# A randomized controlled feasibility trial of internet-delivered guided self-help for GAD among university students in India

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## Declaration of Interest

Megan Jones Bell was employed by Lantern (the guided self-help program used here) when this study was conducted but has no current financial ties to the company as she left her employment there. However, she was not involved in consenting participants, collection of outcome data, or data analysis of any sort. Michelle G. Newman and C. Barr Taylor were unpaid consultants for Lantern. After data collection was completed, Lantern ceased operations and thus nobody involved in the study has any financial interest in Lantern.

## Author Contributions

Michelle G. Newman, Nitya Kanuri, and C. Barr Taylor were involved in the design of the study, recruitment of participants, coach training, running of the study and writing of the manuscript. Megan Jones Bell contributed to the design of the study and oversaw the integrity of the website. Gavin Rackoff and Nicholas Jacobson conducted data analysis and contributed to writing of the manuscript.

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Abstract

**Background:** Online guided self-help may be an effective and scalable intervention for symptoms of generalized anxiety disorder (GAD) among university students in India. **Methods:** Based on an online screen for GAD administered at four Indian universities, 222 students classified as having clinical (DSM-5 criteria) or subthreshold (GAD-Q-IV score ≥ 5.7) GAD were randomly assigned to receive either three months of guided self-help cognitive-behavioral therapy ($n$ = 117) or a waitlist control condition ($n$ = 105). **Results:** Guided self-help participants recorded high program usage on average across all participants enrolled ($M$ = 9.99 hours on the platform; $SD$ = 20.87). Intent-to-treat analyses indicated that participants in the guided self-help condition experienced significantly greater reductions than participants in the waitlist condition on GAD symptom severity ($d$ = -0.40), worry ($d$ = -0.43), and depressive symptoms ($d$ = -0.53). No usage variables predicted symptom change in the guided self-help condition. Participants on average reported that the program was moderately helpful, and a majority (82.1%) said they would recommend the program to a friend. **Conclusions:** Guided self-help appears to be a feasible and efficacious intervention for university students in India who meet clinical or subthreshold GAD criteria. The trial is registered with ClinicalTrials.gov (NCT02410265).

Keywords: Internet intervention, India, generalized anxiety disorder, university students

**Clinical Impact Statement**

**Question:** Can internet-delivered, guided self-help be used to treat generalized anxiety disorder symptoms among university students in India?
**Findings:** Participants who received guided self-help recorded high levels of program usage and had significantly greater symptom reductions than participants in the waitlist control group.
**Meaning:** Internet-delivered, guided self-help appears to be an efficacious and feasible method for treating generalized anxiety disorder symptoms in India's university student population.
**Next Steps:** Research should evaluate the feasibility and efficacy of internet-delivered guided self-help for university students in India delivered at a larger scale and in comparison to existing treatment options.

# A randomized controlled feasibility trial of internet-delivered guided self-help for GAD among university students in India

Generalized anxiety disorder (GAD) is common among university students, with an estimated twelve-month prevalence of 16.7% worldwide, based on self-reported diagnostic criteria (Auerbach et al., 2018). The high prevalence of GAD among university students is also found in India, where reported prevalence rates range from 8% to 19% (Kanuri, Taylor, Cohen, & Newman, 2015a; Sahoo & Khess, 2010). Subthreshold levels of GAD symptoms are even more common among university students in India (i.e., up to 39.4%; Kanuri et al., 2015a). University students worldwide often face academic pressures, social stress, and financial strain, each of which may make this population vulnerable to mental health problems such as GAD (Sheldon et al., 2021). Especially relevant risk factors for GAD in India include pressure to succeed academically, which is reported by a majority of students in India (Deb et al., 2016), as well as hazing between senior and junior students (also termed "ragging"; Garg, 2009). Left untreated, mental disorder symptoms during typical college ages of 18-24 are a leading cause of lower educational attainment, years lost due to disability, physical health problems, and suicidality (Ettner, Frank, & Kessler, 1997; Kessler, Walters, & Forthofer, 1998; Lee et al., 2009; Ormel et al., 2008; Smit et al., 2006; Wittchen et al., 2002). Additionally, untreated symptoms become more severe and persistent over time (Wang et al., 2005). Thus, providing efficacious treatment for GAD symptoms among university students in India is a public health imperative.

Unfortunately, India's mental healthcare infrastructure is not equipped to meet the need for treatment among university students. India has approximately 5,000 mental health professionals in its population of 1.2 billion, or roughly 1 mental health professional per 250,000 people (Fairburn & Patel, 2014). The scarcity of mental health treatment is salient among

university students, where only 1.6% of students in a survey across 86 institutions reported receiving counseling (Task Force for Ministry of Human Resource Development, 2012). Another study of 3,232 students from four Indian universities found that although 9.9% reported a need for help from a mental health professional, only 1.1% had received it (about 11% of those who identified a problem; Newman et al., 2016). With about 28.5 million people enrolled in post-secondary education in India (Choudaha, 2017), these data suggest that at least 6.2 million college students in India need mental health treatment, yet at least 5.5 million do not receive it. Thus, the projected number of students in India who need treatment far outstrips the number of treatment providers.

Beyond the shortage of mental health professionals, students in India also report concerns about stigma and confidentiality, which might reduce their willingness to seek treatment (Menon, Sarkar, & Kumar, 2015; Newman et al., 2016). Thus, adding providers may not fully close the treatment gap. Smartphone-accessible, internet-delivered self-help programs could be an efficient alternative to in-person treatment (Kumar et al., 2013) and reduce concerns about stigma (Newman, Szkodny, Llera, & Przeworski, 2011). Smartphone use is pervasive among college students (Harris Poll, 2015), and in 2018 India had the world's fastest growing and second largest overall national population of smartphone users (GSMA, 2019). A population-level approach would ideally address mental health problems using widely available mobile tools (Mohr, Cheung, Schueller, Hendricks Brown, & Duan, 2013).

Internet-delivered self-help based on cognitive-behavior therapy (CBT) principles is a promising method to provide mental healthcare to university students in India. In developed countries, internet-delivered CBT self-help interventions have proven efficacious for treating symptoms of GAD (Linardon, Cuijpers, Carlbring, Messer, & Fuller-Tyszkiewicz, 2019). More

intensive “guided” self-help interventions, in which a coach provides support via messaging and/or phone, have proven especially effective (Kanuri, Newman, & Taylor, 2014; Newman et al., 2011). Online interventions may therefore address the treatment gap in Indian universities by delivering evidence-based care at scale and in private. Preliminary focus group research in a non-clinical sample suggested that university students in India found an online CBT platform user-friendly (Kanuri et al., 2020), though no study has quantitatively evaluated the feasibility or efficacy of delivering online guided self-help for GAD symptoms among students in India.

The purpose of this study was to test the feasibility and efficacy of online guided self-help treatment for GAD symptoms among university students in India. We collaborated with four Indian universities, as well as a team of mental healthcare providers in India, to administer an online mental health screen and randomized controlled trial (RCT). Participants who screened positive for subthreshold or clinical levels of GAD were randomly assigned to receive an online intervention or a waitlist control condition, and then they were invited to report on mental health symptoms three months later. To study the feasibility of the intervention, we examined levels of program usage among participants who received the guided self-help intervention, as well as the proportion of participants in each condition who completed post-treatment measures. We also attained information on helpfulness of the program from a subsample of the students. To study the efficacy of the intervention, we compared reductions in GAD severity, worry, and depressive symptoms among students who received the guided self-help intervention and students in the waitlist control condition from pre-treatment to post-treatment. We predicted that the guided self-help intervention would result in greater reductions in GAD symptom severity, worry, and depressive symptoms after three months of treatment, compared to the waitlist control condition.

We also conducted exploratory analyses to test whether any program usage variables predicted symptom change from pre-treatment to post-treatment in the intervention group.

## Method

### Participants

Students with clinical or subthreshold levels of GAD symptoms were recruited from four campuses of the Birla Institute of Technology and Science (BITS; Pilani, Dubai, Goa, Hyderabad). Initially, participants were recruited for a three-arm parallel randomized controlled trial comparing guided and unguided self-help interventions to a waitlist control condition. However, data monitoring suggested poor adherence in the unguided self-help condition, and therefore this arm of the trial was discontinued. Given its small sample ($n$ = 31) and differential recruitment methods, we have omitted the unguided self-help condition from the analyses and discussion here. Nonetheless, a description of the intervention and descriptive statistics for this discontinued unguided self-help arm of the trial are reported in the Supplementary Materials. The resulting sample for the present study therefore consisted of 222 participants who were randomly assigned to receive either Lantern, a guided, internet-based self-help intervention for GAD symptoms, or a waitlist control condition.

A summary of participant flow is presented in Figure 1. Of the 222 participants randomized to the guided self-help or waiting list control conditions, 17 (7.7%) were recruited from BITS-Pilani, 34 (15.3%) from BITS-Dubai, 66 (29.7%) from BITS-Goa, and 105 (47.3%) from BITS-Hyderabad. Full GAD criteria were met by 141 participants (63.5%), and the remaining 81 participants (36.5%) had subthreshold GAD. The sample consisted of 153 males (68.9%), 68 females (30.8%), and one trans female. The mean age was 19.90 years ($SD$ = 1.56, range = 18-30). At least intermediate English fluency was reported by 213 participants (95.9%).

Eight participants (3.6%) were taking medication for anxiety or depression at baseline. There were no significant differences between the guided self-help and waitlist control conditions in terms of any demographic variable (all *p*s > .05; see Table 1 for demographics by condition).

**Procedure**

This study was approved by an Institutional Review Board and governing bodies at each participating college. All participants consented to the study. The protocol is registered with ClinicalTrials.gov (NCT02410265). A researcher delivered presentations about the study at each university. Next, a link to an online screening survey was emailed to all students and posted in social media groups. Screening survey responses were used to determine study eligibility.

Eligible participants were aged 18 or older, provided their email address, consented to participate, and met criteria for clinical or subthreshold GAD. GAD status was measured by the Generalized Anxiety Disorder Questionnaire, 4th edition (GAD-Q-IV; Newman et al., 2002) which assesses the complete criteria for GAD as outlined in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5; American Psychiatric Association, 2013). Subthreshold GAD status was determined from scores above 5.7 on the GAD-Q-IV without fulfilling all GAD diagnostic criteria (Kanuri et al., 2015a). Participants were excluded if they were not interested in using the program, were receiving psychotherapy, or scored above 37 on the Posttraumatic Stress Disorder Checklist-5, indicating probable posttraumatic stress disorder (Blevins, Weathers, Davis, Witte, & Domino, 2015; Bovin et al., 2016).

Within four weeks of screening, participants were randomized using a stratified block design, with stratification by diagnostic status (clinical or subthreshold) and a block size of 6 to one of three conditions: guided self-help, unguided self-help, or waitlist control. Allocation was administered by the study coordinator using a web-based randomizer. As noted above, because

of low unguided self-program program usage, we ceased allocation to this arm and thereafter randomized participants to either the guided self-help or waitlist control conditions. Students in the guided self-help condition had intervention access for three months. Participants meeting GAD criteria at the end of the intervention were provided a list of free online resources. Students completed pre- and post-treatment measures using a Qualtrics link provided via email. Please see the study protocol published by Kanuri et al. (2015b) for risk management details. Data collection took place from February 2015 through September 2016.

**Guided Self-Help Intervention.** The intervention was accessible via any Internet-enabled computer, mobile phone, or tablet. The program was based on an empirically supported CBT protocol for GAD (Newman, 1999; Newman, Consoli, & Taylor, 1999; Newman, Przeworski, Consoli, & Taylor, 2014). Content was divided into eight units including five sessions each, resulting in up to 40 10-minute sessions. The units included an introduction to anxiety, automatic thoughts, cognitive reframing, introduction to behavior change, imaginal exposure, situational exposure, mindfulness, and habit formation. Each session appeared to users as a brief agenda with a list of exercises to be completed in the session (typically one "check-in" self-monitoring exercise, one didactic psychoeducation exercise, and one skill practice exercise). For example, one session included (1) an anxiety check-in exercise, (2) an introduction to relaxation psychoeducation exercise, and (3) a progressive muscle relaxation practice exercise. Thus, each session contained multiple pages of content. Starting a session would take users through the exercises contained therein.

Users could access up to one new session per day, and new sessions were only unlocked following the completion of the preceding session. Once unlocked, sessions and the individual exercises therein remained available for users to revisit. There was no expectation that users

needed to access or complete all or even a majority of the sessions available; therefore users were free to either access new content or revisit content they had previously found helpful.

Each intervention user was paired with a coach. Coaches were 27 mental health professionals in India with at minimum six months previous supervised counseling experience. Prior to working with users, coaches completed a six-week training course. The first two weeks of the training course comprised lectures from the first and last author of this paper on CBT for GAD, reading a GAD CBT manual used in a number of prior RCTs (e.g., Borkovec & Costello, 1993; Borkovec, Newman, Pincus, & Lytle, 2002), a book chapter on components of CBT, and an overview of how GAD CBT components were implemented in the online program. The third week comprised a review session, as well as a mid-training assessment of coach progress. The fourth week comprised education on CBT for anxiety disorders that are often comorbid with GAD (social phobia and panic disorder), including reading relevant book chapters and empirically supported treatment manuals. The fifth week comprised focused training on content in the guided self-help program, coach protocols including risk management, and practicing sending and responding to messages and having phone calls with mock users. The final week comprised a review of coach protocols, additional coaching practice exercises, and a final assessment of coaches' progress.

Once assigned to users, coaches sent messages to users at least once per week via a messaging portal to provide support, answer questions, and encourage intervention completion. Coaches also offered a phone call at the start, mid-point, and end of the program. Coaches received at minimum one hour of weekly supervision and could consult with each other using an online listserv. Coaches were expected to spend no more than 15 to 20 minutes weekly per user. Content of all coaches' messages was also overseen by the second author and an advanced

graduate student.

**Waitlist Control Condition.** Students in the waitlist control condition completed surveys three months after being randomized to the waitlist. Waitlist control participants were offered online self-help GAD treatment resources one year after enrolling in the study.

## Measures

The screening measure for study inclusion and primary outcome measure was GAD severity as indicated by the Generalized Anxiety Disorder Questionnaire, 4th edition (GAD-Q-IV; Newman et al., 2002). The GAD-Q-IV assesses complete diagnostic criteria for GAD in the DSM-5 (American Psychiatric Association, 2013). The GAD-Q-IV can be scored dimensionally based on a sum total of item responses or categorically to indicate whether a respondent fulfills all diagnostic criteria for GAD. The dimensional scoring has strong convergent and divergent validity among college students, and the cutoff of 5.7 for high GAD risk demonstrated high specificity and sensitivity, as well as strong two-week test-retest reliability (Cohen's kappa = .64; Newman et al., 2002). Cronbach's alpha for the dimensional GAD-Q-IV was .79.

Secondary outcomes included worry assessed by the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) and depressive symptoms assessed by the Depression Anxiety Stress Scales Short Form (DASS) depression subscale (Antony, Bieling, Cox, Enns, & Swinson, 1998). Both measures have strong construct validity (Brown, Antony, & Barlow, 1992; Brown, Chorpita, Korotitsch, & Barlow, 1997; Henry & Crawford, 2005). Cronbach's alpha was .90 for the PSWQ and .87 for the DASS depression subscale.

Additional secondary outcome measures were administered to assess acceptability and satisfaction with the intervention at post-treatment among participants in the guided self-help group. Participants completed a six-item questionnaire asking how helpful they found the

intervention for (1) learning about anxiety and stress, (2) teaching tools and techniques to manage anxiety and stress, (3) feeling in control of anxiety and stress, (4) tracking anxiety and stress symptoms over time, (5) overcoming mental health stigma and feeling comfortable seeking help, and (6) providing a way to openly express experiences. Each item was rated on a five-point scale (0 = *Not at all helpful*, 1 = *Slightly helpful*, 2 = *Moderately helpful*, 3 = *Very helpful*, 4 = *Extremely helpful*). The six items demonstrated high internal consistency (Cronbach's alpha = .92), and each participant's score across the six items was averaged to provide a summary helpfulness rating. Participants in the guided self-help group were also asked if they would recommend the program to a friend. We computed the percentage of participants who said they would recommend the program to a friend.

Within the guided self-help group, we also computed the following usage characteristics for each participant: number of visits to the program, total time spent logged in to the program, number of sessions completed, number of exercises (i.e., check-in, psychoeducation, or skill practice exercise) completed, number of messages received from coach, number of messages sent to coach.

**Sample Size Estimation**

We aimed to recruit at least 100 participants per condition. A Monte Carlo study with 500 simulations in the *R* package *SIMR* (Green & MacLeod, 2016) suggested that the achieved sample of 222 participants provided 82.2% power to detect a small- to medium-sized (Cohen's *d* = 0.35) difference in symptom change from pre-treatment to post-treatment across the treatment and control groups.

**Data Analyses**

To examine the feasibility of guided self-help, we computed descriptive statistics for each

of the program usage variables in the guided self-help group. We also computed the percentage of participants in each condition who completed post-treatment assessments. Furthermore, we tested if treatment condition (guided self-help or waitlist control), demographic variables, and guided self-help program usage variables predicted rates of post-treatment assessment completion using logistic regression.

To compare symptom change across conditions, we conducted multilevel models in the *R* package *lme4* (Bates, Mächler, Bolker, & Walker, 2015). Multilevel models accommodate nested data structures (e.g., repeated measurements nested within participants). To determine if it was necessary to model an additional level of nesting of guided self-help participants within coaches, we fit a three-level model of GAD-Q-IV scores with a fixed intercept and a fixed effect of time, as well as random effects for the intercept at the participant level and the coach level. This model had an intraclass correlation of .314 at the participant level and .007 at the coach level, indicating that almost one third of the variance in GAD-Q-IV scores was accounted for by the nesting of repeated measures within participants, but less than 1% of variance was accounted for by nesting of participants within coaches. Due to the trivial amount of coach-related variability, we chose to use two-level models for the analyses of efficacy.

Models included random effects varying across participants for the intercept, as well as fixed effects for the intercept, time (pre-treatment to post-treatment), treatment condition (guided self-help or waitlist control), and the interaction between time and treatment condition. Simple slopes analyses were used to examine symptom change from pre-treatment to post-treatment within each condition. Separate models were fit for each outcome measure. In exploratory multilevel models, we also tested whether each usage variable predicted change in the primary outcome measure (GAD-Q-IV) from pre-treatment to post-treatment, with each usage variable

examined in a separate model. Models included random effects for the intercept and fixed effects for the intercept, time (pre-treatment to post-treatment), usage variable (time spent on program, visits to program, sessions completed, exercises completed, messages sent to coach, or messages received from coach), and interaction between time and usage variable.

All symptom change analyses were intent-to-treat (i.e., all participants were included, regardless of amount of guided self-help program usage or post-treatment assessment completion). Cohen's *d* was calculated from *Z* statistics as: $\frac{2(\frac{Z}{\sqrt{N}})}{\sqrt{1-(\frac{Z}{\sqrt{N}})^2}}$ (Rosenthal & DiMatteo, 2001). For analyses of symptom change from pre-treatment to post-treatment, missing data were handled using multilevel multiple imputation in the *R* package *mice* (van Buuren & Groothuis-Oudshoorn, 2011). We imputed missing values using observed associations among outcome measures as well as associations with several auxiliary variables. Auxiliary variables included time, treatment condition, the interaction between time and treatment condition, age, gender, baseline GAD status, and college attended. Inclusion of auxiliary variables in this manner improves efficiency and reduces bias resulting from missing post-treatment data (Collins, Schafer, & Kam, 2001). We generated 50 datasets and pooled results using Rubin's (1987) rules. To ensure that the missing data handling method did not affect statistical inferences, we also conducted alternative versions of the symptom change analyses in which missing data were handled (1) using full information maximum likelihood (FIML) as implemented in the *R* package *lme4* (Bates et al., 2015) and (2) using complete case analyses only incorporating participants who provided data at post-treatment. Please note that all inferences were identical regardless of the missing data approach used. Therefore, multiple imputation results are reported in the main text, and FIML and complete case results are reported in the Supplementary Materials.

## Results

**Guided Self-Help Program Usage**

Within the treatment group, participants spent an average of 9.99 hours using the program (*SD* = 20.87) and averaged 70.85 total visits to the platform (*SD* = 130.49). Participants completed an average of 9.12 treatment sessions (*SD* = 14.39) and an average of 29.83 individual exercises (*SD* = 47.07). Participants sent an average of 10.99 messages to the coach (*SD* = 17.71) and received an average of 23.79 messages (*SD* = 23.36). Thus, overall usage was high, though users on average completed a minority of the 40 possible treatment sessions.

**Post-Treatment Assessment Completion**

As noted in Figure 1, 41% of treatment participants and 39% of waitlist participants provided post-treatment data. Participants who completed the post-treatment measures scored significantly lower on the GAD-Q-IV at pre-treatment (*M* = 8.79, *SD* = 2.05) than those who did not (*M* = 9.52, *SD* = 1.66, *Z* = -2.82, *p* = .005, *d* = -0.39). Participants who completed the post-treatment assessment were also more likely to attend BITS-Hyderabad than BITS-Dubai (*ß* = 1.00, *SE* = 0.43, *Z* = 2.30, *p* = .021, *d* = 0.31). No other variables at baseline (including treatment condition) predicted post-treatment assessment completion (all *p*s > .05). Beginning March 2016, in an effort to shorten survey duration and improve survey completion, the helpfulness and recommendation to a friend questionnaires were removed from the post-treatment survey. As a result, only 26 participants in the treatment group (22.2%) completed the helpfulness questionnaire, and 28 participants (23.9%) completed the recommendation to a friend question. This represented a little over half of the participants who completed the post-treatment measures.

Within the treatment group, post-treatment assessment completion was associated with recording more visits to the program (*M* = 103.28, *SD* = 119.49 among assessment completers vs. *M* = 47.40, *SD* = 133.93 among assessment non-completers; *Z* = 2.027, *p* = .042), completing

more treatment sessions (*M* = 15.85, *SD* = 18.28, vs. *M* = 4.26, *SD* = 7.84, *Z* = 3.543, *p* < .001), completing more exercises (*M* = 50.83, *SD* = 59.63 vs. *M* = 14.65, *SD* = 26.99; *Z* = 3.482, *p* < .001), sending more messages to the coach (*M* = 16.83, *SD* = 21.87 vs. *M* = 6.77, *SD* = 12.54; *Z* = 2.588, *p* = .010), and receiving more messages from the coach (*M* = 32.43, *SD* = 26.65 vs. *M* = 17.54, *SD* = 18.47; *Z* = 2.987, *p* = .002). However, total hours of guided self-help usage did not significantly predict post-treatment assessment completion (*M* = 13.72, *SD* = 16.78 vs. *M* = 7.30, *SD* = 23.13; *Z* = 1.460, *p* = .144). Thus, some metrics of guided self-help program usage were associated with a greater probability of providing post-treatment data in the treatment group. However, even participants who did not provide post-treatment data recorded substantial program usage, suggesting that they still received a nontrivial dose of the treatment.

**Treatment Efficacy**

Descriptive statistics for pre-treatment and post-treatment symptoms are presented in Table 2. At pre-treatment, there were no significant differences between the treatment and control groups on any symptom measure (all *p*s > .05). In multilevel models of symptom change from pre-treatment to post-treatment, there were significant interactions between time and treatment condition in the prediction of GAD-Q-IV scores (*ß* = -1.33, *SE* = 0.45, *Z* = -2.92, *p* = .004, *d* = -0.40), PSWQ scores (*ß* = -8.04, *SE* = 2.56, *Z* = -3.14, *p* = .002, *d* = -0.43), and DASS depression scores (*ß* = -3.90, *SE* = 1.02, *Z* = -3.83, *p* < .001, *d* = -0.53). Simple slope analyses indicated that participants in the treatment group experienced significant reductions on the GAD-Q-IV (*ß* = -3.27, *SE* = 0.31, *Z* = -10.44, *p* < .001, *d* = -1.96), PSWQ (*ß* = -7.66, *SE* = 1.73, *Z* = -4.43, *p* < .001, *d* = -0.62), and DASS depression (*ß* = -3.65, *SE* = 0.70, *Z* = -5.24, *p* < .001, *d* = -0.75). Participants in the control group experienced a significant yet smaller reduction on the GAD-Q-IV (*ß* = -1.94, *SE* = 0.33, *Z* = -5.91, *p* < .001, *d* = -0.84) and did not experience

significant reductions on the PSWQ (*ß* = 0.37, *SE* = 1.91, *Z* = 0.20, *p* = .841, *d* = 0.03) or DASS Depression (*ß* = 0.25, *SE* = 0.79, *Z* = 0.32, *p* = .753, *d* = 0.04). Therefore, participants who received guided self-help experienced moderate to large reductions in GAD symptoms, worry, and depressive symptoms, and these symptom reductions were larger than those experienced by participants in the waitlist control group. In exploratory models, none of the treatment usage variables significantly predicted symptom change from pre-treatment to post-treatment in the treatment group (all *p*s > .05; please see Table 3 for complete results).

### Treatment Satisfaction and Acceptability

Among the 26 guided self-help participants who completed the helpfulness survey at post-treatment, the average helpfulness rating was 2.01 (*SD* = 1.03). Thus, participants on average found the program moderately helpful. Among the 28 guided self-help participants who responded to the treatment recommendation question, 23 (82.1%) said they would recommend the program to a friend. Thus, a large majority of responders found the program satisfactory inasmuch as they would recommend the program to a friend.

## Discussion

This study examined the feasibility and efficacy of an internet-based guided self-help intervention for GAD symptoms among university students in India. Students in the intervention condition recorded nearly ten hours of program access across approximately 70 visits, indicating high program usage. There was a low rate of post-treatment assessment completion, with only 40.1% of participants providing data in the post-treatment survey. Notwithstanding this result, the intent-to-treat efficacy analyses indicated that, compared to the waitlist control condition, participants who received the intervention experienced significantly larger reductions in GAD severity, worry, and depressive symptoms from baseline to post-treatment. Furthermore,

satisfaction and acceptability data indicated that treatment group participants found the program at least moderately helpful, and the majority would recommend the program to a friend. Thus, results provided preliminary support for the feasibility and efficacy of internet-based guided self-help for GAD symptoms among university students in India.

The usage analyses indicated that participants recorded a substantial number of visits and time spent on the program. It is worth noting that we expected each session to require approximately 10 minutes to complete, though despite spending an average of nearly 10 hours on the program, users completed an average of 9.12 sessions out of 40 possible. Thus, sessions might have required greater time than we expected for users to complete. However, given that users on average received 23.79 messages from the coach, visited the program 70 times, and completed 29.83 exercises on the program, the data also suggested that some of users' visits could have been spent viewing coach messages or repeatedly practicing individual exercises without accessing entire sessions. These data also suggested that users accessed the full range of features in the program (i.e., both treatment sessions and coach support). Notably, users of online programs rarely access the entirety of the available content, potentially owing to the less structured nature of online programs versus in-person psychotherapy. For example, in a meta-analysis, Karyotaki et al. (2015) found that 59% of users of online programs for depression completed fewer than half of treatment modules. In addition, in an analysis of real-life digital self-help Fleming et al. (2018) found that from 5% to 28.6% of users completed the program. Furthermore, in our study, none of the usage characteristics predicted change in GAD severity. Our data therefore did not indicate that greater program usage corresponded to better outcomes. This finding converges with other research suggesting that no single pattern of program usage was associated with better outcomes (Arndt et al., 2020). Of note, research on psychotherapy for

GAD has indicated that, for some people, repeated practice of fewer skills generates greater symptom reduction than instruction in a broad variety of techniques (Newman & Fisher, 2013; Newman, Shin, & Lanza, 2019). Analogously, in guided self-help, some users could have benefited from repeated practice of individual exercises rather than broad practice across the full range of sessions. Thus, results suggested generally high usage, though more research should identify usage factors that predict outcomes for particular groups of participants.

At the same time, it is possible that we could have designed some strategies to improve program usage. Studies on ways to improve usage of digital apps suggest that strategies that make use of persuasive design features (e.g., reduction of complexity of the program to simple tasks, efforts to personalize the content, delivering the program in specific sequences, promoting rehearsal of strategies, peer support) and/or behavioral economic strategies (paying participants, providing points for use) can increase engagement and usage (Wu et al., 2021). The current program did include some persuasive design strategies (e.g., reduction of complexity of the program to simple tasks, delivering the program in specific sequences, coach support and coach personalization). However, additional strategies might have been helpful. For example, we could have provided weekly lotteries to improve engagement. We also could have included weekly feedback on user metrics of use compared to the desired metrics and/or compared to individuals whose anxiety was being reduced. Furthermore, it might have been helpful if the digital program content was personalized to the individual or adapted based on the individual's use patterns.

A challenge in the present study was the dissemination of a CBT app that was developed and marketed in North America. The delivery of this app outside of a Western country raises the possibility that language or cultural barriers could have affected the extent to which users accessed, engaged, and benefited from the treatment. To attempt to overcome some of these

barriers, the coaches who led users through intervention content in the present study were mental health professionals recruited directly from India. The use of India-based coaches provided users with guides who were knowledgeable of CBT principles and the use of the app but who also shared a similar cultural background. The coaches were encouraged to make use of their cultural knowledge in their messages and for any examples they might use to help make the program understandable and personally relevant to users. Furthermore, at the Indian universities in the present study and many other universities in India, English was the primary language of instruction, and 95.9% of the current sample reported at least intermediate English fluency, suggesting that the university student population had the English language skills to grasp the intervention content. Post-treatment data on a subsample of users suggested that they generally found the program moderately helpful, and a large majority of them would recommend the program to a friend, indicating good satisfaction with and acceptability of the treatment, despite its development outside of India.

Although we made several efforts to optimize the intervention for the student population in India, several further steps could have been taken to culturally adapt the intervention. For example, it could be helpful to make greater efforts to integrate the philosophy of CBT with the worldviews of India's student population. The psychotherapy literature has highlighted that traditional and third-wave CBT overlap in several ways with teachings of Hinduism and Islam, the two most common religions in India (Beshai, Clark, & Dobson, 2013; Bhatia, Madabushi, Kolli, Bhatia, & Madaan, 2013). Coach training was designed to maximize coaches' knowledge of CBT principles and the intervention technology, though additional time spent training coaches more explicitly on methods of framing CBT principles in terms that were consistent with clients' worldviews might have improved usage and outcomes of the treatment. It might have also been

helpful to conduct focus groups and theatre testing to get feedback from student users on how to improve the program and/or how to make it feel more culturally relevant (e.g., Kanuri et al., 2020). Collecting such data and experimenting with aspects of the coach role (e.g., frequency of messages, explicit homework provided by coach) could reveal methods for optimizing online programs for students in India. The results of this trial suggested that guided, internet-delivered CBT self-help is a promising anxiety intervention for students in India, and exploring further methods of cultural adaptation is critical to optimize usage and outcomes.

There was also a low rate of post-treatment assessment completion, with only 40.1% of participants providing data for the three-month assessment. Although internet-delivered self-help trials average low rates of post-treatment assessment completion (around 65%), the rate of post-treatment assessment completion in the present study was within the lower bound of previously published rates, as reported in a recent meta-analysis (Linardon & Fuller-Tyszkiewicz, 2020). Of note, our intent-to-treat efficacy analyses included all participants regardless of post-treatment assessment completion, and efficacy results were consistent regardless of the method used to handle missing data. Moreover, even treatment group participants who did not provide post-treatment data recorded moderate levels of guided self-help usage (e.g., an average of 7.30 hours on the program across 47.70 visits), indicating that they likely still received a minimally necessary dose of treatment. Thus, we believe the post-treatment data from the present study still provided valuable information. In prior internet intervention research, paying participants for completing post-treatment assessments, as well as having direct contact between researchers and participants (e.g., phone calls to help participants sign up for the intervention) were associated with greater rates of post-treatment assessment completion (Linardon & Fuller-Tyszkiewicz, 2020); the present study did not employ these methods, which could account for the low rate of

assessment completion. For innovative methods to improve post-treatment assessment rates, future research in the Indian student population could also seek input from university stakeholders regarding what they believe would motivate participation. It might also be helpful to involve the Indian coaches in motivating post-treatment assessment adherence and/or in sending a personalized message.

Analyses of symptom change from pre-treatment to post-treatment indicated that participants receiving guided self-help experienced greater reductions in GAD severity, worry, and depressive symptoms from pre-treatment to post-treatment than participants in the waitlist control condition. The effect sizes for these comparisons were in the medium range (-0.40 to -0.53), which correspond closely to effect sizes observed in other RCTs of smartphone-accessible CBT-based interventions for GAD symptoms (pooled effect size of 0.42; Linardon et al., 2019). Moreover, effect sizes within the treatment group indicated large reductions in GAD symptoms among those receiving guided self-help. These results, and the similarity of effect sizes with prior research conducted outside India, suggested that guided self-help could be an efficacious method of treating GAD symptoms among university students in India. These results are promising given the need for effective interventions that expand access to treatment without burdening India's existing workforce of mental health professionals (Fairburn & Patel, 2014), such as by using widely available resources like smartphones (GSMA, 2019). Thus, larger-scale delivery of internet-based guided self-help could have a significant public health impact in India. Additional methods to inform efficacy in future RCTs include measuring symptoms at a longer-term follow-up and comparing guided self-help to an active control condition (e.g., in-person psychotherapy, supportive text messaging). These methods are critical to examine the durability

of symptom reductions, as well as the efficacy and cost-effectiveness of guided self-help relative to existing treatment options.

Several limitations of the present study should be noted. We initially planned to examine an additional unguided self-help treatment, though due to low adherence in the unguided self-help arm of the trial, allocation to this condition was terminated. Additionally, although we used intent-to-treat analyses, and efficacy results were identical across three missing data handling methods, the low rate of survey completion limited the data available for the post-treatment assessment. Due to our desire to shorten the survey and increase rates of completion we had particularly limited data for the treatment acceptability and satisfaction questions. Furthermore, the present study's waitlist control group provides only preliminary evidence for efficacy; comparison to a traditional "active" treatment comparison group (e.g., individual psychotherapy) would enable more stringent tests of efficacy. Relatedly, long-term follow-up data were unavailable. This information would help determine the durability of gains made in the treatment condition. Additionally, despite providing aggregate usage data for participants given access to the online program, the present trial did not address how campus-wide knowledge and access of such programs could be improved. Relatedly, detailed data on the order in which users accessed specific components of the program were not available. Accessing such data could reveal more complex usage patterns (e.g., repeated practice of the same skills vs. sequential progression through the program) that might be associated with intervention satisfaction or outcome. The trial also used measured developed outside of India and that haven't been tested for cross-cultural invariance. Finally, the participants in the present study were largely English speaking male university students, which could limit generalizability across all students and/or the general population in India. Although the large sample of males with GAD symptoms likely arose

because male students comprised the majority of students at BITS (i.e., 75% of the 2015-2016 graduating class; BITS, 2016), it will be important to evaluate guided self-help programs at less predominantly male institutions in India, as well as outside the university context and for a more diverse range of mental health problems.

In sum, the results of this trial support the feasibility and efficacy of internet-accessible guided self-help for GAD symptoms among Indian students. Given the need for efficient and efficacious GAD treatments in India, the results suggest that internet-delivered guided self-help could have a major public health impact, especially if implemented at a larger scale. Future studies should seek to improve program usage and rates of post-treatment assessment completion and compare guided self-help to existing treatments with longer-term follow-up assessments. Through such efforts, we believe that research can inform effective and efficient population-level methods for treating GAD symptoms among students in India.

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Table 1

*Demographic Characteristics by Condition*

| | Guided self-help | | Waitlist control | |
|---|---|---|---|---|
| | *N* | % | *N* | % |
| BITS-Pilani | 10 | 8.55 | 7 | 6.67 |
| BITS-Dubai | 17 | 14.53 | 17 | 16.19 |
| BITS-Goa | 35 | 29.91 | 31 | 29.52 |
| BITS-Hyderabad | 55 | 47.01 | 50 | 47.62 |
| Male | 81 | 69.23 | 72 | 68.57 |
| At least intermediate English fluency | 113 | 96.58 | 100 | 95.24 |
| Pretreatment anxiety/depression medication | 3 | 2.56 | 5 | 4.76 |
| | *M* | *SD* | *M* | *SD* |
| Age at pre-treatment | 20.10 | 1.72 | 19.70 | 1.35 |

*Note.* $N = 222$. BITS = Birla Institute of Technology and Science.

Table 2

*Pre-treatment and Post-treatment Symptoms by Condition*

| | Guided self-help | | | | Waitlist control | | | |
|---|---|---|---|---|---|---|---|---|
| | Pre-treatment | | Post-treatment | | Pre-treatment | | Post-treatment | |
| | *M* | *SD* | *M* | *SD* | *M* | *SD* | *M* | *SD* |
| GAD-Q-IV | 9.34 | 1.78 | 5.89 | 3.16 | 9.10 | 1.95 | 6.82 | 3.10 |
| PSWQ | 58.39 | 9.62 | 49.19 | 12.43 | 55.29 | 13.79 | 53.84 | 13.79 |
| DASS-D | 10.78 | 5.01 | 6.84 | 5.63 | 10.37 | 5.12 | 10.13 | 5.28 |

*Note.* $N = 222$. *GAD*-Q-IV = Generalized Anxiety Disorder Questionnaire, 4th edition. PSWQ = Penn State Worry Questionnaire.

DASS-D = Depression Anxiety Stress Scales-Short Form, Depression subscale.

Table 3

*Associations Between Guided Self-Help Usage and Symptom Change*

| | *ß* | *SE* | *Z* | *d* |
|---|---|---|---|---|
| Hours on platform | 0.00 | 0.01 | -0.25 | -0.05 |
| Logins to platform | 0.00 | 0.00 | -0.36 | -0.07 |
| Sessions completed | -0.01 | 0.02 | -0.27 | -0.05 |
| Exercises completed | 0.00 | 0.01 | -0.16 | -0.03 |
| Messages to coach | -0.01 | 0.02 | -0.72 | -0.13 |
| Messages from coach | -0.01 | 0.01 | -0.71 | -0.13 |

*Note.* $N$ = 117 participants randomly assigned to receive guided self-help. Statistics reflect interaction between usage characteristic and time (pre-treatment to post-treatment) in the prediction of scores on the primary outcome measure, Generalized Anxiety Disorder Questionnaire, 4$^{th}$ edition. All $p$ values were greater than .05.

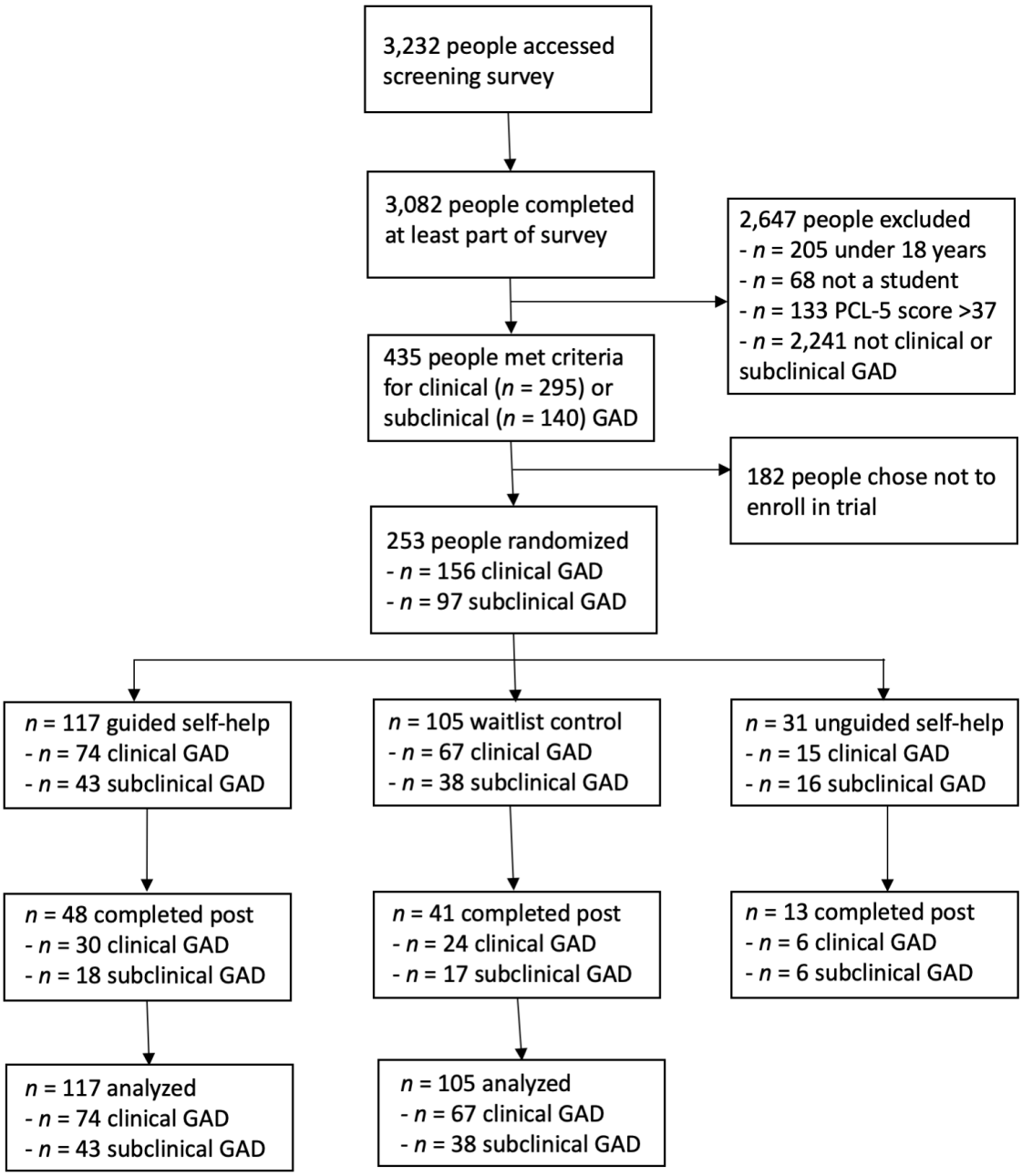


*Figure 1.* This flowchart depicts participant recruitment, selection, and randomization, post-assessment completion, and data analysis. Descriptive statistics for the unguided self-help arm of the trial at pre-treatment and post-treatment are presented in the Supplementary Materials.

# Supplementary Materials

## Description of Unguided Self-Help Intervention

The unguided self-help program, "GAD Online," was based on CBT principles and was accessible via any Internet-enabled computer, mobile phone, or tablet via the Mental Health Online website (Klein, Meyer, Austin, & Kyrios, 2011). GAD Online employed techniques comparable to those provided in the guided self-help condition (e.g., coping with worry, relaxation), yet participants did not have access to a coach. Content was divided into 12 modules. Users were encouraged to use one module per week, but could proceed through the program at their desired pace.

Supplementary Table 1

*Descriptive Statistics in Unguided Self-Help Condition*

| | Unguided self-help | |
|---|---|---|
| | *M* | *SD* |
| Age at pretreatment | 19.70 | 1.55 |
| Pre-treatment GAD-Q-IV | 8.26 | 1.74 |
| Pre-treatment PSWQ | 52.13 | 10.41 |
| Pre-treatment DASS-D | 8.16 | 4.51 |
| Post-treatment GAD-Q-IV | 4.69 | 2.35 |
| Post-treatment PSWQ | 45.40 | 8.88 |
| Post-treatment DASS-D | 6.80 | 6.68 |
| | *N* | % |
| BITS-Pilani | 0 | 0.00 |
| BITS-Dubai | 0 | 0.00 |
| BITS-Goa | 0 | 0.00 |
| BITS-Hyderabad | 33 | 106.45 |
| Male | 26 | 83.87 |
| At least intermediate English fluency | 29 | 93.55 |
| Pretreatment anxiety/depression medication | 0 | 0.00 |

*Note.* $N = 31$. *GAD*-Q-IV = Generalized Anxiety Disorder Questionnaire, 4th edition. PSWQ = Penn State Worry Questionnaire. DASS-D = Depression Anxiety Stress Scales-Short Form, Depression subscale. BITS = Birla Institute of Technology and Science.

**Efficacy Results with Missing Outcome Data Handled by Full Information Maximum Likelihood**

Supplementary Table 2

*Efficacy Results with Missing Data Handled by Full Information Maximum Likelihood*

| | *ß* | *SE* | *Z* | *d* |
|---|---|---|---|---|
| GAD-Q-IV | | | | |
| Time X Treatment Group Interaction | -1.19 | 0.49 | **-2.41** | -0.33 |
| Guided Self-Help Simple Slope | -3.31 | 0.34 | **-9.83** | -1.75 |
| Control Simple Slope | -2.11 | 0.36 | **-5.83** | -0.85 |
| PSWQ | | | | |
| Time X Treatment Group Interaction | -8.49 | 2.38 | **-3.57** | -0.49 |
| Guided Self-Help Simple Slope | -8.45 | 1.68 | **-5.02** | -0.72 |
| Control Simple Slope | 0.04 | 1.68 | 0.03 | 0.00 |
| DASS-Depression | | | | |
| Time X Treatment Group Interaction | -3.70 | 1.12 | **-3.31** | -0.46 |
| Guided Self-Help Simple Slope | -3.60 | 0.79 | **-4.55** | -0.64 |
| Control Simple Slope | 0.10 | 0.79 | 0.12 | 0.02 |

*Note. N* = 222. *GAD*-Q-IV = Generalized Anxiety Disorder Questionnaire, 4th edition. PSWQ = Penn State Worry Questionnaire. DASS-Depression = Depression Anxiety Stress Scales-Short Form, Depression subscale. *Z* statistics printed in boldface are significant with $p < .05$.

**Guided Self-Help Usage Results with Missing Outcome Data Handled by Full Information Maximum Likelihood**

Supplementary Table 3

*Usage Results with Missing Data Handled by Full Information Maximum Likelihood*

| | *ß* | *SE* | *Z* | *d* |
|---|---|---|---|---|
| Hours on platform | -0.01 | 0.02 | -0.30 | -0.04 |
| Logins to platform | -0.00 | 0.00 | 0.41 | -0.06 |
| Sessions completed | 0.02 | 0.02 | 1.06 | -0.14 |
| Exercises completed | 0.01 | 0.01 | 1.20 | 0.16 |
| Messages to coach | 0.01 | 0.02 | 0.72 | 0.10 |
| Messages from coach | 0.01 | 0.01 | 1.14 | 0.15 |

*Note. N* = 117 participants randomly assigned to receive guided self-help. Statistics reflect interaction between usage characteristic and time (pre-treatment to post-treatment) in the prediction of scores on the primary outcome measure, Generalized Anxiety Disorder Questionnaire, 4$^{th}$ edition. All *p* values were greater than .05.

**Efficacy Results Based on Complete Case Analysis**

Supplementary Table 4

*Efficacy Results Based on Complete Case Analysis*

| | *ß* | *SE* | *Z* | *d* |
|---|---|---|---|---|
| GAD-Q-IV | | | | |
| Time X Treatment Group Interaction | -1.23 | 0.61 | **-2.02** | -0.27 |
| Guided Self-Help Simple Slope | -3.03 | 0.41 | **-7.36** | -1.14 |
| Control Simple Slope | -1.80 | 0.44 | **-4.04** | -0.56 |
| PSWQ | | | | |
| Time X Treatment Group Interaction | -9.58 | 2.59 | **-3.70** | -0.51 |
| Guided Self-Help Simple Slope | -8.33 | 1.82 | **-4.59** | -0.65 |
| Control Simple Slope | 1.25 | 1.84 | 0.68 | 0.09 |
| DASS-Depression | | | | |
| Time X Treatment Group Interaction | -3.66 | 1.21 | **-3.03** | -0.42 |
| Guided Self-Help Simple Slope | -3.20 | 0.85 | **-3.76** | -0.52 |
| Control Simple Slope | 0.46 | 0.86 | 0.54 | 0.07 |

*Note. N* = 222. *GAD*-Q-IV = Generalized Anxiety Disorder Questionnaire, 4th edition. PSWQ = Penn State Worry Questionnaire. DASS-Depression = Depression Anxiety Stress Scales-Short Form, Depression subscale. *Z* statistics printed in boldface are significant with $p < .05$.

**Guided Self-Help Usage Results Based on Complete Case Analysis**

Supplementary Table 5

*Usage Results Based on Complete Case Analysis*

| | *ß* | *SE* | *Z* | *d* |
|---|---|---|---|---|
| Hours on platform | -0.01 | 0.02 | -0.44 | -0.06 |
| Logins to platform | -0.00 | 0.00 | -0.59 | 0.08 |
| Sessions completed | 0.02 | 0.02 | 0.80 | 0.11 |
| Exercises completed | 0.01 | 0.01 | -0.86 | 0.12 |
| Messages to coach | 0.01 | 0.02 | 0.52 | 0.07 |
| Messages from coach | 0.01 | 0.02 | 0.79 | 0.11 |

*Note.* $N$ = 117 participants randomly assigned to receive guided self-help. Statistics reflect interaction between usage characteristic and time (pre-treatment to post-treatment) in the prediction of scores on the primary outcome measure, Generalized Anxiety Disorder Questionnaire, 4$^{th}$ edition. All $p$ values were greater than .05.

References

Klein, B., Meyer, D., Austin, D. W., & Kyrios, M. (2011). Anxiety Online—A virtual clinic: Preliminary outcomes following completion of five fully automated treatment programs for anxiety disorders and symptoms. *J Med Internet Res, 13*, e89. doi:10.2196/jmir.1918

## Clinical Impact Statement

**Question:** Can internet-delivered, guided self-help be used to treat generalized anxiety disorder symptoms among university students in India?
**Findings:** Participants who received guided self-help recorded high levels of program usage and had significantly greater symptom reductions than participants in the waitlist control group.
**Meaning:** Internet-delivered, guided self-help appears to be an efficacious and feasible method for treating generalized anxiety disorder symptoms in India's university student population.
**Next Steps:** Research should evaluate the feasibility and efficacy of internet-delivered guided self-help for university students in India delivered at a larger scale and in comparison to existing treatment options.