and main effects of group for primary and secondary outcomes in ITT analyses.

	Group	Mean	SE	95% CI	F	P
Depression	Control	6.23	0.67	4.81-7.65	1.03	0.313
	Experimental	5.76	0.84	4.00-7.53		
Anxiety	Control	4.86	0.51	3.84-5.88	0.12	0.735
	Experimental	4.56	0.54	3.47-5.66		
Rumination	Control	78.89	1.59	75.73-82.05	2.17	0.144
	Experimental	81.84	1.68	78.50-85.18		
Intolerance of Uncertainty	Control	29.45	0.85	27.78-31.13	0.01	0.92
	Experimental	29.06	0.85	27.39-30.73		
Self-Compassion	Control	83.08	1.67	79.75-86.40	1.97	0.163
	Experimental	84.45	1.9	80.60-88.30		
Guilt and Shame	Control	39.28	1.08	37.13-41.14	1.63	0.205
	Experimental	39.88	1.38	37.04-42.72		

primary and secondary outcomes (Table 3). Pooled means and standard error of means for the control and experimental groups at post-treatment when controlling for pre-treatment scores are also presented in Table 3.

Discussion

The current study examined the efficacy of a fully automated, AI-powered conversational agent (Woebot) in alleviating the symptoms of anxiety and depression in a non-clinical sample, compared to an active control who received psychoeducational materials. An additional aim of the study was to examine Woebot's *vs.* the psychoeducational intervention's effect on the transdiagnostic factors involved in the etiology and maintenance of depression and anxiety.

While both conditions showed changes over time, there were no significant differences in the primary outcomes (i.e., anxiety and depression,) between the two groups from pre-intervention to post-intervention, suggesting a lack of added efficacy associated with the experimental condition.

As far as the transdiagnostic factors were concerned, there were no significant group-by-time interactions, as well as no significant

effects of group, suggesting that the examined transdiagnostic factors are not mediators of treatment outcomes in this case. While there were no significant interactions, the results, however, did show a significant main effect of time on anxiety and transdiagnostic factors, suggesting that the experimental and the control condition were similarly beneficial. Across both groups, increases in rumination, self-compassion, guilt, and shame, as well as decreases in anxiety and intolerance of uncertainty were observed. As the participants in both groups appeared to show improvements in their anxiety levels as well as increases in self-compassion and decreases in intolerance of uncertainty, it is possible that both interventions contributed substantially towards these effects. However, this assertion is not fully supported by the increases in rumination, guilt, and shame. It is possible that, through psychoeducation, both interventions raised the participants' awareness of their mental symptoms, thus potentially increasing their tendencies to ruminate and become ashamed of them. Moreover, since both the experimental and active control conditions were focused on reflections on oneself, and given that guilt is a self-conscious emotion [38], it is also possible that participants were primed for the intensification of these emotions, especially since the data were collected during the ongoing COVID-19 pandemic,

which is associated with mental health consequences as yet not fully elucidated.

Our results also showed that there was a trend towards more dropouts in the experimental group. While non-significant, this difference could be linked to the fact that AI chatbots are still grappling with limitations in terms of content, with users reporting impersonal remarks, repetitions, misunderstandings, and lack of meaningful interactions [21], factors that can be associated negatively with retention.

To our knowledge, this is the first study to examine the efficacy of an AI-powered conversational agent compared to a non-passive control condition; however, no differential efficacy was found. This suggests that the psychoeducational components in both conditions were the only significant drivers of the improvement. This, in turn, suggests that simple methods, such as regular emails sent to people, may be enough to obtain the same therapeutic benefits as technically sophisticated solutions, which, in most cases, incur substantial development and maintenance costs, which are passed to the consumers.

Strengths and Limitations

The present study adds to the body of evidence regarding the efficacy of AI-powered conversational agents on emotional disorders and attempts to shed light on the effects of such an agent on the transdiagnostic factors associated with depression and anxiety.

Despite the intriguing results we obtained, the study also has several important limitations. First, it was not possible to track the time spent in-app engaging with Woebot with high precision, because our participants had different mobile operating systems, which made this impractical or impossible. Therefore, we relied solely on the check-in diagram completed by the participants to assess treatment adherence (at least one check-in daily), which approximated their app usage. Second, we conducted our study on a non-clinical sample, drawn from the general population. While previous studies on conversational agents also used non-clinical samples e.g., [22], future studies should try to examine these relationships on clinical samples, in order to draw more definite conclusions regarding the efficacy of such solutions in reducing symptoms of anxiety and depression. Third, an almost exclusive female sample was examined, which makes the generalization of these findings to males questionable.

Future studies should incorporate these limitations and, also, include other AI-powered conversational agents, to better understand their efficacy in relation to simple interventions such as regular psychoeducational materials delivered to the inboxes.

Comparison with Prior Work

In contrast to results from a previous study [22], using an AI-powered chatbot was not associated with a more significant reduction in self-reported symptoms of anxiety and depression than a control condition. Unlike previous studies, our research included an active control condition, to better evaluate the potential benefits of a conversational agent in reducing symptoms of depression and anxiety.

Conclusion

Our findings support and expand on previous studies e.g., [39],

which found that the effects of web-based interventions are smaller when compared to active, as opposed to passive controls. In our study, we found that employing a simple form of active intervention (emails requiring an answer) is comparable in benefits to a fully automated, AI-driven chatbot. Further research is needed to better understand the areas where automated bots might have an edge over simpler, potentially more economical interventions.

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