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Evaluation of the Efficacy of Group Cognitive Behavioral Therapy on Anxiety in College Students Based on Wearable Devices and Mobile Applications: A Randomized Controlled Trial

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Abstract

Background: Anxiety disorders are highly prevalent worldwide and have significant comorbidities including depression and substance use disorders. The global burden of anxiety disorders necessitates early intervention for high-risk populations, including college students

facing stress during major life transitions. Objective measures and ecological momentary assessments may advance the development of early interventions.

Objective: To test the efficacy of group cognitive-behavioral therapy (GCBT) intervention by implementing a randomized controlled trial and identifying potential objective measures.

Methods: College students with a Generalized Anxiety Disorder Scale 7 scores ≥ 5 were randomized into GCBT (n= 31) and wait-list control (WLC; n= 28) groups. For both groups, self-reported symptom severity was assessed at baseline and follow-up in weeks 4, 8, and 28. Continuous heart rate and step counts measurements were captured by wearable sensors, along with ecological momentary assessments of mood and energy, which were obtained within 4 weeks of treatment.

Results: Compared to the WLC group, the GCBT group showed significant improvements in anxiety symptoms at week 28. Moreover, the GCBT group had significantly increased step counts and faster heart rates, more stable moods in the morning and evening, and better energy in the morning. Improvements in anxiety symptoms were closely associated with increases in step counts in the GCBT group.

Conclusion: Preliminary findings suggest that GCBT is associated with improvements in anxiety symptoms in college students over the long term. Changes in daily heart rates and step counts were correlated with mood and energy levels, suggesting that physiological markers may be useful in assessing treatment response.

Trial registration: ClinicalTrials.gov (NCT05913349), trial registration date: June 13, 2023 (retrospectively registered).

Keywords: Anxiety, Group Cognitive-Behavioral Therapy, Wearable Devices, Ecological Momentary Assessments

1. Introduction

Anxiety symptoms are widely experienced among college students. Indeed, findings from a meta-analysis have suggested a 39% prevalence rate of anxiety symptoms among college students[1], which are often accompanied by physical and cognitive symptoms such as insomnia, irritability, and difficulty concentrating[2, 3], all of which seriously affect daily life and academic performance[4, 5]. Factors such as intense academic pressure, social challenges, discomfort with new living arrangements and physical environments, financial stress, and decreased sleep quality increase mental health risks [6-9]. Therefore, special support and attention is required for this cohort, and long-term behavioral management and assessment are critical for reducing symptoms and restoring their social functioning.

Previous methods used to assess anxiety levels, such as interviews and self-report scales, have been limited by the reliance of participant recall and reported symptoms based on past experiences, which may have led to recall bias. Furthermore, there have been a lack of any corresponding objective biological measurements associated with such interviews and self-reports. Nowadays, the growth of wearable devices (WDs) and mobile applications (MAs) has improved the accuracy of mental health assessments by enabling real-time, repeated sampling of symptoms and behaviors in natural environments. These technologies have also demonstrated the potential in predicting the risk of future emotional symptoms and identifying emotional states in a cross-sectional manner[10]. Indeed, WDs can capture metrics such as heart rate, physical activity, sleep time, and exercise, and studies have found that physiological and behavioral metrics collected by WDs indicate a strong correlation with negative emotions, suggesting their integration could provide information on valuable biomarkers[10, 11]. It has also been hypothesized that features of WDs may translate into biomarkers for disorders such as depression, anxiety, bipolar disorder, and schizophrenia[12]. However, a review of previous studies has revealed that there is a significant lack of research utilizing WDs to assess and predict the treatment effects of anxiety symptoms. While WDs excel in the real-time detection of physiological data, limitations still remain in terms of prompt evaluation of subjective symptoms[13].

Ecological momentary assessment (EMA) captures real-time data on diverse behaviors (such as those related to school, work, socialization, and recreation) through mobile devices, providing insights into participants' real-world experiences as opposed to controlled laboratory settings[14]. In previous studies, EMA has helped to monitor mental health status, and its application in everyday life is not only limited to transient assessment of mood, but

has also explored longer term substance abuse[15], physical activity and diet[16], and location movement[17, 18]. Studies combining EMA with WDs have found a strong correlation between behavior and mood[19]. EMA offers real-time assessment of subjective experiences, overcoming limitations of traditional measures reliant on error-prone retrospective reports. It also captures detailed natural environment experiences through brief, repeated questionnaires. However, to date there has been limited research focusing on the efficacy prediction of EMA. Likewise, the use of WDs during EMA of psychiatric disorders has rarely addressed anxiety disorders.

Although such technologies offer new perspectives for treatment monitoring, the current evaluation of group cognitive-behavioral therapy (GCBT) efficacy still primarily relies on self-report scales, and thus lack both objective biological and behavioral indicators.

Regardless, a large number of studies have supported the efficacy of GCBT in improving symptoms of anxiety disorders[20]. However, treatment monitoring in previous studies has relied mainly on questionnaires and clinical observations of patients by psychiatrists. As a result, the accuracy and consistency of the obtained data may be compromised, which may hinder the accurate assessment of clinical severity and treatment response[21]. To overcome this limitation, researchers have proposed the use of objective measures, such as WDs and complementary EMA assessment of GCBT efficacy. In a recent study, CBT efficacy was assessed using a daily sleep diary in a mobile app and sleep-related data from a WD; however, the results were not significantly different from traditional assessments in terms of treatment efficacy, adherence, or satisfaction[22]. It is worth noting, no study to date has used physiological and behavioral features to assess the effectiveness of GCBT.

Therefore, the current study aimed to explore the efficacy of GCBT in alleviating anxiety symptoms among college students from multiple domains and to investigate the potential associations between factors. A WD was combined with EMA to simultaneously collect data on symptoms to assess the efficacy of GCBT in terms of physiological and behavioral characteristics. In addition, the research aimed to demonstrate the long-term efficacy of GCBT by conducting symptom assessments at baseline (T0) and follow-ups at week 4 (T1), week 8 (T2), and week 28 (T3). We aimed to examine the relationship between biological markers and clinical symptoms to determine the added value of digital markers obtained from WDs and MAs in mental health assessments. We hypothesized that WDs that collect data on biobehavioral functioning, combined with EMA, would exhibit day-to-day changes during GCBT programs and reveal meaningful associations with clinical outcomes, which may highlight their added value in assessing treatment effectiveness. As existing research supported the behavioral activation of CBT could increase physical activity and thus reduce anxiety symptoms[23, 24], we expected that individuals with higher step counts would show greater reductions in anxiety symptoms.

2. Materials and Methods

2.1 Study Design and Recruitment

This study has been approved by the Ethics Committee of Xinxiang Medical College of Henan Province (XYLL-2020235) and registered with the ClinicalTrials.gov (NCT05913349), which includes the primary outcomes. As part of their routine medical check-ups, students at Xinxiang Medical College of Henan Province in China are required to participate in an annual web-based mental health assessment. An electronic informed consent form was provided before the start of the questionnaire. Once the students completed the

mental health assessment, we initiated the screening process and confirmed their willingness to participate in the following intervention. Those who not only expressed their **interest** to **participate** in the GCBT intervention but **who** also demonstrated a willingness to wear WDs throughout the intervention were formally enrolled in the study. **A random allocation sequence was generated by an independent research assistant using a web-based randomization procedure (<https://www.random.org/lists/>), and participants were assigned to different groups based on the **output** sequence.** The CONSORT flow diagram and overall steps for using WDs and MAs to understand the efficacy assessment of GCBT for college students with anxiety symptoms are shown in Figure 1 and Figure 2, respectively.

Figure 1 CONSORT flow diagram. Exclusion criteria were asked sequentially as listed. If an exclusion criterion was met, individuals automatically received a message indicating that they were not eligible to participate, and further exclusion criteria were not queried. GCBT, Group Cognitive-Behavioral Therapy; WLC, wait-list control group

Figure 2 Flow chart for using WDs and MAs to understand the efficacy assessment of GCBT for college students with anxiety symptoms. We recruited college students with anxiety symptoms and continuously collected daily heart rates and step counts from WDs and EMA data from MAs. We **then** computed statistical value features from the data. After the GCBT intervention, changes in symptoms and features were observed at baseline (T0) and at follow-up at T1, T2, and T3 to determine possible associations between extracted features from **WDs** and **MAs** and symptom improvement. GCBT, Group Cognitive-Behavioral Therapy; WLC, wait-list control group; PHQ-9: Patient Health Questionnaire-9; GAD-7: Generalized Anxiety Disorder Scale-7; PSS-14: Perceived Stress Scale-14; ISI: Insomnia Severity Index; BSSI: Beck Scale for Suicide Ideation

2.2 Sample Selection

We recruited a total of 60 college students for our study. To be eligible for inclusion, participants needed to meet the following criteria: (a) Generalized Anxiety Disorder Scale-7 (GAD-7) scores ≥ 5 ; (b) willingness to engage in a 4-week GCBT intervention; (c) aged between 18 and 25 years old; and (d) possessed valid contact information and had access to the internet and proficiency in using mobile phones for online tasks. Exclusion criteria: (a) previous diagnosis of bipolar disorder, schizophrenia, or other psychotic disorders, assessed using questionnaire-based history of mental illness; (b) current suicidal ideation or self-harm thoughts, assessed using the Beck Scale for Suicide Ideation (BSSI); (c) history of significant physical illness, especially illnesses that may alter brain function, e.g., hypertension and diabetes, assessed using questionnaire-based history of physical illness; (d) history of abnormal neurological disorders, including head trauma, seizures, brain vascular disease, or brain tumors, assessed through a questionnaire-based history of past head injuries or brain-related illnesses; (e) and history of alcohol or drug abuse, or dependence, assessed using three a questionnaire-based history of past alcohol consumption, smoking habits, and substance dependence, respectively.

2.3 Procedure

Since current students were also enrolled in on-campus courses, we organized the weekly GCBT intervention on every Saturday evening. The intervention spanned a total of 1 month, taking place once a week for 90 min each session. Simultaneously, we required students to wear the Huawei Band 6 (Huawei Technologies Co., Ltd., Shenzhen, Guangdong, China) to monitor their heart rates, step counts, and sleep time every day during the intervention period. Before the intervention began, we organized the participants in a WeChat group to convey the

study requirements and information, although the participants were not informed as to their group. Additionally, we asked them to respond to two questions about their mood and energy every morning and evening using the "Brain Structures" WeChat public account. Automatic reminders for this collection were sent every morning and evening. Furthermore, the WeChat public account also facilitated participants' self-assessments of symptoms related to anxiety, depression, insomnia, and stress. This tool effectively integrates self-assessment and data collection into a single platform. Finally, students were reassessed for symptoms of anxiety, insomnia, depression, and stress at baseline (T0) and follow-up at T1, T2, and T3 through the same WeChat public account. The baseline assessment was conducted as part of the general mental health evaluation required for all students. For the follow-up assessments, we first contacted the participants and invited them to complete the questionnaire again via the "Brain Structures" WeChat public account.

2.4 GCBT Intervention

The treatment program involved group activities, including two face-to-face sessions (at weeks 1 and 4) and two web-based sessions (at weeks 2 and 3). The intervention encompassed the following components: (a) Member introductions and understanding of depression, anxiety, and CBT. (b) Identification and exploration of distorted cognitions and negative behaviors. (c) Acquisition of corrective skills to address distorted cognitions. (d) Consolidation of cognitive changes and application of corrective skills. (Table S1) The GCBT group received a total of 4 weeks GCBT intervention, while the wait-list control (WLC) group received a delayed intervention, during which they received weekly follow-up phone calls to closely monitor their emotional state during the 4-week period.

2.5 Measures

2.5.1 Assessment of Mental Health Problems

Anxiety symptoms and symptom severity were measured using GAD-7[25-27]. The scale consists of seven self-rated items with a total score ranging from 0 to 21. Higher scores reflect higher levels of anxiety[25]. The Insomnia Severity Index (ISI) was used to assess the severity of insomnia and consisted of seven items[28-30]. Participants responded to seven questions, yielding total scores ranging from 0 to 28, where higher scores denote more severe insomnia[29]. The Patient Health Questionnaire-9 (PHQ-9) was used to screen and evaluate depressive symptoms[31-33]. The scale consists of nine items, with total scores ranging from 0 to 27, with higher scores indicating more severe depressive symptoms[33]. The Perceived Stress Scale-14 (PSS-14) is a measure of perceived stress and has shown good reliability and validity[34-36]. The scale, comprising 14 items, has a total score range of 0 to 56, obtained by summing scores across all items, with higher scores indicating elevated levels of perceived distress[37]. The Beck Scale for Suicide Ideation scale (BSSI) mainly evaluates the level of suicidal ideation[38-40].

During the intervention, anxiety, insomnia, depression, and stress symptom severity were assessed at T0 and follow-up T1, T2, and T3. Table S1 lists the data we collected and the characteristics we extracted.

2.5.2 Collection of Daily Heart Rates and Step Counts

During the intervention phase, college students were asked to wear the Huawei Band 6[41] [42, 43] continuously to collect real-time daily heart rates and step counts. The collected data were stored on the device, and data from the sensor devices were transferred to the research server **each** night. Text message reminders were sent to those who failed to upload on time.

Similarly, step counts and heart rates were measured with the Huawei Band 6, which has two sensors: one that measures acceleration as an indicator of overall movement, which is the step counts; and another photoelectric sensor for blood pulses to capture heart rates. Step counts and heart rates were recorded at 1-minute intervals. In addition, we collected daily heart rates and step counts, which were used to assess participants' physiological and behavioral characteristics.

2.5.3 Collection of EMA Data

From week 1 to 4, participants were told to answer two questions about mood and energy on MAs at 7 am and 9 pm each day. We used a separate 7-point Likert scale to measure participants' mood and energy such as "On a scale of 1 (very happy) to 7 (very sad), how would you rate your current mood?"; and "On a scale of 1 (very tired) to 7 (energetic), how would you rate your current energy?".

2.5.4 Data Pre-processing

The collected data were pre-processed before conducting the following analysis. We prepared the raw data obtained from the WDs into hourly, daily, and weekly data, which were then integrated into data for statistical analysis throughout the study. The data processing procedure and cleaning process were as follows: (a) to analyze the data collected during the period when subjects were wearing the device correctly, we used heart rate as an inclusion criterion. For the daily data, we included data where the patient's mean heart rate was between 30–200 beats/min and discarded any data outside of these parameters. We chose heart rate as a control because there is a biologically defined acceptable range [44] for heart rate data regardless of device lifestyle and wearing style, and it is easy to identify data that deviate

from this criterion. (b) We included blood oxygen as an inclusion criterion, excluding daily data with concentrations exceeding 100% as potentially erroneous measurements from the bracelet that deviate from biological norms.

2.5.5 Features Extraction

In our study, we conducted a comprehensive statistical analysis of the daily heart rate and step count data. This included calculating a variety of statistical parameters such as the average, median, maximum, minimum, 25th percentile, 75th percentile, standard deviation, skewness, total sum, and total completion of entries. Similarly, we applied the same statistical approach to the EMA data to gain insights into the fluctuations in participants' mood and energy levels throughout the study period. These parameters were all calculated on a weekly basis.

Furthermore, we also conducted individual assessments of the mood and energy data collected weekly, allowing us to isolate and examine the unique emotional and energetic characteristics of each participant. Specifically, the EMA data collection was scheduled daily from 7:00 to 21:00 and divided into morning and evening periods. Consistent with the feature extraction method applied to the wristband data, we performed feature extraction on each participant's EMA mood and energy values, further distinguishing between morning and evening characteristics. This meticulous analytical method enabled us to generate distinctive EMA features for each participant. Through this multifaceted evaluation approach, we were able to thoroughly capture and understand the changes in participants' heart rate, step count, mood, and energy levels.

2.5.6 Outcomes

The primary outcome was the change, relative to baseline, in severity of anxiety symptoms integrated over three follow-ups spanning 6 months. The severity of anxiety symptoms was assessed T0 and at T1, T2, and T3 using the GAD-7.

The secondary outcomes involved changes in heart rate, step count, and EMA results relative to the first week over a 4-week period. In addition, the severity of depressive, stress, and insomnia symptoms, relative to baseline, integrated over three follow-ups spanning 6 months were noted. Specifically, the severity of depressive, stress, and insomnia symptoms were assessed at baseline (T0) and follow-up at T1, T2, and T3 using the PHQ-9, PSS-14, and ISI, respectively.

3. Statistical Analysis

The Mann-Whitney U test and χ^2 tests were used to examine between-group differences in demographics between the GCBT and WLC groups. Linear mixed models were used to analyze differences in depressive, anxiety, insomnia, and stress symptoms at baseline (T0) and follow-up at T1, T2, and T3. The same methods were then used to compare differences in values of daily heart rate, step count, and EMA data results at week 1, 2, 3, and 4 during the intervention and observe trends in value changes over the 4-week-period. Spearman analysis was then performed to explore the correlation between symptom improvement and differential heart rate, step count, and EMA results in the GCBT group.

4. Results

4.1 Demographic

Sixty college students with anxiety symptoms were eligible based on the criteria. At the end of the intervention, when the heart rates and step counts were collated, 58 were included in

the final analysis. However, only 35 individuals ultimately had all daily heart rate, step counts, and daily mood assessment records from the intervention period, resulting in a data validity rate of 60.3%. Only college students who completed the baseline survey and recorded 4 weeks of data during the intervention were included in our final analysis (35/58, 60.3%). We included a total of 35 participants and divided them into GCBT ($n = 18$) and WLC ($n = 17$) groups according to the randomization grouping procedure. Table 1 presents the analysis of the general information of the participants. We found that there were no significant differences between participants in terms of age, gender, ethnicity, smoking history, drinking history, psychiatric history, or family history.

Table 1: Demographic characteristics between the group cognitive-behavioral therapy and wait-list control groups

	GCBT ($n=18$)	WLC ($n=17$)	Z/χ^2	P value
Mean age, years (SD)	20.11 (0.90)	20.41 (1.372)	-0.396	0.708
Sex, n (%)			0.238	0.625
male	7 (38.90)	8 (47.10)		
female	11 (61.10)	9 (52.90)		
Education, n (%)			2.246	0.134
Undergraduate	18 (100.00)	15 (88.20)		
Master's degree	0	2 (11.80)		
Smoking rules, n (%)			2.003	0.157
never smoke	16 (88.90)	17 (100.00)		
Sometimes smoke ^a (cumulative smoking <10 packs)	2 (11.10)	0		
Alcohol history, n (%)			0.015	0.903
never drink	12 (66.70)	11 (64.70)		
Drink occasionally ^b (less than one time per week)	6 (33.30)	6 (35.30)		
Family history of mental illness,			0.004	0.952

n (%)				
no	16 (88.90)	15 (88.20)		
yes	2 (11.10)	2 (11.80)		

χ^2 test for categorical variables and Mann–Whitney U test for continuous variables. a: Sometimes smoke: cumulative smoking <10 packs; b: Drink occasionally: less than one time per week; *P value ≤ 0.05 , ** P value ≤ 0.01 , *** P value ≤ 0.001

4.2 Intervention Outcomes

4.2.1 Primary Outcomes

Linear mixed models showed a progressive and significant improvement in anxiety symptoms over time. Results indicated no significant interaction between anxiety symptoms and the effect of GCBT at T1 and T2 ($p > 0.05$ for both). However, there was a significant interaction between anxiety symptoms and group at T3, with anxiety symptoms more severe in the WLC group than in the GCBT group ($p < 0.05$; Table 2). The means and standard deviations for anxiety, insomnia, depression, and stress scores at all four time points for both groups are presented in Table S2.

Table 2: Linear mixed model of questionnaire variables: coefficients, standard errors, and P values

Variable	Intercept (T0)	Time			Condition	Interaction		
		W4 (T1)	W8 (T2)	W28 (T3)		W4 (T1)	W8 (T2)	W28 (T3)
Anxiety								
B	5.222	−2.056	−3.222	−4.144	−1.412	2.010	−0.240	3.274
SE	0.513	0.715	0.715	0.737	0.747	1.034	1.062	1.049
P value	<0.001	0.005	<0.001	<0.001	0.068	0.055	0.822	0.002
Insomnia								
B	4.389	−0.944	−2.556	−2.345	−0.391	1.535	1.085	2.700
SE	0.715	0.920	0.920	0.952	1.041	1.332	1.372	1.354
P value	<0.001	0.307	0.007	0.016	0.710	0.252	0.431	0.049

Depression								
B	6.835	-2.279	-3.224	-3.113	-0.606	1.286	-0.123	1.942
SE	0.678	0.887	0.887	0.887	0.992	1.287	1.287	1.287
<i>P</i> value	<0.001	0.012	0.001	0.001	0.545	0.321	0.924	0.135
Stress								
B	22.278	-2.333	-0.833	-0.222	0.016	0.039	0.127	0.163
SE	1.833	2.372	2.372	2.372	2.630	3.403	3.403	3.403
<i>P</i> value	<0.001	0.328	0.726	0.926	0.995	0.991	0.970	0.962

4.2.2 Secondary Outcomes

During the intervention phase, we observed significant interactions related to time and group for several parameters. For physical activity measures, both mean and maximum step counts, as well as the standard deviation, skewness, and total counts, showed distinct differences between groups. Similarly, heart rate indicators such as the mean, 25th, and 75th percentiles also demonstrated significant time/group interactions (Table 3). Furthermore, an upward trend was noted in the aggregates of morning mood and energy, as well as the frequency of mood assessments conducted in both morning and evening sessions. Notably, during the 4-week treatment, substantial differences emerged between the GCBT and WLC groups concerning standard deviation, minimum values, and total scores for morning mood and energy, and the minimum evening mood values. It is particularly interesting to observe that participants in the GCBT group were more active in the mornings compared to evenings, unlike those in the WLC group. This shift in activity correlates with the observed improvements in mood and energy, suggesting a positive impact of morning physical activity on daily emotional well-being. These patterns indicate enhanced mood stability and improved energy levels in the morning among the GCBT participants compared to the WLC group (Table 4). Regarding depressive and stress symptoms, no significant time/group interactions were detected at T1,

T2, and T3. Post-intervention, a significant difference in insomnia symptoms developed at T3, with the WLC group recording higher scores within the normal range compared to the GCBT group, implying that the intervention may contribute to better sleep quality among college students (Table 2).

Table 3: Linear mixed model of wearable devices: coefficients, standard errors, and *P* values

Variable	Intercept (W1)	Time			Condition	Interaction		
		W2	W3	W4		W2	W3	W4
Step count								
mean								
B	8176.031	1036.468	67.348	74.102	247.856	-616.440	-786.586	1953.003
SE	722.788	556.924	545.670	568.257	1037.100	790.845	782.960	798.866
<i>P</i> value	<0.001	0.066	0.902	0.897	0.813	0.438	0.318	0.016
max								
B	2047.852	339.834	218.455	279.729	260.382	-315.905	-462.538	-868.415
SE	162.268	157.150	157.150	163.924	232.956	231.393	228.605	230.901
<i>P</i> value	<0.001	0.033	0.168	0.092	0.272	0.176	0.046	<0.001
std								
B	713.627	84.424	41.908	67.355	24.563	-27.880	-63.008	-154.429
SE	51.853	44.605	43.724	45.656	74.431	62.753	63.515	64.175
<i>P</i> value	<0.001	0.062	0.341	0.144	0.744	0.658	0.324	0.018
skew								
B	0.958	0.056	0.152	0.142	0.188	-0.092	-0.220	-0.494
SE	0.083	0.105	0.103	0.107	0.121	0.152	0.149	0.152
<i>P</i> value	<0.001	0.592	0.143	0.185	0.128	0.545	0.144	0.002
sum								
B	7882.517	1332.551	506.497	427.208	811.185	-1468.062	-1523.124	-2543.923
SE	748.773	581.931	581.931	608.113	1085.904	851.079	831.762	850.285
<i>P</i> value	<0.001	0.025	0.387	0.484	0.461	0.088	0.071	0.004

Heart rate								
mean								
B	79.293	0.837	0.778	0.750	0.488	-2.263	-3.291	-1.777
SE	1.606	1.112	1.112	1.121	2.293	1.579	1.579	1.585
<i>P</i> value	<0.001	0.454	0.486	0.505	0.833	0.155	0.040	0.265
25th percentile								
B	67.698	1.346	1.544	0.504	0.538	-2.084	-3.500	-0.934
SE	1.917	1.186	1.186	1.186	2.762	1.720	1.720	1.720
<i>P</i> value	<0.001	0.259	0.196	0.672	0.847	0.229	0.045	0.589
75th percentile								
B	87.296	1.349	0.505	0.306	0.652	-3.845	-3.131	-1.826
SE	1.518	1.226	1.226	1.250	2.147	1.734	1.751	1.751
<i>P</i> value	<0.001	0.274	0.681	0.807	0.763	0.029	0.077	0.300

Table 4: Linear mixed model of daily diary: coefficients, standard errors, and *P* values

Diary Variable	Intercept (W1)	Time			Condition	Interaction		
		W2	W3	W4		W2	W3	W4
Mood-morning								
std								
B	0.559	-0.094	0.016	-0.098	-0.070	0.212	0.049	0.377
SE	0.099	0.119	0.119	0.119	0.146	0.176	0.187	0.175
<i>P</i> value	<0.001	0.430	0.896	0.412	0.635	0.232	0.792	0.034
min								
B	5.408	1.110	1.414	1.508	0.154	-0.048	-0.111	-0.821
SE	0.165	0.175	0.179	0.187	0.238	0.250	0.258	0.258
<i>P</i> value	<0.001	<0.001	<0.001	<0.001	0.522	0.849	0.668	0.002
sum								
B	11.778	3.389	4.500	4.167	8.105	-0.389	0.559	-3.578
SE	1.934	1.181	1.181	1.181	2.775	1.694	1.694	1.694
<i>P</i> value	<0.001	0.005	<0.001	0.001	0.006	0.819	0.742	0.037
Mood-evening								
min								
B	1.833	-0.111	0.056	-0.056	0.701	0.459	-0.002	0.756

SE	0.321	0.177	0.177	0.177	0.462	0.256	0.256	0.256
<i>P</i> value	<0.001	0.531	0.754	0.754	0.139	0.077	0.994	0.004
Energy-morning								
sum								
B	23.930	5.028	7.125	7.181	3.172	-0.903	-2.580	-4.605
SE	1.859	1.617	1.605	1.605	2.609	2.249	2.235	2.264
<i>P</i> value	<0.001	0.003	<0.001	<0.001	0.233	0.689	0.251	0.045
The number of daily entries - morning								
B	5.408	1.110	1.414	1.508	0.154	-0.048	-0.111	-0.821
SE	0.165	0.175	0.179	0.187	0.238	0.250	0.258	0.258
<i>P</i> value	<0.001	<0.001	<0.001	<0.001	0.522	0.849	0.668	0.002
The number of daily entries - evening								
B	5.351	1.629	1.643	0.983	-0.054	-0.514	-0.376	-0.691
SE	0.172	0.238	0.239	0.222	0.250	0.333	0.342	0.322
<i>P</i> value	<0.001	<0.001	<0.001	<0.001	0.831	0.127	0.275	0.035

4.3 Correlation Analysis of Clinical Symptoms and Heart Rates, Step Counts, and EMA Results

In the GCBT group, an inverse correlation was observed between the improvement in anxiety symptoms and both the 75th percentile and the sum of changes in step counts. Specifically, a significant increase in step counts was strongly associated with a marked reduction in anxiety symptoms. Conversely, improvements in insomnia symptoms exhibited a negative correlation with maximum and total heart rates, as well as the frequency of heart rate measurements and weekly changes in the 75th percentile of step counts. This suggests that elevated heart rates were linked to reduced insomnia symptoms. Additionally, the daily mood (morning and evening) of participants in the GCBT group showed a positive correlation with various

metrics of step counts, such as mean, 25th percentile, 75th percentile, and skew. Similarly, the energy levels recorded in the morning and evening correlated positively with several heart rate metrics, such as mean, 75th percentile and standard deviation. Consequently, higher step counts were associated with better mood states, and increased heart rates corresponded with heightened energy levels during both morning and evening periods (Figure 3).

Figure 3 Correlation analysis of extracted features from **WDs** and **MA**s and symptom improvement. **(A)**. The correlation between symptoms and heart rate and step count results. **(B)**. The correlation between EMA and step count results. **(C)**. The correlation between EMA and heart rate results

5. Discussion

This study preliminary suggested the lasting treatment effect of GCBT within the short period, with additional improvement in reducing anxiety and insomnia symptoms found at long-term follow-ups, suggesting a potential delayed treatment effect. The study also used WDs to collect daily heart rates and step counts, which could serve as preliminary physiological indicators of changes associated with GCBT, as well as improvements in morning mood and energy, and evening mood in college students. This randomized controlled trial combined longitudinal methods and objective measures, offering a novel approach to preliminarily evaluate the efficacy of GCBT. As the current gold standard for assessing efficacy relies on standardized scales, these results are exploratory. Future research should aim to further investigate the role of objective biomarkers of efficacy based on WDs and MAs with larger sample sizes.

In our study, remission of anxiety and insomnia symptoms after GCBT treatment appeared to be sustained at 6-month follow-up, aligning with trends observed in previous studies[45, 46]. Additionally, several studies have observed no significant changes in anxiety and sleep outcomes when comparing adolescents receiving GCBT with those receiving delayed intervention[47, 48]. Considering the methodological and sample differences across studies, we observed that the WLC group showed a decrease in anxiety and insomnia scores within the 4-week period. However, their symptoms were significantly higher compared with those in the GCBT group at T3. We speculate that the placebo effect of WDs and short-term effects of receiving EMA may have influenced these observations, a hypothesis that further supported by final outcomes that excluded the influence of WDs and EMA during the follow-up period. Thus, college students without intervention may face heightened risks due to academic pressures, social transitions, and lack of coping resources, making them more prone to such instability, since initial improvements in those without treatment may not be sustained over time, as suggested by our findings. These findings underscore the potential long-term benefits of GCBT on anxiety and insomnia, emphasizing its potential as a valuable treatment approach for anxiety and insomnia; meanwhile, EMA has a potential of adjunctive treatment in previous research[49].

GCBT may enhance mental well-being and focuses on challenging maladaptive cognitive distortions and activating behavior[50]. Previous research has highlighted a strong association between prolonged sedentary behavior and symptoms of anxiety, depression, and insomnia[51, 52]. After treatment, participants' step count activity increased significantly, and this increase among patients may serve as an initial behavioral indicator. Meanwhile, increased physical activity may contribute to enhanced effects of GCBT on improving mental well-being[53]. In

contrast to previous studies [54], our investigation found increased heart rates during the third week of GCBT intervention, suggesting that higher heart rates may reflect increased physiological arousal associated with engagement in therapy. It is possible that in our cohort, the initial emotional and cognitive involvement induced by GCBT may have led to these increased heart rates as participants activated their behaviors. This may suggest that the increase in heart rate, together with the improvement in anxiety symptoms and physical activity, may reflect a complex interaction in which engagement in treatment provides both physiological and psychological benefits.

By utilizing MAs, EMA enables real-time evaluation of therapeutic effectiveness in psychotherapy. Our findings suggest that GCBT may improve patients' morning mood and energy, and evening mood in the context of daily diary changes during the study period. Meanwhile, EMA allows individuals to assess the emotional impact of situations and determine the most desirable emotional response, facilitating the recognition of one's current emotional state and activating emotional expression[55-58]. These outcomes provide a longitudinal perspective on the potential efficacy of GCBT and serve as a potential complementary measures[59].

Previous GCBT studies have generally not included daily heart rates, daily step counts, and EMA data as well as objective indicators for evaluating the efficacy of GCBT. By combining WDs with real-time self-reporting of emotions and energy through MAs, we observed that higher step counts were associated with better morning and evening moods, while higher energy levels were correlated with faster heart rates. The findings suggest a potential correlation between mood improvement and behavioral activation[60]. Increases in

participants' step counts were observed as early as the third week, suggesting the potential effectiveness of GCBT in promoting physical activity. Based on these findings, the GCBT group appeared to experienced improvements in anxiety and insomnia symptoms after intervention, as reflected in daily mood and energy ratings, accompanied by changes in step counts and heart rates. Therefore, the increase in step counts and heart rates may serve as preliminary indicators for assessing GCBT efficacy. A multidimensional evaluation of GCBT may offer a more comprehensive approach to assessing intervention outcomes by incorporating symptom evaluation, EMA data, and daily heart rates and step counts.

Despite the study's valuable findings, several limitations should be acknowledged. First, the daily heart rate, step count, and EMA data collection were limited to 4 weeks, which hindered the determination of sustained effects of GCBT. Second, the accuracy of wrist-worn WDs may vary between individuals. Although the Huawei Band 6 generally provides relatively stable heart rate readings, regardless of how it is worn, the accuracy may be compromised if the wearer moves their arm, leading to motion artifacts in the signal. Third, as the effect sizes observed may not fully represent the impact of the intervention on individuals with more severe anxiety symptoms, future research designs should include selection of participants with higher baseline anxiety scores to better isolate the effects of the intervention in populations with more substantial symptoms. Fourth, the high dropout rate from WD data collection may have introduced selection bias and limited the generalizability of the biobehavioral findings. Finally, although the sample size of the current study was relatively small, we believe the sample effectively reflects individuals in need of intervention, rather than a selectively motivated group. This focus on students experiencing emotional distress, rather than those driven solely by intrinsic motivation, strengthens the relevance of our findings. Future

research should aim to include a larger and more diverse sample to enhance the robustness and representativeness of the results.

6. Conclusion

Our findings suggest both short- and long-term efficacy of GCBT on anxiety symptoms in college students. We suggest that changes in step counts and heart rates could potentially reflect the treatment response to GCBT, and mood and energy levels in the morning and evening may also offer valuable insights for assessing treatment response. Such preliminary findings may inform the exploration of WD- and MA-based approaches for mental health treatment, potentially enhancing the likelihood timely intervention. Data from WDs may help reduce the reliance on subjective reports, provide timely insights into individual treatment dynamics, and suggest future directions for personalized treatment.

Abbreviations

GCBT Group Cognitive-Behavioral Therapy

EMA Ecological Momentary Assessments

WLC wait-list control

WDs wearable devices

Mas mobile applications

PHQ-9 Patient Health Questionnaire-9

GAD-7 Generalized Anxiety Disorder Scale-7

PSS-14 Perceived Stress Scale-14

ISI Insomnia Severity Index

BSSI Beck Scale for Suicide Ideation

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Author Contributions

FW and YW designed the study. YW and KZ managed the literature searches and analyses. YW, YgW, and RL participated in the collection of data. ZS, YW, and JZ undertook the statistical analysis. YW, KZ, and ZL wrote the first draft of the manuscript. FYW, YW, RZ, XZ, and YxW participated in the revision of the manuscript. All authors contributed to and have approved the final manuscript.

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Data Availability

The authors do not have the right to share any data information as per the ethics committee rules and regulations but are available upon a reasonable request from the corresponding author (FW).

Declarations

Ethics approval and consent to participate

This study protocol was reviewed and approved by the Ethics Committee of Xinxiang Medical College of Henan Province, approval number: XYLL-2020235). An electronic informed consent form was provided before the start of the questionnaire, and after completing the informed consent form, participants completed the online questionnaire. We confirmed that informed consent was obtained from all participants. Moreover, all methods in this study were performed by the relevant guidelines and regulations.

Consent for publication

Not available.

Competing interests

The authors have no conflicts of interest to declare.

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