The Effectiveness of a Mobile App Intervention for Anxiety and Depression Symptoms in University Students: a Randomised Controlled Trial

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Abstract

**Background:** Depression and anxiety symptoms are common among university students, but many do not receive treatment. This is due to lack of availability, reluctance to seek help and many students not meeting the diagnostic criteria required to access services. Internet-based interventions including smartphone applications can overcome these issues, but there are a large number available and little evidence of their effectiveness.

**Objective:** To evaluate for the first time the effectiveness of a self-guided mobile app, “Feel Stress Free”, for the treatment of depression and anxiety symptoms in students.

**Methods:** A web-based randomised controlled trial (RCT) compared a cognitive behavioural therapy-based mobile app “Feel Stress Free” with a wait list control. University students self-identified as experiencing symptoms of anxiety and/or depression, and were randomised to six weeks of intervention (n=84) or control (n=84), unblinded. The app is self-guided and incorporates behavioural relaxation activities, mood tracking and thought challenging, and mini-games. Participants completed the Hospital Anxiety and Depression Scale (HADS) online at baseline and fortnightly.

**Results:** At Week 6, the primary endpoint, there was evidence that the “Feel Stress Free” app reduced depression symptoms (mean difference: -1.56; 95% CI: -2.67 to -0.44; \( P = .006 \)), but only very weak evidence that it reduced anxiety symptoms (mean difference: -1.36; 95% CI: -2.93 to 0.21; \( P = .09 \)). At Week 4, there was evidence to support the effectiveness of the intervention for anxiety symptoms (mean difference: -1.94; 95% CI: -3.11 to -0.77; \( P = .001 \)) and, though weaker, depression symptoms
(mean difference: -1.08; 95% CI: -2.12 to -0.04; \( P = .04 \)). At Week 6, 83% of participants indicated that they were using the app weekly or more.

**Conclusions:** The “Feel Stress Free” app is a promising mobile intervention for treating symptoms of anxiety and depression in students, and overcomes many of the barriers to traditional CBT. Further research is needed to establish its effectiveness at and beyond 6 weeks.

**Trial Registration:** ClinicalTrials.gov NCT03032952

**Keywords:** Anxiety; Depression; Cognitive Behavioural Therapy; CBT-based apps; e-Health; Mobile interventions; Mental Health Mobile Applications; Randomised Controlled Trial.
**Introduction**

Depression and anxiety are common and disabling disorders, and often co-occur [1]. Around 25% of people with depression or anxiety experience symptoms before the age of 20 [2], and rates are high among university students relative to other sections of the population [3]. A systematic review of international studies estimated the prevalence of depression to be 30.6% in university students [4]. Prevalence is also increasing: a recent report indicated that from 2006/7 to 2015/16 the number of UK higher education students who disclosed mental health disorders to their institution rose five-fold, and university deaths by suicide increased by 79% [3]. Early intervention could prevent adverse outcomes often associated with anxiety and depression such as substance misuse, educational under-achievement and suicide [5,6], but for university students there can be numerous barriers to help-seeking, including lack of time, privacy concerns, financial constraints, a lack of perceived need for formal help, and stigma [7]. Innovative approaches are therefore needed to address the high burden of mental health problems in university students.

The most established psychological treatment for depression and anxiety, cognitive behavioural therapy (CBT), often has long waiting lists in the UK and services are not evenly spread throughout the country [8]. Students who would benefit from timely CBT may also not meet the criteria required to access services, particularly if their symptoms appear to be mild (though still distressing). University mental health services are struggling with increasing demand [3], and a collective of executive heads representing 136 universities in the UK (Universities UK) has called for higher education leaders to prioritise student mental health care as an imperative [9]. In the absence of professional help, self-help approaches have been shown to be a
somewhat effective alternative highly valued by young people, particularly when in a
digital form [10,11].

There is evidence that computerised forms of self-directed CBT (cCBT) can be as effective as traditional CBT in the treatment of depression and anxiety [10,12–14], and cCBT is now recommended in the UK for treating subclinical to moderate depression [15]. Mobile CBT applications (“apps”) used primarily on smartphones represent an opportunity to distribute cCBT to the 2.6 billion active smartphone users worldwide [16], at a low cost to the provider and the user. Among 18-24 year olds in the UK, it was recently estimated that 93% own or have ready access to a smartphone [17], and an average of over 4 hours per day is spent using them [18]. This eliminates the need for therapist input, formal help-seeking or a clinical diagnosis, and the lack of wait time has been shown to be particularly attractive among a UK student sample [19].

Promising findings have been reported regarding the effectiveness of app-based interventions for depression and anxiety in student populations. In 2014, a systematic review by Davies et al. [20] suggested that Internet- and computer-based interventions could be beneficial in improving depression and anxiety, particularly as an adjunct to university support services. Indeed, Internet-based self-help is often recommended by university counselling services struggling to cope with high demand [21]. More recently, a 2019 systematic review [22] on digital health interventions for improving depression and anxiety in students found that mobile-based interventions such as apps appear to be as promising as computer-, Web- and virtual reality-based interventions. However, the authors found a comparative scarcity of research in this area: only 8 out of 71 included studies tested interventions delivered via mobile
phone. The issue remains that a large number of mental health apps are available, and there is little or no evidence of effectiveness for the vast majority [23–26].

The aim of the present study (ClinicalTrials.gov registration: NCT03032952) was to examine for the first time the effectiveness of a particular CBT-based mobile app, “Feel Stress Free”, as a treatment for symptoms of anxiety and depression in university students.
Methods

Design

This was a six-week web-based parallel-group unblinded randomised controlled trial with a wait list control. Participants were individually randomised in a 1:1 ratio.

Participants and Setting

Eligible participants were aged 18 or over; scored 8 or above on one or both subscales of the Hospital Anxiety and Depression Scale (HADS), indicating at least a possible case of depression and/or anxiety [27]; were currently a student at one of the four partnered universities; had access to an Apple or Android phone or tablet, or a computer with Firefox, Safari or Chrome installed; and were computer and Internet literate.

Four universities partnered with Thrive Therapeutic Software Limited agreed to take part: University College London (UCL), School of Oriental & African Studies University of London (SOAS), University of Buckingham and University of Roehampton. Students were recruited between March and June 2016 through their university student union or student welfare services, via email, poster and social media advertisements and university welfare staff recommendations. Recruited participants were directed to the Thrive website, where they could enrol by entering their university email address. Participant IDs were then provided in an email to this address, with a link to the online information sheet and consent form. Participants were always contacted via their university email to prevent multiple sign-ups.
Participants were not compensated in any way for their participation. All data were collected online.

Signing the consent form was the only time during the trial when participants had to give their names; they were contacted via email and identified using participant IDs only from this point onwards. Participants answered a series of questions confirming that they had read the information about the trial and understood what would be asked of them. If a participant answered ‘No’ to any of the questions, a representative of the trial emailed them to clarify any queries and ensure consent was given before continuing. Next, participants were sent the online baseline questionnaires via email, which contained demographics questions and the HADS, which was also used to determine eligibility.

**Sample size**

Sample size was estimated using both subscales of the self-rated HADS as co-primary outcome measures, and aiming to detect an intervention effect of half a standard deviation. Whilst the estimated standard deviation differs for each subscale, we chose the most conservative and calculated that at least 64 participants were needed in each arm, with a two-tailed significance level of 0.05 and 80% power. Owing to the high dropout rates usually observed in web-based trials [28], it was decided that up to 300 participants would be randomised.

**Randomisation and allocation**

Participants were individually randomised in batches of 30 each time this number of students had been screened and confirmed as eligible. Random numbers were generated by a statistician (RJ) to allocate participants within each batch to the
two study arms in a 1:1 ratio, using prespecified code written in Stata (version 14). The list of participant IDs and group allocations was then returned to the researcher (TM). At the close of the recruitment period, a final batch of 18 participants was randomised.

The researcher (TM) then emailed a link to download the “Feel Stress Free” app to those allocated to the intervention group. As participants were required to sign up for an account in order to use the app, it was possible to monitor which participants had downloaded the app, and reminders were sent to those who had not. Those allocated to the wait list group were sent an email informing them that they would receive access to the app at the end of the trial. Day one of the trial was defined as the date of randomisation for each batch of participants. Owing to the nature of a wait list control group, we could not blind the researcher or participants to group allocation. However, apart from the allocation email, all participants received exactly the same emails regardless of group, and trial staff had no other way of influencing the participants.

**Intervention**

The “Feel Stress Free” app (version 1.5; see Figure 1), developed by Thrive Therapeutic Software Limited, uses CBT-based activities to help users manage symptoms of depression and anxiety. The app comprises: four behavioural relaxation activities - calm breathing, mindfulness-style meditation, deep muscle relaxation and self-hypnosis; one cognitive activity, incorporating both mood tracking and thought challenging; a relaxing mini-game; and a ‘positive messages in a bottle’ feature. “Feel Stress Free” is self-guided (fully automated, with no additional human involvement) and individuals are led around the app by a friendly robot character that makes
activity recommendations. Each activity has several options for duration, and a short audiovisual guide explaining its use and benefits. Participants were instructed to use the app at least once per week, spending at least ten minutes on one or more of the main activities, throughout the trial. There were no prompts or reminders to use the app. Further details of the application and its basis can be found in Multimedia Appendix 1. A very similar version of this app (version 1.3) was also tested as a treatment for agoraphobia in 2017 [29]. More information can be found at https://thrive.uk.com/.

“Feel Stress Free” can be used on any Apple or Android smartphone or tablet, or any computer with Firefox, Safari or Chrome installed. “Feel Stress Free” is available on the web though it is primarily a mobile app. Users must be connected to the Internet. Participants randomised to receive the intervention were able to download and access the app and all of its features free of charge. Those in the wait list group were able to do so at the end of the study. The app was offered to participants exactly as it is publicly available. No app usage data was available to study researchers, as per Thrive’s privacy policy. Participants in both groups were not limited in the (additional) care they could receive throughout the trial, but were asked at baseline whether they were receiving any concurrent treatment (medication and/or psychological interventions) for anxiety or depression.

Figure 1. Screenshots of the “Feel Stress Free” app on a smartphone. These show the landing page for the meditation activity (A), and the mood tracker with an activity recommendation (B).
Measures

The HADS [27] is an established measure of the severity of anxiety and depression symptoms, and has been validated for online use in a student population [30]. There are seven items scored from 0-3 on each subscale, giving a possible range of 0-21 for each; a score between 8 and 10 inclusive indicates a possible case, and a score of 11 or above indicates a probable case [27]. Specificities and sensitivities are usually reported as being 80% or higher in UK-based research [31]. A previous study did not reveal any differences between online and pen-and-paper versions of the scale [30]. The internal consistency (Cronbach’s alpha) of the HADS in this study was 0.68 and 0.77 at baseline for the anxiety and depression subscales respectively, and 0.81 and 0.86 at Week 6.

The joint primary outcomes were depression and anxiety symptom severity at Week 6, as measured by the two subscales of the HADS (the HADS-A, for anxiety symptoms, and the HADS-D, for depression symptoms). Secondary outcomes were HADS-A and HADS-D scores as repeated measures at baseline (screening), Week 2 and Week 4. The web link to complete the questionnaires online was sent to all participants via email on the first day of each of the relevant weeks, followed by prompts throughout the week.

Participants were asked how often they had been using the app in the past fortnight as a measure of treatment adherence (‘not at all’, ‘fortnightly’, ‘weekly’, ‘a few times’, ‘several times a week’, ‘once a day’, ‘more than once a day’, or ‘I am not in the app group’). A response indicating weekly or more was considered to indicate adherence. Participants also had the opportunity to indicate whether they had experienced any adverse events in the past two weeks. If a participant indicated that
they had, details of the event and its severity (on a scale of one to three, with one being mild and three being severe) were requested within the questionnaire.

**Statistical analyses**

All main analyses were intention to treat (ITT). Primary outcomes (HADS-D and HADS-A scores at 6 Weeks) were analysed using linear mixed models (a separate model for each outcome) with the scores from each time point treated as a repeated measures outcome. Models were adjusted for age, gender and concurrent treatment, as these variables were expected to be strongly associated with the outcome. An interaction between each covariate and time permitted the effect of the covariates to differ at each time point. We first report the effect on the primary outcomes (HADS-D and HADS-A scores at Week 6) and then on the secondary outcomes. A random effect of participant with an unstructured residual covariance matrix allowed for correlations between these repeated measures on individuals over time. Fixed effects of treatment (intervention vs wait list), time (baseline and 2, 4 and 6 Weeks follow-up) and the interaction between treatment and time were specified. The estimated baseline score was constrained to be identical in the two study arms, equivalent to adjusting for baseline and permitting the relationship between baseline and follow up scores to differ at each time point. Standardised effect sizes were produced by performing similar analyses with outcome variables standardised by the mean and standard deviation of the whole sample at baseline. A per-protocol analysis was also undertaken, to examine the effectiveness of the intervention under ideal conditions. This analysis compared all participants in the wait list group with only those participants in the intervention group who had indicated treatment adherence at all
three time points, using similar statistical models to the main trial analysis. All analyses were conducted using Stata, version 14 [32].

**Ethical approval**

This research was approved by the University College London Ethics Committee (reference number: 8227/001). All participants gave informed consent via online form before participating, and adverse events were monitored at each time point. Data were anonymised, stored and protected according to the UK Data Protection Act (2018) and the General Data Protection Regulation guidelines (2018). The trial was registered and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT)-EHEALTH checklist [29]. Protocol changes can be found in Multimedia Appendix 2.

**Results**

**Participants**

During the recruitment period 372 students enrolled in the trial, of whom 195 (52%) completed the consent form. The baseline questionnaires were sent to these consenting participants, and 176 (90%) completed them, 8 of whom were ineligible. The remaining 168 participants were randomised – 84 to each study arm. Figure 2 shows the flow of participants through the trial.

In the intervention group, one participant was unable to download the app owing to an unexpected lack of access to a device. A further ten participants did not download the app. All participants were sent questionnaires at all three follow-up time points, regardless of whether they had completed the previous questionnaire(s).
participants were included in the main analyses in the groups they were randomised to.

**Figure 2.** Flow of participants through the trial.
Baseline characteristics

The mean age of all 168 participants was 24.3 years (SD 6.71; range 18-54 years), 83% (n=139) were female whilst 1% (n=2) preferred not to say, and 62% (n=104) were undergraduate students. At baseline, the mean score on the HADS-A was 13.7 (SD 3.33) and on the HADS-D was 8.31 (SD 3.96). Also at baseline, 45% (n=225) reported that they would have an exam or a dissertation deadline during the trial period, and 25% (n=42) reported that they were receiving another treatment concurrently. These characteristics were well balanced across groups, apart from concurrent treatment; more participants in the intervention group were receiving other forms of treatment during the study than in the wait list control group (30% and 20% respectively). Baseline demographic and clinical information for all randomised participants are presented in Table 1.
Table 1. Baseline demographic and clinical characteristics by study arm.

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 84)</th>
<th>Wait list (n = 84)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) – mean (SD)</td>
<td>25.1 (7.68)</td>
<td>23.5 (5.53)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13 (15%)</td>
<td>10 (12%)</td>
</tr>
<tr>
<td>Female</td>
<td>69 (82%)</td>
<td>74 (88%)</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>2 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>University(^a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCL</td>
<td>37 (44%)</td>
<td>37 (44%)</td>
</tr>
<tr>
<td>University of Roehampton</td>
<td>34 (40%)</td>
<td>35 (42%)</td>
</tr>
<tr>
<td>SOAS</td>
<td>8 (10%)</td>
<td>7 (8%)</td>
</tr>
<tr>
<td>University of Buckingham</td>
<td>5 (6%)</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>Graduate status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate</td>
<td>51 (61%)</td>
<td>53 (63%)</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>33 (39%)</td>
<td>31 (37%)</td>
</tr>
<tr>
<td>Assessment during trial</td>
<td>38 (45%)</td>
<td>37 (44%)</td>
</tr>
<tr>
<td>Concurrent treatment</td>
<td>25 (30%)</td>
<td>17 (20%)</td>
</tr>
<tr>
<td>No. with HADS(^b) score &gt; 8(^c)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety subscale (HADS-A)</td>
<td>83 (99%)</td>
<td>82 (98%)</td>
</tr>
<tr>
<td>Depression subscale (HADS-D)</td>
<td>46 (55%)</td>
<td>45 (54%)</td>
</tr>
<tr>
<td>Comorbid depression and anxiety</td>
<td>45 (54%)</td>
<td>43 (51%)</td>
</tr>
</tbody>
</table>

Note: Statistics are counts and percentages unless otherwise specified. SD = standard deviation.

\(^a\)UCL = University College London. SOAS = School of Oriental and African Studies, University of London.

\(^b\)HADS = Hospital Anxiety and Depression Scale.

\(^c\)A HADS score of more than 8 indicates ‘possible’ depression or anxiety. Participants who met this criterion on both subscales of the HADS are additionally indicated as being HADS comorbid.
Main analyses

Mean scores for each HADS subscale by study arm and time point can be found in Table 2. We found evidence that the “Feel Stress Free” app reduces depression at 6 weeks follow-up (adjusted mean difference: -1.56; 95% CI: -2.67 to -0.44; \( P = .006 \); standardised effect size: 0.39), but only very weak evidence of a reduction in anxiety (-1.36; 95% CI -2.93 to 0.21; \( P = .09 \)). At Week 4, there was evidence for the effectiveness of the app at reducing symptoms of both depression (-1.08; 95% CI -2.12 to -0.04; \( P = .04 \); ES 0.27) and anxiety (-1.94; 95% CI -3.11 to -0.77; \( P = .001 \); ES 0.58). There was weak evidence for an effect of the intervention on anxiety symptoms at week 2, but no evidence of a treatment effect for depression symptoms. These results were consistent with the unadjusted model, with the exception of Week 2, where there was weak evidence of the app’s effectiveness in reducing both anxiety and depression symptoms in the unadjusted model. The multilevel model results are presented in Table 3. Figure 3 shows HADS anxiety and depression subscale scores by study arm, estimated by Model 2. A sensitivity analysis adjusting additionally for university can be found in Multimedia Appendix 3 (Table 1).

Table 2. Mean (SD) HADS anxiety and depression scores by study arm at baseline and 2, 4 and 6 weeks follow-up.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>N</th>
<th>Mean (SD)</th>
<th>N</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HADS Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6</td>
<td>41</td>
<td>10.8 (4.25)</td>
<td>57</td>
<td>11.8 (4.60)</td>
</tr>
<tr>
<td>Week 4</td>
<td>45</td>
<td>10.1 (3.85)</td>
<td>61</td>
<td>12.1 (4.19)</td>
</tr>
<tr>
<td>Week 2</td>
<td>58</td>
<td>11.2 (3.75)</td>
<td>70</td>
<td>12.6 (3.88)</td>
</tr>
<tr>
<td></td>
<td>HADS Depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-----------------</td>
<td>------------</td>
<td>--------</td>
<td>------</td>
</tr>
<tr>
<td></td>
<td>Week 6</td>
<td>Week 4</td>
<td>Week 2</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>41</td>
<td>45</td>
<td>58</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>5.8 (3.72)</td>
<td>5.9 (3.63)</td>
<td>6.3 (3.20)</td>
<td>8.3 (3.73)</td>
</tr>
</tbody>
</table>

**HADS = Hospital Anxiety and Depression Scale, by subscale.**

N = number of observations. SD = standard deviation.

**Table 3.** Estimated effect of “Feel Stress Free” intervention on HADS anxiety and depression scores at 2, 4 and 6 weeks follow up.

<table>
<thead>
<tr>
<th></th>
<th>Model 1</th>
<th></th>
<th>Model 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate (95% CI)</td>
<td>P value</td>
<td>Effect size</td>
<td>Estimate (95% CI)</td>
</tr>
<tr>
<td><strong>HADS Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6</td>
<td>-1.08 (-2.62 to 0.47)</td>
<td>.172</td>
<td>0.32</td>
<td>-1.36 (-2.93 to 0.21)</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>-1.94 (-3.06 to -0.82)</td>
<td>.001</td>
<td>0.58</td>
<td>-1.94 (-3.11 to -0.77)</td>
</tr>
<tr>
<td>Week 2</td>
<td>-1.27 (-2.39 to -0.15)</td>
<td>.026</td>
<td>0.38</td>
<td>-1.10 (-2.28 to 0.07)</td>
</tr>
<tr>
<td><strong>HADS Depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6</td>
<td>-1.26 (-2.37 to -0.16)</td>
<td>.025</td>
<td>0.32</td>
<td>-1.56 (-2.67 to -0.44)</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>-1.20 (-2.21 to -0.19)</td>
<td>.019</td>
<td>0.30</td>
<td>-1.08 (-2.12 to -0.04)</td>
</tr>
<tr>
<td>Week 2</td>
<td>-0.98 (-1.91 to -0.06)</td>
<td>.037</td>
<td>0.25</td>
<td>-0.67 (-1.62 to 0.27)</td>
</tr>
</tbody>
</table>

*Estimates are from linear mixed models with scores from each time point treated as a repeated measures outcome. In both models, baseline score was constrained to be identical in the two study arms, equivalent to adjusting for baseline. Model 2 adjusted additionally for age, gender, and presence of concurrent treatment.

**HADS = Hospital Anxiety and Depression Scale.**

*Effect size standardised by mean and standard deviation of sample at baseline.
Attrition and Adherence

Overall, 58% of participants randomised (98 of 168) completed the Week 6 questionnaires. A larger proportion of participants in the wait list group provided outcome data at Week 6 (n=57, 68%) than in the intervention group (n=41, 49%; $\chi^2 = 6.27; P = .01$). We used univariable logistic regression models to identify baseline variables associated with having incomplete outcome data (missing questionnaire data at any time point). Postgraduates were less likely to have missing outcome data than undergraduates (OR 0.44; 95% CI 0.23 to 0.84; $p = .013$), but there were no differences in terms of any other baseline characteristics. We therefore conducted a sensitivity analysis adjusting for graduate status, to investigate the possible effect of missing outcome data. The treatment effect was similar. More details can be found in Multimedia Appendix 3 (Table 2).

Adherence with the treatment was defined as using the app weekly or more frequently. By this definition, 98% of participants reported adherence at Week 2, 89%
at Week 4, and 83% at Week 6 (Table 4). Of the participants who completed all of the follow-up questionnaires, 80% (32 of 40) indicated adherence at every time point.

Table 4. Usage data for the intervention group at each time point. Adherence was defined as using the app weekly or more, measured via self-report questionnaire.

<table>
<thead>
<tr>
<th>Usage – N (%)</th>
<th>Week 2 (n = 56)</th>
<th>Week 4 (n = 45)</th>
<th>Week 6 (n = 41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than weekly</td>
<td>1 (2%)</td>
<td>5 (11%)</td>
<td>7 (17%)</td>
</tr>
<tr>
<td>Weekly</td>
<td>9 (16%)</td>
<td>10 (22%)</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>A few times a week</td>
<td>28 (48%)</td>
<td>19 (42%)</td>
<td>20 (49%)</td>
</tr>
<tr>
<td>Several times a week</td>
<td>17 (29%)</td>
<td>8 (18%)</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Daily or more</td>
<td>3 (5%)</td>
<td>3 (7%)</td>
<td>3 (7%)</td>
</tr>
</tbody>
</table>

**Per-protocol Analysis**

We performed a pre-specified per-protocol analysis including only those in the intervention group who indicated treatment adherence at every time point (n=32, 38%) and all of the participants in the wait list control group (n=84). Whilst no longer an unbiased sample, the estimated adjusted treatment effects at the primary endpoint (Week 6) were similar to those from the intention to treat analysis for both anxiety symptoms (-1.37; 95% CI: -3.17 to 0.42; P = .13) and depression symptoms (-1.88; 95% CI: -3.12 to -0.64; P = .003). At Week 4, there was also evidence to support the effectiveness of the app at reducing both anxiety (-2.11; 95% CI: -3.50 to -0.73, P = .003) and depression symptoms (-1.13; 95% CI: -2.35 to 0.08; P = .067), again in line with the intention-to-treat analysis.

**Safety**
Two participants in the app group reported adverse events associated with the intervention. One participant reported at Week 4 that they were “feeling reliant on it” and “recognising deeper thoughts and emotions”, and rated the severity of these unpleasant effects as mild. The second participant reported that they experienced feelings of stress and anxiety when they had technical difficulties with the app, which they reported as being of moderate severity at Week 2 and of mild severity at Week 6. There were no other reports of any adverse events experienced as a result of the intervention.

**Discussion**

**Principal Findings**

We found evidence that the “Feel Stress Free” app reduced depression and anxiety symptoms after six weeks. At secondary time points, we observed greater reductions in depression and anxiety symptoms in the app group compared with the control group after four weeks. Treatment adherence and usage of the app were encouraging (83% reported using the app weekly or more at Week 6), and very few adverse events were reported. These results provide preliminary support for the effectiveness of this mobile CBT-based application in treating depression and anxiety symptoms in a student population.

The standardised effect sizes for statistically significant comparisons were 0.39 (Week 6) and 0.27 (Week 4) for depression, considered small [34], and 0.58 (Week 4) for anxiety, considered medium[34]. These are in line with other recent studies which compare CBT apps with waitlist or inactive controls; meta-analyses by Firth et al. reported standardised mean difference effect sizes of 0.45 for anxiety [35] and 0.56 for depression [36]. Whilst these meta-analyses reported smaller effect sizes
for studies comparing similar apps with active controls (0.19 and 0.22 for anxiety and depression, respectively), for students on a waiting list or for whom therapist-supported CBT or face-to-face CBT is not an option, a readily available intervention that produces even a relatively small effect after four weeks would be of value.

Whilst a minimum clinically important difference (MCID) has not been established for the HADS in the general population, the best estimate we have is from trials of those with chronic pulmonary obstructive disorder (COPD). Whilst MCIDs are a complex issue likely to be best represented by percentage rather than absolute score changes [37], in these trials a change in score of 1.5 points is generally accepted as the MCID [38,39]. Our adjusted mean difference estimate slightly exceeded this value at Week 6 for depression but was below it at Week 4. For anxiety, the adjusted mean difference estimate was below this value (and not statistically significant) at Week 6 but exceeded this value at Week 4. Based on the 95% confidence intervals for these estimates, we cannot rule out the potential for a clinically significant effect of this intervention, but we also cannot rule out the values in the lower range, which would be small and not clinically important. Overall these findings should be treated with caution regarding clinical importance.

**Strengths**

The present study avoided many methodological issues common throughout the Internet-based CBT literature. In particular, adherence to the app treatment was clearly defined and measured, and not just assumed from completion of outcome measures. This allowed us to make observations regarding app usage separate from study participation – for instance, postgraduates were less likely to have missing data than undergraduates, but not more likely to indicate treatment adherence, as may have
been assumed otherwise. We can therefore report the important positive outcome that 83% of those in the intervention group were continuing to use the app regularly at Week 6.

Offering the app to users as it would be in a real-world setting and without supervision allowed the study a higher level of external validity than most trials. Additionally, the intention-to-treat approach to analysis gives a more valid estimate of the effectiveness of the intervention, by reflecting the protocol deviations and non-compliance common in clinical practice. Participants self-administered all outcome measures online and had no personalised contact with trial personnel, which means that observer bias can be discounted.

This study contributes new data to the body of literature surrounding cCBT, and more specifically to the emerging field of mobile and app-based CBT. Our findings suggest that mobile CBT without therapist support or a structured session-based approach may improve symptoms of anxiety and depression in a sample with a range of symptom severities, including subclinical and severe. This study also provides preliminary evidence for the effectiveness of the attributes of this particular app, which can be directly compared with other apps of this kind in order to consider the ideal characteristics of cCBT and Internet-based CBT to optimise effectiveness.

**Limitations**

There are several limitations of this study. One issue was attrition, with 58% of participants completing the Week 6 questionnaires. However, this rate is comparable to what is seen at similar time points in other trials of mobile and web-based CBT where therapist contact is minimal or absent [28,40,41]. Furthermore, whilst the sample size at Week 6 was relatively small, the multilevel modelling
analysis technique used allows all participants to contribute to analyses, even those with missing follow-up data, which increases statistical power. Nevertheless, future research should focus on trying to ascertain the reasons behind dropouts, particularly in relation to app design. In the present study, it is unclear whether those in the intervention group who stopped completing questionnaires were doing so because of the questionnaires or because they did not want or need to use the app any more. Fewer participants dropped out in the wait list group (see Table 2), which may be because they remained interested in the trial as a way to access the app. Overall, the attrition observed appears to be realistic for a web-based trial comparing a CBT-based app with a wait list control group [41]. Future web-based trials could try to incorporate some elements of interaction with participants in order to improve retention – for example, an in-person consent procedure and demonstration of the app, and regular reminders to use the app.

It must be considered that our estimate of adherence was based on self-report data subject to social desirability bias, and the true rate of adherence may be lower. However, if we did overestimate adherence, the fact that low levels of usage produced a benefit would provide support for the effectiveness of the app even without frequent use, in line with findings by Firth et al. [35]. Nevertheless, more detailed data on participants’ usage of the app, potentially including qualitative feedback on its perceived usefulness and user experience, would be beneficial to the field. Future studies should incorporate direct monitoring of participants’ app usage where possible in order to ascertain whether there is a ‘dose-response’ relationship and whether usage of certain activities within the app may be associated with better outcomes and/or preferred by participants [42].
A further limitation of this study is the use of a wait list control group. As it was not possible to blind participants, the groups differed in their expectation of improvement, and a placebo effect in the intervention group could have inflated effect sizes or made a Type I error more likely. In particular, a so-called “digital placebo” has been suggested by some researchers, in that the observed benefits could be arising from increased use of the electronic device itself [43]. Nevertheless, this intervention requires such little investment on the part of distributors and patients alike that this would not discredit its use entirely, particularly for those who are waiting for another treatment. In this way, the comparison between a mobile CBT-based app and a control group lacking in expectation of improvement can be considered to reflect the real-world situation of those at whom this intervention is aimed, and should be considered in this context of increased external validity. Additionally, the wait list group also showed improvement during the trial, thus reducing the differences between groups. This is common in trials and likely to be due to the spontaneous improvement, fluctuations in symptoms and regression to the mean which accompanies the passage of time [44]. However, we cannot rule out the possibility that the control group sought out and used other CBT-based mental health apps or other treatments during the course of the trial, thus diminishing the observed effect of the “Feel Stress Free” app.

Our sample was 85% female, which could be said to limit the generalisability of our results. Whilst we had more female students taking part than expected, some gender imbalance is common in trials and likely to partly reflect gender differences in prevalence and help-seeking behaviours. Further research could investigate whether female students are more interested in mobile app interventions than male students, and apps could be then tailored accordingly. The results of this trial may also not be
generaliseable beyond university students, but arguably these are the individuals who are most likely to benefit from the accessibility of this type of treatment [45]. The sample was a mix of those with subclinical and clinical symptoms to reflect this population. The promising results indicate the possible effectiveness of the app in potentially treating and preventing clinical levels of symptoms.

**Future directions**

Further research is needed in order to confirm the effectiveness of this mobile intervention at and beyond six weeks, particularly for anxiety. Our results are in line with the oft-reported finding that the majority of the improvement associated with a CBT app (and traditional CBT [46]) is seen in the short term [47,48], but a longer follow-up period will be needed to ascertain whether our Week 6 results represent a fluctuation typically seen around the 6 week time point. In order to rule out the digital placebo effect as an explanation for our results, this app should also be compared with an active, smartphone-based control. As more evidence is gathered for individual CBT apps, comparisons between different apps are warranted followed by a consideration of the characteristics that the most effective have in common – a recent meta-analysis attempted this but was not able to draw robust conclusions [36].

This app could be offered to university students, particularly where the demand for therapies exceeds the provision. The app could be offered to those who are on the waiting list for traditional CBT; it may be particularly useful when a rapid improvement is imperative, such as before exams. Trying self-directed forms of CBT may also make individuals more likely to seek traditional CBT [49], and can be an alternative for those who are unable to attend therapy. Students are unlikely to have a problem accessing a device on which the app can be used, and benefits were observed
regardless of age and gender. Internet-based interventions such as “Feel Stress Free” would also fit well within a stepped care model, such as is currently in place in the UK; it could be offered during the period of ‘guided self-help’ [15, 50, 51], followed by traditional CBT if this is not beneficial. Future research could also explore the usage of Internet-based interventions as an adjunct to traditional CBT, for use between sessions.

Conclusions

We found evidence to support the use of “Feel Stress Free”, a CBT-based mobile app, as a short-term intervention for students experiencing symptoms of depression and anxiety. Further research is needed to establish the potential benefit of the app, in particular by comparing it with an active control in a larger sample less vulnerable to dropouts.

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Multimedia Appendix 1: Feel Stress Free app activities.

Multimedia Appendix 2: Protocol changes.

Multimedia Appendix 3: Sensitivity analyses.
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