Trends
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JOURNAL ARTICLE PRE-PROOF
(as accepted)

Original Article

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http://doi.org/10.47626/2237-6089-2023-0713

Original submitted Date: 31-Jul-2023

Accepted Date: 08-Nov-2023

Randomized Clinical Trial on the Comparison of Effect of Asynchronous Mobile Application and Guided Brief Cognitive Behavioral Therapy in Managing Anxiety among Medical Students

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Abstract

Introductions: Medical students are a population at increased risk for anxiety due to their demanding schedule and concerns about potential stigmatization, which often leads to discouragement when seeking help. COVID-19 pandemic has been reported to worsen this issue by restricting social interaction and mobility. To address this problem, an innovative method known as Asynchronous Digital Cognitive Education GAMA-AIMS (DCE GAMA-AIMS) has been introduced. Compared to traditional therapy, this modality can be accessed independently without the guidance of a therapist.

Objectives: To compare the effectiveness of DCE GAMA-AIMS in reducing anxiety scores compared to guided brief Cognitive Behavioral Therapy (guided bCBT).

Methods: A non-blinding RCT was conducted on 66 medical students. The participants were equally divided into two groups, namely intervention and control. The intervention

group was given DCE GAMA-AIMS, while the control was administered with guided bCBT. The data obtained were analyzed using independent t-test and ANOVAs.

Results: The application had a significant effect on reducing anxiety scores from the 2nd week (M TMAS = 18) to the 8th week (M TMAS = 13). A faster and more significant improvement was observed in the intervention group from the 1st to the 2nd week compared to the control, which began to improve in the 4th week. Furthermore, the intervention group had larger effect sizes (1.32) compared to the control (0.79) from the 1st to 8th week.

Conclusion: Asynchronous DCE GAMA-AIMS and guided bCBT could reduce TMAS scores in medical students with anxiety, but DCE GAMA-AIMS yielded a greater effect size.

Keywords (6): medical students, anxiety, mobile application, psychotherapy, brief CBT

1. Introduction

Medical students are a population with an elevated risk of mental health disorders, particularly anxiety, due to the extended duration of their education and demanding curriculum[1]. Previous reports have shown a global prevalence of 33.8% for anxiety among this population. Furthermore, this percentage significantly exceeds prevalence in the general population and represents a marked increase compared to previous studies, reporting a rate of 11.5%.[2, 3] In the broader context of global demographics, the onset of the COVID-19 pandemic caused an increase in the number of affected individuals. The incidence increased up to 25%, with an overall prevalence of 47% during the initial year of the pandemic. The most pronounced increment was observed among college students, with a rate of 81.8%.[4,5] According to a previous study, the lack of treatment for anxiety can be detrimental and disrupt productivity, leading to a decline in the quality of life.[6]

Various modalities for treating anxiety are presently accessible, comprising pharmacotherapy, neurofeedback, psychoeducation, cognitive therapy, behavioral therapy, mindfulness, relaxation methods, and religious therapy, but several limitations still persist within these treatment options. These limitations include the potential side effects of medication, constraints in accessing healthcare facilities, strict schedules, stigma, and uneven distribution of therapists. Furthermore, this condition can lead to

reduced medical students' motivation as patients to seek treatment, limited reach of therapy services, low patient compliance, and increased dropout rates.[7,8]

Brief cognitive behavioral therapy (bCBT) has shown effectiveness as an alternative treatment for social anxiety disorder (SAD) among medical students. This option has also shown efficiency in situations where a shortage of qualified therapists exists, but it still experiences several drawbacks.[9] To address the challenges posed by globalization and constraints of existing therapy, there is a need for therapy modalities that are cost-effective, easily accessible, efficacious, free from stigma, and consistent with technological advancements. Several related studies have recommended strategies, such as comparing smartphone-accessible interventions to existing treatments, investing in user-centered design reports, and exploring the applicability and efficacy of other theories/models.[10,11] Therefore, this study aims to assess the effectiveness of mobile application-based psychotherapy compared to conventional face-to-face psychotherapy (guided synchronous brief CBT) in mitigating anxiety among medical students in Indonesia.

2. Methods

2.1. Participants

This study was a single-center, non-blinding, and randomized clinical trial, with a purposive sampling method. The participants of the randomized controlled phase were recruited from the Faculty of Medicine, Public Health, and Nursing at Gadjah Mada University Yogyakarta, Indonesia from April to June 2022. This pilot study was conducted in line with the Health Promoting University (HPU) program initiated by Gadjah Mada University for medical students, who were known to be at high risk of experiencing anxiety.[1,2,3]

The sample population consisted of all undergraduate or professional education students (batch 2017-2021) who experienced anxiety symptoms based on the GAD-7 questionnaire and were willing to participate in the procedures by voluntarily providing informed consent. The diagnosis and psychiatric condition of having anxiety were established by psychiatric trainees who were supervised by psychiatrists. Furthermore, this process was conducted by a symptomatic method to anxiety based on DSM-5 to

exclude subjects who met the exclusion criteria. Participants receiving therapy for psychiatric conditions, having a history of drug abuse, or showing other symptoms leading to a more severe disorder (subjects with psychotic symptoms, severe mood disorder, and psychiatric emergencies such as self-harm and suicidal thoughts) were excluded. To detect a large effect size with a power of 90% and an alpha error of 0.05, a minimum sample size of 36 for each group was required.[12]

Among the population of 994 students, 568 were willing to complete the GAD-7 Questionnaire and 179 met the GAD-7 criteria (GAD score ≥ 5). Furthermore, only 86 medical students agreed to participate in the study and were divided into two groups. In the control group, 43 participants were given brief bCBT guided by a therapist through a *Zoom call* for 8 weeks. The intervention group was given Asynchronous Digital Cognitive Education, a mobile-based online application. A total of 66 students, 33 in each group, were able to complete the study, while 20 dropped out during the treatment. During the procedures, 10 participants in the intervention group and 9 participants in the control were lost to follow-up because they could not be contacted through chat and telephone calls. Meanwhile, 1 respondent in the control group, as monitored and evaluated by the psychiatric trainee, showed worsening symptoms (psychotic) and was referred to a psychiatrist in the hospital for further treatment and assessment.

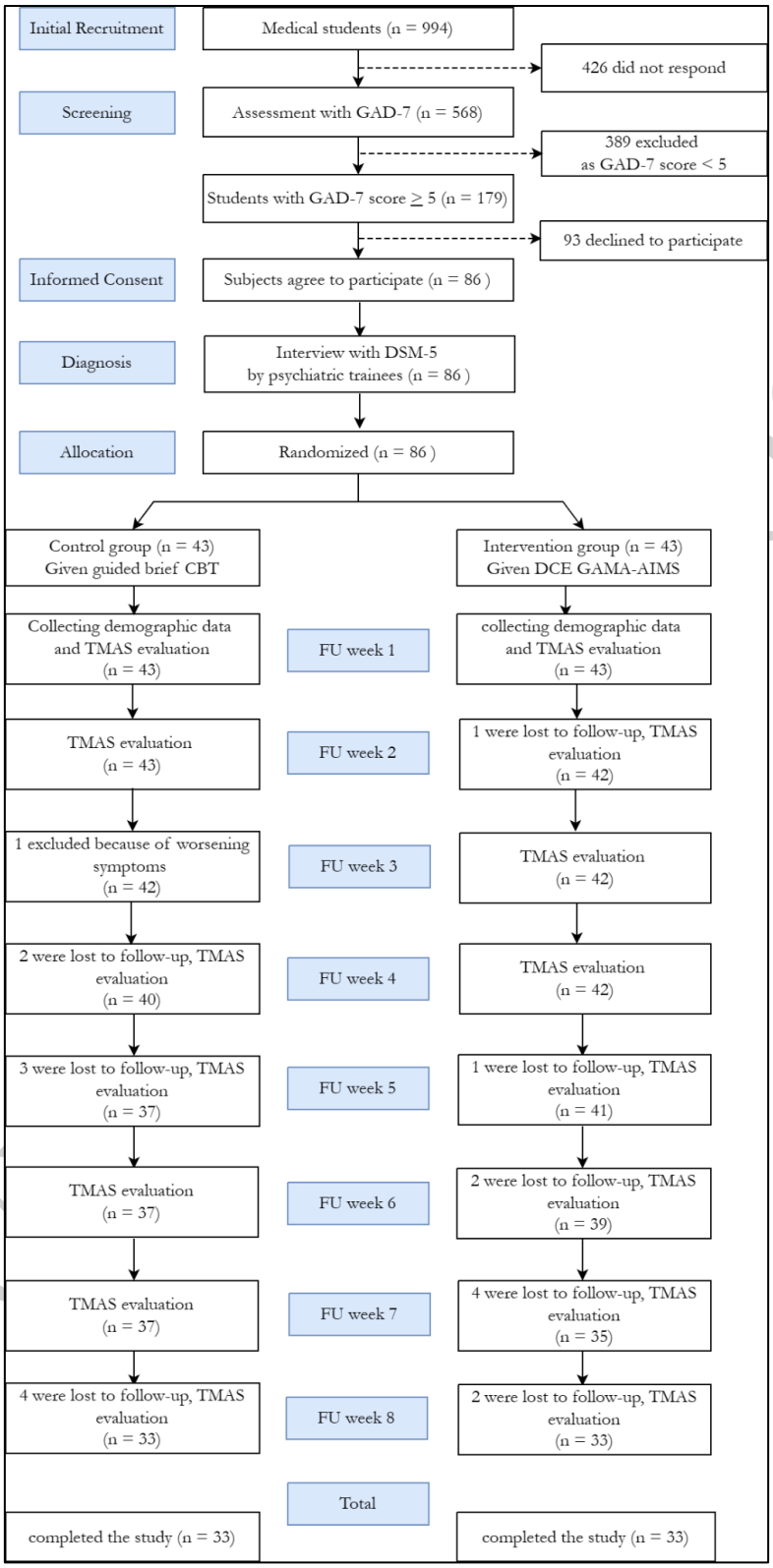

Figure 1. Participants Flow in Sample Allocation

GAD-7 = General Anxiety Disorder-7; TMAS = Taylor Manifest Anxiety Scale; CBT = Cognitive Behavioral Therapy; DCE GAMA-AIMS: Digital Cognitive Education Gadjah Mada Anxiety Intervention for Medical Students; FU = Follow Up

2.2. Measures

The tool used for anxiety screening was GAD-7, with cut points of 5, 10, and 15 indicating mild, moderate, and severe levels, respectively.[13] The participants included in this study were medical students from batch 2017 to 2021 who had GAD scores ≥ 5 and were later diagnosed with anxiety based on DSM-5 criteria.[29] Anxiety score was assessed with the Taylor Manifest Anxiety Scale (TMAS) for the baseline before intervention and evaluated each week for a total of 8 weeks. TMAS, as part of the Minnesota Multiphasic Personality Inventory (MMPI), was a self-report questionnaire comprising 50 items and increasing TMAS scores correlated with higher levels of anxiety.[30] All data collection and monitoring were carried out using online questionnaire forms and meetings.

2.3. Intervention

2.3.1 Guided bCBT

Guided brief CBT was given to the control group as gold standard non-pharmacological treatment. Brief psychotherapy consisted of eight weekly brief CBT sessions, each of a one-hour online meeting, and guided by psychiatry trainees who already had the clinical authority to manage patients with anxiety. The psychiatric trainees were trained by a professional clinical psychologist with more than 5 years of experience in performing CBT and directly supervised by psychiatrists utilized in this study. The comparison to treatment aimed to strengthen the conclusion that therapy obtained by the intervention group produced significant effects and output. Furthermore, it could minimize errors, such as the placebo effect and threats of validity in making conclusions about intervention results.

2.3.2. Asynchronous DCE GAMA-AIMS

Asynchronous DCE-GAMA AIMS was the intervention modality designed in this study. Furthermore, it was created based on cognitive psychoeducational methods and delivered digitally through the GAMA-AIMS smartphone-based application. In the process of psychotherapy, patients actively engaged with the material through a device used independently without the presence of a therapist (unguided real-time self-help). This application was created in collaboration with medical education experts, psychiatrists,

clinical psychologists, and mobile application developers. The application menu was divided into three parts, including the information, therapy, and daily journal sections. The information section contained an explanation of anxiety from the definition, signs, and symptoms, as well as how to seek help. The therapy section was developed based on Beckian Cognitive Therapy and consisted of 8 submenus, namely therapy concept explanation, problem identification, negative thoughts identification, reframing, behavioral activation, problem-solving, relaxation, and evaluation. The daily journal section consisted of a mood tracker, e-diary, and journal of activity. This module had passed various trials to test its internal validity, reliability, safety, and usability.[14,15]

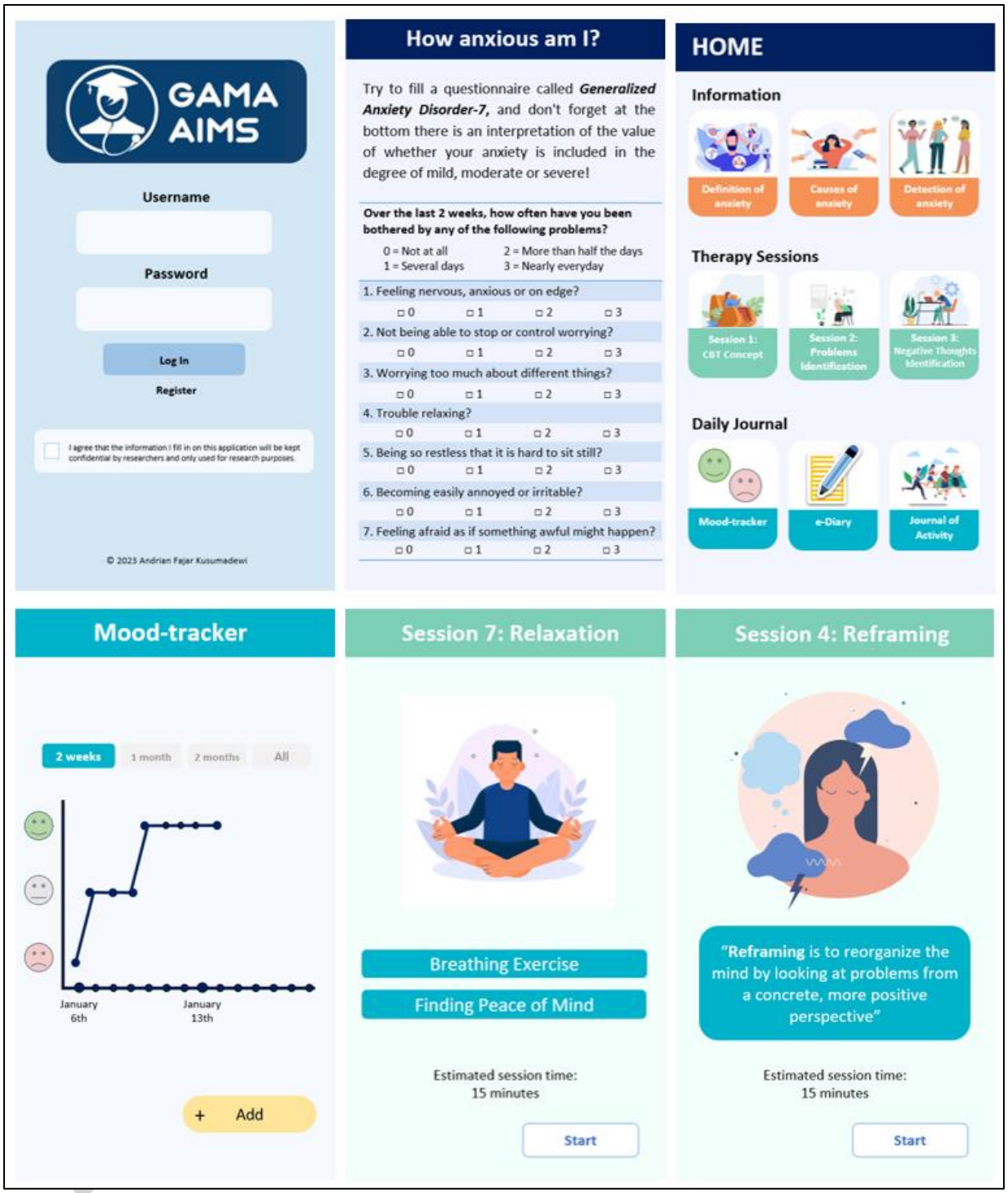

Image 1. Interface of GAMA-AIMS Application. This image shows the login page, list of menus, and types of menus on the application

2.4. Statistical Analysis

The characteristics of the variables were tested using an independent t-test. The extent of symptom change over an 8-week follow-up period within the two groups was determined using the linear mixed model analyses of variance (ANOVAs). Subsequently, the data were analyzed using SPSS version 25 (IBM Corp, Armonk, NY). The study participants provided online consent and the procedures were carried out based on the ethical principles of human studies, as outlined in the Declaration of Helsinki.

3. Results

3.1 Baseline Characteristics

The average age of the respondents was 20.45 years (SD = 0.71), and 78.79% of them were females. The results showed that there were no statistically significant differences between intervention and control groups in terms of anxiety severity and the two baseline characteristics (Table 1).

Table 1. Demographic data

Variables	Guided Brief CBT	Asynchronous DCE	Z/X2	p
Age, mean (SD)	20.58 (1.48)	20.33 (1.22)	-.430	.667
Sex female, n (%)	26 (78.79)	26 (78.79)	.00	1.00
GAD-7 category, n (%)			1.50	.471
Mild	15 (45.5)	11 (33.3)		
Moderate	11 (33.3)	11 (33.3)		
Severe	7 (21.2)	11 (33.3)		

3.2 Treatment Outcome and Effect Size

Linear mixed model ANOVAs were used to assess the extent of symptom change over an 8-week follow-up period within the two groups. Considering the significance of Mauchley's Test of Sphericity, the Greenhouse-Geisser correction was applied.

Furthermore, an important treatment interaction between group and time was observed on the self-report outcome (TMAS), yielding a statistically significant result {F (4.39, 68.10) = 3.65, p = .005}.

Within-group analyses were conducted using paired-sample t-tests (refer to Table 2), showing a significant improvement in the DCE group from the first week to the second week. The results showed that this improvement continued until the 8th week for the TMAS measure {t(33) = 2.66 - 6.71, p < 0.05}. However, guided brief CBT group did not show significant recovery during the 2nd {t(33) = 1.94, p = 0.062} or the 3rd week {t(33) = 1.63, p = 0.113}. When considering the guided brief CBT group, subsequent paired-sample t-tests showed a significant improvement from the 4th week to the 8th week in comparison to the initial TMAS score {t(33) = 2.68-5.90, p < 0.05}.

Table 2. Treatment Outcomes

	TMAS 1 M (SD)	TMAS 2 M (SD)	TMAS 3 M (SD)	TMAS 4 M (SD)	TMAS 5 M (SD)	TMAS 6 M (SD)	TMAS 7 M (SD)	TMAS 8 M (SD)
Guided Brief CBT	22.28 (5.80)	21.22 (5.45)	21.38 (5.77)	20.78 (5.91)	19.09 (5.98)	19.31 (5.84)	19.09 (6.41)	17.41 (6.38)
Asynchronous DCE	21.16 (6.50)	18.78 (6.68)	17.13 (6.25)	16.78 (6.49)	14.59 (7.36)	14.00 (7.11)	12.97 (6.82)	12.16 (7.06)
Between-group *t* value (*p-value*) df = 66	t = -.731 (.468)	t = -1.60 (.115)	t = -2.82 (.006)	t = -2.58 (.012)	t = -2.68 (.009)	t = -3.27 (.002)	t = -3.70 (.000)	t = -3.12 (.003)
Within group *t* value (*p-value*), compared to TMAS 1								
Guided Brief CBT, df = 33		t = 1.94 (.062)	t = 1.63 (.113)	t = 2.68 (.012)	t = 3.37 (.002)	t = 5.46 (.000)	t = 4.61 (.000)	t = 5.90 (.000)
Asynchronous DCE, df = 33		t = 2.66 (.012)	t = 4.18 (.000)	t = 3.86 (.001)	t = 5.63 (.000)	t = 6.17 (.000)	t = 6.71 (.000)	t = 6.39 (.000)

Although the results indicated that Asynchronous DCE was superior to guided brief CBT, additional analyses were carried out to determine the magnitude of the treatment effect within each group. This was achieved by calculating within-group effect sizes using Cohen's d formula, as presented in Table 3. Following Cohen's established classification of effect sizes into small (0.20–0.49), medium (0.50–0.79), and large (0.80 and above),

the large and medium categories were observed in this study for Asynchronous DCE (1.32), and guided brief CBT (0.79) from the 1st to the 8th week, respectively.

Table 3. Effect Sizes (Cohen`s d)

Assessment	Guided Brief CBT	Asynchronous DCE
TMAS		
1st - 8th week	0.79	1.32
Between-group size effect (8th week)	0.78	

4. Discussion

This current study provided evidence supporting the effectiveness of Asynchronous DCE as a treatment for anxiety among medical students in Yogyakarta, Indonesia. Participants who received DCE showed significant improvements in symptoms, as indicated by the TMAS score. Furthermore, the treatment effects of intervention were found to be superior to those of guided brief CBT. The analysis showed large effect sizes for the eight-week Asynchronous DCE treatment, while moderate sizes were observed for guided brief CBT.

These results were consistent with previous studies using Asynchronous psychotherapy protocol, but these reports incorporated additional psychological measures and used a general health information module as a control. Batterham et al. observed a significant impact of the self-guided intervention on reducing anxiety after four weeks of treatment.[16]

In another study, a treatment intervention consisting of nine ten-week modules comprising psychoeducation, iCBT, and physical activity promotion was implemented, while this study consisted of eight-week sessions. This previous study showed a significant secondary effect on anxiety sensitivity (measured by the Anxiety Sensitivity Index - ASI), worry, and depression. However, Christensen (2014) stated that the primary outcome measure for anxiety, assessed using the GAD-7, did not show superiority over the placebo website condition. Although it was challenging to pinpoint the exact cause of

this difference, several factors could contribute. Several studies stated that while the GAD-7 was effective in detecting various anxiety disorders, it possibly could be a less sensitive measure of changes compared to the ASI.[17]

The reduction in symptoms was consistent with Miller et al. (2021), that the anxiety levels of participants, assessed using the GAD-7 (out of a total of 21 respondents), decreased among the majority of participants who engaged in digital CBT weekly from baseline to the end of the 6th week of intervention. The levels also continued to decrease during the follow-up period in the 10th week.[18] According to Kackzurkin et al. (2015), exposure therapy combined with relaxation methods and CBT yielded better outcomes among affected individuals.[19]

The results of this study were inconsistent with Carl et al. (2020), McCloud et al. (2020), and Ponzo et al. (2020). Carl et al. (2020) stated that there was a significant reduction in anxiety levels after the use of digital CBT in the 6th week.[20] Meanwhile, McCloud et al. (2020)[14] using the FeelStressFree application, and Ponzo et al. (2020)[21] using RCT based on the BioBase application, found a decrease in the 4th week.[14, 20, 21] Based on these results, Asynchronous DCE's ability to reduce the condition in the 7th week remained superior compared to conventional CBT, which required a minimum of 10 weeks for symptom improvement.[22, 23] Dafroyati also identified a decrease in TMAS anxiety levels, with the majority experiencing mild anxiety after 10 sessions (10 hours) of conventional CBT.[23] Several reports considered psychoeducation therapy effective because it was in line with the medical model of illness, emphasizing that mental conditions could be method and treated in a similar manner as physical conditions.[24]

During the 8-week intervention based on relaxation methods and cognitive therapy, a reduction in anxiety levels was successfully achieved. However, the results showed that the conditions experienced by the participants did not completely disappear. This result was consistent with a previous report on internet intervention on a campus, where the average level of stress did not decrease after intervention. This was due to a lack of time to implement the methods, as well as the presence of workload and chronic stress that continued to the symptoms.[25] Based on the weekly intervention results and the use of the application over 8 weeks, the use of Asynchronous DCE intervention of GAMA-AIMS at least once a week could reduce participant condition starting from the 5th week.

Furthermore, a significant decrease was observed when the application was used for 7 weeks.

It was important to emphasize that interventions used in this study were conducted weekly over a total of 8 weeks based on psychoeducation principles. Furthermore, psychoeducation guidelines recommended a minimum of 1 intervention per week, lasting for 6-12 weeks to achieve results similar to psychotherapy.[26] The difference in results lied in the form of the GAMA-AIMS application menu, which was specifically tailored to health science students and the language and content were more understandable for the participants.

The results obtained were similar to the intervention results of the Healthy Mind application. In the first 2 weeks, users accessed the application an average of 2 times, with an average duration of 19 minutes per access, showing a wide variation in login frequency and duration (users could access the application up to 26 times).[27] The choice of accessing the anxiety psychoeducation module through the application was based on previous studies and applications that showed better frequency of usage compared to web-based intervention. Compared to the web-based module "Healthy Paths," the Healthy Mind application was accessed twice as often, with slightly shorter durations per login.[27] Previous studies also indicated that people tended to use mobile applications for very short periods, considering their habit of using smartphones during leisure time. The application must be quickly accessible, have simple interactions, and support one or a limited set of tasks, preferably related to previous conditions and intervention.[28]

Asynchronous DCE GAMA-AIMS therapy presented a multitude of advantages in comparison to alternative therapy methods. This therapy was able to reduce anxiety scores by frequently engaging in therapy sessions on a mobile application weekly. Given its digital nature, this mobile application presented easier access and had the potential as the primary resource for medical students experiencing anxiety. Furthermore, it was in line with the demands of medical students who underwent heavy academic loads and tight schedules and facilitated ease of access compared to conventional or online CBT. Conventional or online CBT must have appointments with therapists, which necessitated the coordination of schedules either through the use of the Zoom application or face-to-face meetings. Considering the prevailing stigma surrounding mental health disorders,

this mobile application provided medical access to mental health services, thereby facilitating the treatment of anxiety. This indicated that it could be a part of the medical faculty's mental health provision for their students.[35, 36]

In this study, a dropout rate of 23.25% was observed during the course of the treatment. Although there was no absolute consensus or recommendation, several journals mentioned that a dropout rate exceeding 20% potentially affected the quality of results in RCTs. This was observed particularly in the aspects of statistical power, bias, and generalizability, especially when the distribution of missing data varied significantly between the two groups.[31, 32, 33] Other references stated that it was very difficult to achieve a <20% dropout rate, especially in non-pharmacological intervention (e.g., psychotherapy, including CBT) with repeated outcome measurements and long-term therapy duration (>4 weeks), as implemented in this study. Therefore, a rate below 30% could still be considered acceptable.[31, 32, 34]

A meta-analysis examining the attrition in CBT intervention studies reported an average weighted dropout rate during treatment of 26.2%, slightly higher compared to this study. CBT in the e-therapy format exhibited a higher average, reaching 34.2%.[37] The results identified several factors that could lead to the discontinuation of participation in the intervention, including time-related factors (especially for the control group), personal interest and commitment to therapy, as well as perceived improvements in symptoms.[32, 33] However, due to the high rate of informal dropout (loss to follow-up without formal notice), the exact cause of the action could not be further explored.

Although Psychotherapy Asynchronous DCE GAMA-AIMS had a significant effect in reducing anxiety scores among medical students, some limitations must be acknowledged, such as a relatively small sample size from one center. This indicated that further studies must use larger populations in various settings to obtain more generalizable results. In this study, there was no physical examination or biological markers related to anxiety. The data collection mostly relied on self-report assessments and online meetings due to pandemic situations. This led to sub-optimal monitoring and evaluation, as well as the loss of participants to follow-up. Therefore, future studies were advised to determine the long-term effect of therapy and its role in preventing relapse.

5. Conclusion

In conclusion, Asynchronous DCE GAMA-AIMS and online guided brief CBT could reduce TMAS scores in medical students with anxiety. However, it was observed that DCE GAMA-AIMS yielded a slightly greater effect size. This indicated that the application could be considered as an accessible alternative initial therapy or self-help. Further studies and developments were necessary to maximize effect and generalizability before implementing intervention.

Declaration of Interest statement

The authors declare no conflict of interest.

Authors' Contributions

AFK led the study, developed the application, and conducted result analyses. CRM, W, and RTW proposed the review background and methods, developed the application, and gave writing feedback. All authors read and approved the final manuscript.

Acknowledgments

The authors are grateful to mentee Soewadi (professor in psychiatric department Universitas Gadjah Mada), Aris Sudiyanto (professor in psychiatric department Universitas Sebelas Maret), Gandes Retno Rahayu (professor in medical education Universitas Gadjah Mada), Sumarni (associate professor of psychologist Universitas Gadjah Mada), and Irwan Supriyanto (assistant professor in psychiatric department Universitas Gadjah Mada). The authors are also grateful to all study assistants from the beginning of the study.

Funding

This study was approved by the Medical and Health Research Ethics Commission, Faculty of Medicine, Public Health and Nursing, Gadjah Mada University on September 21, 2021, with No: KE/FK/1051/EC/2021, the amendment to Ethics on January 9, 2023, with No: KE/ FK/0048/EC, and the last ethical amendment was made on June 5, 2023,

with No. KE/FK/0048/EC. Furthermore, funding assistance was obtained from The Indonesia Endowment Funds for Education (LPDP).

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