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Efficacy of an online intervention for anxiety prevention: A clinical trial

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Abstract

This study aimed to test the effectiveness and the sustained effect (follow-up) of a four-week mindfulness intervention in reducing anxiety and stress in a group of Brazilian university students. The intervention was adapted to be made available through the *Neurosaúde* application, created as part of this work to serve as a platform for the intervention. The research took place in a virtual environment, with 48 participants recruited, who were randomly allocated to the intervention group or to the waiting list control group. Measures were used to access the levels of mindfulness, anxiety, and stress before and after the intervention and at the 4-week follow-up. Applying the intention-to-treat analysis, we found significant differences between the groups regarding the measurement of anxiety in the follow-up, with a large effect size ($F(2, 92) = 10.275$, $p = .000$, $\eta^2 = 0.183$). The results suggest that the 4-week mindfulness intervention through a mobile application was able to act as a protective factor against the anxiety developed by university students during the COVID-19 pandemic. While the treatment group maintained reduced levels of anxiety the control group demonstrated a continuous increase in anxiety in the post-test and follow-up that coincided with the first wave of COVID-19 in the region where the participants lived.

Keywords: mindfulness, stress, anxiety, online interventions, covid-19

EFICÁCIA DE UMA INTERVENÇÃO ONLINE PARA PREVENÇÃO DA ANSIEDADE: UM ENSAIO CLÍNICO

Resumo

O propósito desse estudo foi testar a eficácia e o efeito sustentado (*follow-up*) de uma intervenção de *mindfulness* de quatro semanas na redução da ansiedade e estresse em um grupo de estudantes universitários brasileiros. A intervenção foi adaptada para ser disponibilizada através do aplicativo Neurosaúde, criado como parte desse trabalho para servir de plataforma para a intervenção. A pesquisa como um todo ocorreu em ambiente virtual, sendo recrutados quarenta e oito participantes que foram alocados randomicamente para o grupo intervenção ou para o controle de lista de espera. Medidas foram utilizadas para acessar os níveis de *mindfulness*, ansiedade e estresse antes, após a intervenção e no *follow-up* de 4 semanas. Aplicando a análise por intenção de tratar, encontramos diferenças significativas entre os grupos para a medida de ansiedade no *follow-up* com um tamanho de efeito grande ($F (2, 92) = 10,275$, $p= 0,000$, $\eta^2 = 0,183$). Nossos resultados sugerem que a intervenção de *mindfulness* de 4 semanas através de um aplicativo móvel foi capaz de agir como um fator protetor contra a ansiedade desenvolvida pelos estudantes universitários durante a ocorrência da pandemia causada pelo COVID-19 visto que, enquanto o grupo tratamento manteve níveis reduzidos de ansiedade, o grupo controle demonstrou um continuo aumento de ansiedade no pós-teste e *follow-up* que coincidiu com a primeira onda de COVID-19 na região onde os participantes residiam.

Palavras-chave: mindfulness, estresse, ansiedade, intervenções on-line, covid-19

EFECTIVIDAD DE UNA INTERVENCIÓN ONLINE PARA PREVENCIÓN DE ANSIEDAD: UN ENSAYO CLÍNICO

Resumen

El propósito de este estudio fue probar la eficacia y el efecto sostenido (seguimiento) de una intervención de atención plena de cuatro semanas para reducir la ansiedad y el estrés en un grupo de estudiantes universitarios brasileños, la intervención se adaptó para estar disponible a través del app. Neurosaúde, creada como parte de este trabajo para servir como plataforma de intervención. La investigación en su conjunto se llevó a cabo en un entorno virtual, siendo reclutados cuarenta y ocho participantes que fueron asignados aleatoriamente al grupo de intervención o al control en lista de espera. Se utilizaron medidas para evaluar los niveles de atención plena, ansiedad y estrés antes, después de la intervención y en el seguimiento a las 4 semanas. Al aplicar el análisis por intención de tratar, encontramos diferencias significativas entre los grupos para la medida de ansiedad en el seguimiento con un tamaño de efecto grande ($F (2,92) = 10,275$, $p = 0,000$, $\eta^2 = 0,183$). Nuestros resultados sugieren que la intervención de mindfulness de 4 semanas a través de una aplicación móvil fue capaz de actuar como factor protector contra la ansiedad

desarrollada por estudiantes universitarios durante la ocurrencia de la pandemia de COVID-19, ya que mientras el grupo de tratamiento mantuvo niveles, el grupo control demostró un aumento continuo de la ansiedad en el postest y seguimiento que coincidió con la primera ola de COVID-19 en la región donde residían los participantes.

Palabras clave: mindfulness, estrés, ansiedad, intervenciones en línea, covid-19

Entering university can be associated with a series of stressful and anxiogenic life changes, especially for young adults. These include the challenge of reconciling academic tasks with employment, raising children, and moving away from the family due to leaving the hometown (Mussi et al., 2019). With all these changes, the academic environment does not only bring growth and positive impacts. This variety of stressors to which the student is exposed can increase the chances of developing depression, anxiety, and cardiovascular disease, as well as increased use of drugs and alcohol, contributing to a generalized decrease in levels of well-being, empathy, and compassion (Birks et al., 2009; Jones et al., 2018).

In addition, the risk of psychological problems associated with university life increased considerably with the emergence of the COVID-19 pandemic in 2020 (Maia & Dias, 2020). With the transition from face-to-face teaching to online teaching, many students suffered the impacts of confinement and social isolation that contributed to exacerbated anxiety and stress (Silva & Rosa, 2021). Therefore, exploring treatment and prevention alternatives for the increased levels of anxiety and stress in this public is justified as a relevant and urgent task. In this context, an evidence-based option that is considered safe, inexpensive, and easy to apply is mindfulness-based interventions, which seek to develop the awareness that emerges from the process of paying attention, purposefully and without judgment, to the experience of the present moment (Kabat-Zinn, 2003; Leyland et al., 2019).

Studies have shown that mindfulness training helps mitigate the impact of negative experiences and reduces anxiety and stress levels (Bamber & Morpeth, 2019; Kuyken et al., 2016; O'Driscoll et al., 2019). When compared to individual therapies such as cognitive behavioral therapy (CBT), mindfulness-based interventions have shown equivalent results for reducing anxiety and stress levels (Hofmann & Gómez, 2017). During this context, the research field of online interventions has been growing rapidly in recent years and it is already well documented that the effectiveness of these interventions is similar to face-to-face interventions, with protocols for the most varied types of disorders, including mindfulness to reduce anxiety and stress (Andersson et al., 2018). The latest aspect of this research pertains to mindfulness interventions provided through smartphones. Although there are fewer studies on this topic as compared to interventions delivered via computers, there is already research indicating the effectiveness of these interventions in reducing anxiety and stress levels (Economides et al., 2018; Flett et al., 2019; Huberty et al., 2019; Victorson et al., 2020).

Because of the above, this study aimed to investigate the effectiveness of a 4-week mindfulness-based intervention, which was made available through a mobile application to reduce anxiety and stress in university students.

Method

Participants

The non-probabilistic convenience sample of this study was composed of 48 adults randomly divided into 2 groups. Group A: Brief mindfulness intervention; and Group B: Waiting

list control group. To participate in the study, volunteers had to meet the following criteria: (1) to be between the ages of 18 and 35; (2) to be a university student (undergraduate or graduate); (3) to reside in Brazil; (4) to have internet access and a cell phone with Android 4.4.4 or higher; (5) to be willing to download and use the application on their cell phone; and (6) to achieve a score greater than 0 in anxiety and stress symptoms, measured by the stress and anxiety subscales of the Depression, Anxiety, and Stress Scale (DASS-21) (Vignola & Tucci, 2014). Exclusion criteria were (1) having already adopted a frequent practice of mindfulness in the last 6 months; (2) using some type of psychotropic medication; (3) undergoing psychological treatment; and (4) having a diagnosis of a psychiatric or neurological illness considered serious (e.g. schizophrenia, borderline personality disorder, panic disorder, post-traumatic stress disorder).

Ethical aspects

This study obtained authorization from the Research Ethics Committee (CAAE 26449619.2.0000.5188) and followed the guidelines of Resolution nº 466/12 regarding the ethical aspects of research involving human subjects. It was also registered on the Brazilian Clinical Trials Registry (ReBEC) platform, with the registration code RBR-9s6tc8. Participation in the study was voluntary and subject to reading and agreeing with the consent form.

Study characterization

This is a randomized, unblinded, waiting list-controlled trial.

Procedure

The intervention carried out in this study began on July 6, 2020, and ended on September 6, 2020, and all work took place in a virtual environment. Disclosure and recruitment took place through social networks such as Facebook, WhatsApp, and YouTube, through a brief promotional video. The video provided relevant information about the study and a link directing participants to a registration form containing more information about the research and a brief registration questionnaire generated by Google Forms that served for prior screening of the participants according to the eligibility criteria.

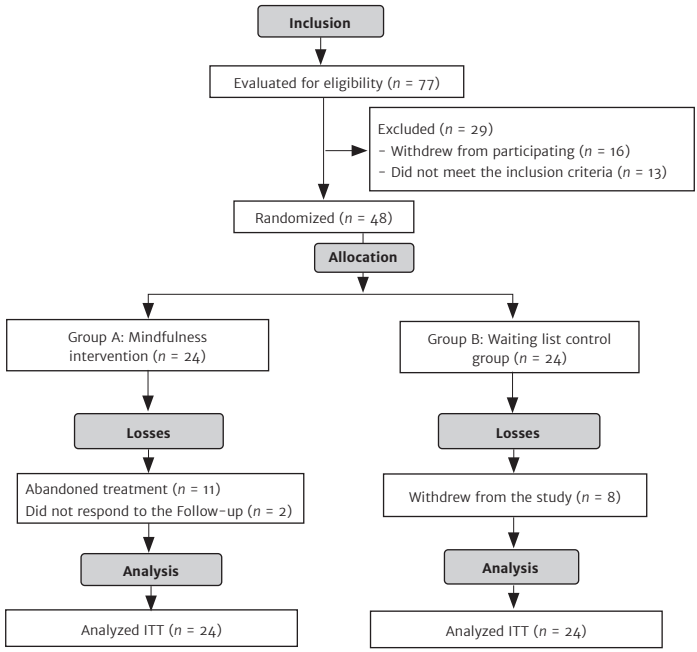
In a second moment, after the end of the recruitment period, the registered participants were contacted to verify whether they were still interested in participating in the study. Those who confirmed were invited to complete an online instrument generated by Google Forms composed of the consent form and the study questionnaires. All participants who responded to this online instrument were randomized into two groups, with group A receiving the intervention immediately and group B participating as a waiting list control group. For more information, see the CONSORT flowchart (Figure 1).

Finally, the intervention was carried out through the application called *Neurosaúde*, created to serve as a platform for the proposed intervention. WhatsApp served as the main

means of communication with the participants. During the process, the broadcast list resource was used, which allows a message to be sent to several contacts at once. The lists were predetermined and allowed messages to be sent to the participants of each group separately. Contact with the participants only took place at specific times: at the beginning, when they were welcomed and instructed on how to install the application and proceed during the study; at the end of each week of the intervention, when the weekly questionnaires were sent to collect information about the experience of performing the application and carrying out the practices; at the end of the intervention; and four weeks after its end, when users were asked to answer the follow-up questionnaires. Throughout this process, the messages were delivered individually, and no participant had contact with another.

Figure 1

CONSORT flowchart



Sample calculation

The sample size estimate was performed using the G*Power 3.1.9.4 program (Faul et al., 2009). The a priori type was used in the power analysis, based on the ANOVA 2 x 3 (within-between interaction) statistical test for repeated measures, where the 2 represents the number of groups and the 3 is related to the repetitions (before the intervention, after the intervention and follow-up). An effect size (f = 0.25) was defined with an error of 5% (α = 0.05) and a power of 95% (β = 0.95), indicating a minimum sample of 44 subjects.

Randomization and Blinding

Randomization was performed by a person that was not involved in the research, who had no contact with the participants and was blind to the study's hypotheses. The website (randomization.com) was used to allocate the participants into 2 groups in a 1:1 ratio. At the end of this stage, the list with the allocation of participants was sent to the researcher responsible for the study, who, in turn, sent a message informing the participants of their condition (Group A or B) and other instructions.

The mindfulness instructor responsible for creating the intervention was blind to the performance obtained by the participants throughout the study and did not have direct contact with them, since the interaction with the participants took place only through previously produced audios and videos. There was no active control and, therefore, the participants in the waiting list group knew that they were not receiving the intervention.

Intervention

The intervention used in this study was based on a 4-week face-to-face mindfulness protocol (Demarzo et al., 2017) that was adapted for the virtual environment. The intervention developed consisted of 4 videos of approximately 30 minutes, released weekly over a 4-week period. Each of these videos included a didactic part and recorded experiential exercises, which participants had access to through the mobile application developed exclusively for this intervention.

Each week, participants received mp3 audio recordings of the video received during the week. The participants were instructed to watch the video on the day of its publication (Monday) and to practice the recorded exercises over the following 6 days. The weekly audios lasted approximately 10 to 15 minutes (which could vary according to the type of practice proposed for the week) with guided mindfulness exercises (Table 1). The videos and recordings were prepared by an instructor with more than 5 years of experience, trained by the *Centro Mente Aberta* – Brazilian Center for Mindfulness and Health Promotion. *Mente Aberta's* professional certification follows the British and Brazilian guidelines for good mindfulness practices.

Table 1

Overview of the intervention

Week	General theme	Aspects covered	Practice of the week
1	What is mindfulness?	• Presentation of the program. • What is mindfulness? • Mindlessness.	• Grounding Exercise.
2	Formal and informal practice	• Formal and informal practices • Exploring the breath. • Dealing with thoughts and emotions during practice.	• Mindfulness of breathing.
3	Mindfulness challenges	• First and Second Suffering. • Mindfulness challenges.	• Body scan.
4	Closing and review	• Compassion and mindfulness. • Review of the program.	• Compassion practice.

Both groups answered the questionnaires at three moments: immediately before the beginning of the intervention, at the end of 4 weeks (when the intervention ended), and at the follow-up (4 weeks after the end of the intervention). After applying the follow-up questionnaires, participants in the control group were offered the opportunity to participate in the entire intervention process provided to the experimental group.

Instruments

Depression, Anxiety, and Stress Scale (DASS-21): with 21 items answered on a Likert-type scale ranging from 0 (does not apply at all) to 3 (applies a lot or most of the time). The instrument was adapted and validated for Brazil (Vignola & Tucci, 2014), with a Cronbach's alpha of 0.92 for the depression subscale, 0.90 for the stress subscale, and 0.86 for the anxiety subscale, indicating good internal consistency.

Five Facets of Mindfulness Questionnaire (FFMQ-BR): translated and validated for Brazil (Barros et al., 2014), with good results in the internal consistency analysis (0.81). It consists of 39 items, with responses ranging from 1 (never or rarely true) to 5 (almost always true) on a Likert-type scale. The five facets measured are: (1) Observing; (2) Describing; (3) Acting with awareness; (4) non-judging of inner experience; (5) non-reactivity to inner experience.

Losses and adherence

Participants who stopped responding to the weekly questionnaires about their experience with the application and frequency of carrying out the practices over the 4 weeks, as well as those who did not respond to the post-intervention or follow-up questionnaires, were considered study losses. As adherence strategy, an open contact line was maintained via WhatsApp to resolve difficulties or doubts of the participants. See Figure 1 for more information on the number of participants who dropped out of the study at some point or did not respond to the follow-up.

Data analysis

The SPSS version 24.0 software was used for the data analysis. The intention-to-treat (ITT) analysis, which postulates that once the subject is randomized, they must be included in the data analysis, was used for the treatment and analysis of missing responses (McCoy, 2017). Therefore, the data lost for each variable throughout the study (*missing data*) were corrected by replicating the last answer collected (*carry forward*), which characterizes the application of the intention-to-treat method in cases of treatment withdrawal (n = 11) and in cases where the follow-up was not answered (n = 2) (Hollis & Campbell, 1999).

For all data to meet the prerequisites for using parametric analysis, data referring to anxiety were transformed using the square root method. A mixed ANOVA test (within-between interaction) was used, where the variable "group" with two levels (mindfulness intervention and control group) was used as the between participants factor, and the variable "time" with three levels (before the intervention, after the intervention and follow-up) as the among participants factors.

Mauchly's sphericity test was used to assess whether the assumption of sphericity of the variables was violated. The Bonferroni post-hoc test was used to verify any statistical differences found by the ANOVA. Finally, the effect size was calculated from the eta-square (η^2), applying the conventional values of 0.01, 0.06, and 0.14 that represent, respectively, small, medium, and large effects (Cohen, 1988; Lenhard & Lenhard, 2016). The similarity between the intervention and control groups for the DAAS-21 before the start of the intervention was tested using Student's t-test. For all statistical tests used, the significance level $p < 0.05$ was established as the standard.

Results

Of the 48 participants recruited, there was a predominance of females (75.0%), most were undergraduates (91.6%) and were only studying (81.2%). Of these, 85.4% were single with a predominance of monthly family income between 1 and 3 minimum wages (39.6%). Participants' ages ranged from 18 to 34 years, with a mean of 24.67 years (SD = 4.8) for group A, and from 18 to 31 years, with a mean of 23.00 years (SD = 3.7) for group B. No significant age difference was found between the groups ($t(46) = 1.333$; $p = 0.095$). All participants were Brazilian, and most were from the northeast of Brazil (97.9%) where they were taking their university courses.

DAAS-21

Regarding the anxiety and stress scores measured by the DAAS-21 in the pre-intervention, most participants in both groups presented normal levels. Seeking to verify whether there were differences between the groups before the intervention, Student's t-test was applied, which found that there were no significant differences in anxiety ($t(46) = 0.121$; $p = 0.904$) or stress ($t(46) = 0.169$; $p = 0.867$). The results of the mixed ANOVA for the anxiety and stress variables measured by the Depression, Anxiety and Stress Scale (DASS-21), about the factors

within and between subjects, as well as the mean and standard deviation over time (pre-intervention, post-intervention, and follow-up), are presented in Table 2.

Table 2

Mean levels of anxiety and stress measured by the DASS-21 (n = 48)

Anxiety			
Time	**Pre, *M* (*SD*)**	**Post, *M* (*SD*)**	**Follow-up, *M* (*SD*)**
Group A	0.91 (0.77)	0.72 (0.69)	0.69 (0.66)
Group B	0.88 (0.68)	0.92 (0.73)	1.29 (0.65)
Within-subjects effect			
(Time) *F*, *p*, η^2	(F(2, 92) = 4.065, p = 0.020, η^2 = 0.081)		
(Time*Group) *F*, *p*, η^2	(F(2, 92) = 10.275, p = 0.000, η^2 = 0.183)		
Between-subjects effect			
Groups *F*, *p*, η^2	(F(1, 46) = 1.688, p = 0.200, η^2 = 0.035)		
Stress			
Time	**Pre, M (SD)**	**Post, *M* (*SD*)**	**Follow-up, *M* (*SD*)**
Group A	1.43 (0.72)	1.24 (0.72)	1.15 (0.72)
Group B	1.40 (0.76)	1.51 (0.73)	1.28 (0.76)
Within-subjects effect			
(Time) *F*, *p*, η^2	(F(2, 92) = 4.839, p = 0.010, η^2 = 0.095)		
(Time*Group) *F*, *p*, η^2	(F(2, 92) = 2.247, p = 0.111, η^2 = 0.047)		
Between-subjects effect			
Groups *F*, *p*, η^2	(F(1, 46) = 0.485, p = 0.490, η^2 = 0.010)		

Note. M: mean; *SD*: standard deviation; *F*: ANOVA result, *p*: significance, η^2: Effect size.

Regarding the results of the within-subjects comparisons, we can see that the time factor had a significant impact on the anxiety (F(2, 92) = 4.065, p = 0.020, η^2 = 0.081) and stress (F(2, 92) = 4.839, p = 0.010, η^2 = 0.095) scores, with a medium effect size obtained in both cases. Also considering the within-subjects comparisons, there was a significant impact of the time versus group factor for anxiety (F(2, 92) = 10.275, p = 0.000, η^2 = 0.183), with a large effect size, while no significant differences were found for stress (F(2, 92) = 2.247, p = 0.111, η^2 = 0.047).

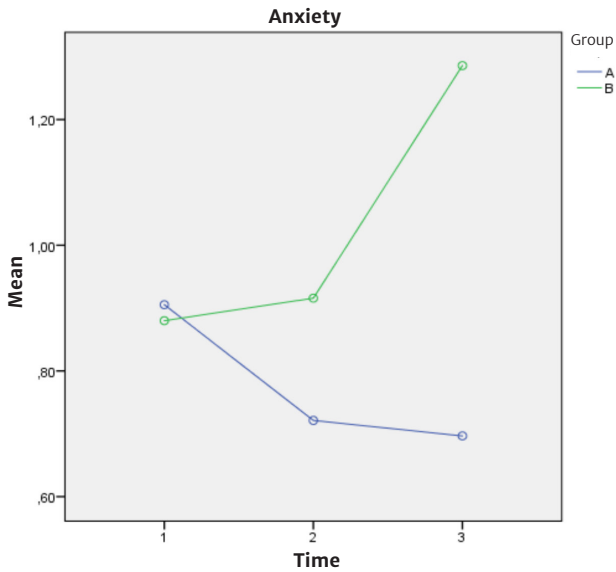
From the verification of the statistically significant differences described above, relating the time factor and the measures of anxiety and stress, as well as the relation with the group factor, the Bonferroni post-hoc test was applied to verify where these differences were found. Analyses using the Pairwise method showed that when comparing the moments of anxiety assessment, the intervention group did not present significant differences (p > 0.05) between any of the times (Pre-intervention (1), post-intervention (2), Follow-up (3)), indicating that, although there was a decrease over time, anxiety levels remained relatively stable. For the control

group, the comparisons showed a significant difference (p = 0.001) between the pre-intervention (M = 0.88 SD = 0.68) and follow-up (M = 1.29 SD = 0.65) times, and post-intervention (M = 0.92 SD = 0.73) and follow-up times, indicating that throughout the entire period of the study there was an increase in the anxiety of the participants in this group, as shown in Figure 2.

About the analysis of comparisons between the time versus group factors, the analysis using the Pairwise method only found statistically significant differences at time 3 (p = 0.002) between the groups for the anxiety variable, indicating that the participants in the intervention group had significantly lower anxiety scores than the control group participants at follow-up, as depicted in Figure 2.

Figure 2

*Mixed ANOVA result for the Time*Group – Anxiety comparison*

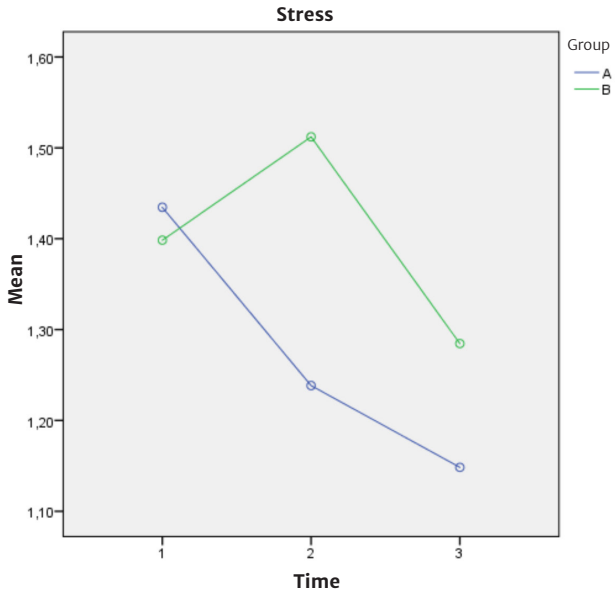


Regarding the stress scores, the analyses using the Pairwise method showed that when comparing the evaluation times, the experimental group showed a significant difference (p = 0.024) between the pre-intervention (M = 1.43 SD = 0.72) and follow-up (M = 1.15 SD = 0.72) times, indicating that although there was a decrease in the participants' stress between the pre- and post-intervention moments, this difference was not significant; however, at follow-up this difference became significant. Concerning the control group, the comparisons showed that there was no significant difference (p > 0.05) between the evaluation moments, indicating that although, throughout the study, the stress variation of the participants in this group increased

and decreased, this variation was not significantly different from the pre-intervention moment, as shown in Figure 3.

Figure 3

*Mixed ANOVA result for the Time*Group – Stress comparison*



With regard to the results of the between-subjects analysis, no significant differences were found for the group factor in anxiety ($F(1, 46) = 1.688$, $p = 0.200$, $\eta^2 = 0.035$) or stress ($F(1, 46) = 0.485$, $p = 0.490$, $\eta^2 = 0.010$), indicating that there was no significant group effect on these variables.

FFMQ-BR

Regarding the total mindfulness score measured by the FFMQ and its subscales, there was a similarity of means between the groups. Student's *t*-test showed that there were no significant differences for the total score between the groups ($t(46) = -0.916$; $p = 0.364$), with the same being the case for the other factors of the questionnaire, except for the Observing factor, where group B presented a significantly higher score than group A ($t(46) = - 2.675$; $p = 0.010$).

Considering the Five Facets of the Mindfulness Questionnaire, no significant effect sizes were found for any of the types of analysis (within-groups, between-groups). However, the results of the within-group analysis show that for group A there was a significant impact of the time factor on the scores of the subscales Acting with awareness ($F(1.183, 54.435) = 4.645$,

p = 0.030) and Non-judging (F(1.137, 52.301) = 5.207, p = 0.023), and for the total FFMQ score, which was also significant (F(1.155, 53.118) = 5.661, p = 0.017). Regarding the comparisons of the time versus group factor, there was no significant impact for any of the variables.

Comparisons using the Pairwise method showed that only Group A showed significant differences when comparing time levels. For the variable "Acting with awareness" there was a marginally significant difference (p = 0.057) between the pre-intervention (M = 3.09 SD = 1.02) and post-intervention (M = 3.40 SD = 1. 08) times, and a significant difference (p = 0.021) between the pre-intervention and follow-up times (M = 3.45 SD = 1.00). For group B, the comparisons showed no significant difference (p > 0.05) between times.

Significant differences (p = 0.028) were also found for Group A in the Non-judging variable between the pre-intervention (M = 2.85 SD = 0.91) and post-intervention (M = 3.27 SD = 0.96) times, and also a significant difference (p = 0.009) between the pre-intervention and follow-up (M = 3.39 SD = 1.00) times, indicating that, in relation to the pre-intervention, there was an increase in this trait throughout the study. In Group B, there was no significant difference (p > 0.05) between times, indicating that this trait did not change throughout the study.

Regarding the total FFMQ score for Group A, there was a significant difference (p = 0.016) between pre-treatment (M = 2.69 SD = 0.61) and post-treatment (M = 2.93 SD = 0.69) times and a significant difference (p = 0.009) between pre-treatment and follow-up (M = 2.95 SD = 0.71) times, which means that there was an increase in this trait for participants over the course of the entire study when compared to time 1. As for Group B, no statistically significant differences were found (p > 0.05), indicating that for Group B, this trait remained stable over time.

Regarding the results of the between-group analysis, no significant differences were found in the effect test for any of the subscales or for the total FFMQ score, indicating that there was no significant effect of the groups on these variables.

Discussion

As far as is known, this clinical trial was the first Brazilian study to test the effectiveness of a brief mindfulness intervention made available via a mobile application. The result found in the comparison of the time versus group factor for the anxiety variable at follow-up can be highlighted. They indicate that the anxiety scores of the intervention group were significantly lower than the scores of the participants in the control group, with a large effect size (Table 2, Figure 2). This result is promising since the study took place in parallel with the first wave of the COVID-19 pandemic, which may have contributed to this increase in anxiety, as is shown in more detail in the next section.

Context in which the intervention was carried out

Due to the challenges encountered at the university, the university public may present higher levels of anxiety compared to the public (Ariño & Bardagi, 2018; ul Haq et al., 2018).

Furthermore, it should be emphasized that at the moment when this research was carried out, the participants also faced another major challenge, this being the initial phase and the worsening of the pandemic caused by COVID-19 (Ministério da Saúde do Brasil, 2020), which naturally tended to increase people's anxiety and stress (Faro et al., 2020; Lima et al., 2020). In Brazil, the first cases of COVID-19 were registered in February, and the first case of death occurred on March 17, 2020 (Cavalcante et al., 2020). On March 30, 2020, the federal government declared through Ordinance No. 340, several recommendations for measures to combat COVID-19, including social isolation measures (Ordinance No. 340, 2020).

The intervention applied in this study began on July 6, 2020. On that same day, according to the World Health Organization – WHO daily bulletin, Brazil was already the country with the second highest number of confirmed cases, with a total of 1,577,004, and also of deaths, with 64,265 deaths (WHO, 2020b). On August 6, Brazil continued to be the second country; however, with an evolution of confirmed cases to 2,801,921 and total deaths to 95,819 (WHO, 2020a). On September 6, 2020, when data collection was completed with the follow-up questionnaires, Brazil recorded a total of 4,092,832 confirmed cases and 125,521 deaths from COVID-19, being the country with the second-highest number of confirmed cases and deaths (WHO, 2020c).

Anxiety

Mindfulness-based interventions have empirical support for their effectiveness for cases of anxiety in clinical (Hofmann et al., 2010) and non-clinical (Eberth & Sedlmeier, 2012) populations, as demonstrated in this study. The significant effect of the intervention only manifested itself in the follow-up phase, when the control group showed a continuous increase in anxiety levels while the group that had received the intervention maintained or reduced their mean anxiety levels to the intervention baseline. The hypothesis is that the skills learned during the online mindfulness program enabled participants in the intervention group to better deal with the anxiogenic agents associated with the first wave of the COVID-19 pandemic – which ended up leading to social isolation and the impossibility of these students continuing their classes and social interactions face-to-face – reflected in the significant decreases in anxiety levels found in the follow-up.

These findings corroborate another study conducted during the time of the pandemic, which used the Symptom Checklist-90 scale (SCL-90) to measure participants' anxiety scores. The authors of this work found a moderately significant correlation between the mindfulness trait and anxiety symptoms: with higher mindfulness scores equating to lower anxiety scores, indicating that mindfulness was a possible protective agent against anxiety during the pandemic period (Conversano et al., 2020).

One hypothesis about what may have contributed to the fact that the present study did not find significant differences between the groups in the post-intervention period was the use of a subclinical sample with low levels of anxiety. Therefore, with the worsening of the pandemic,

the control group increased the level of anxiety in the follow-up, while the group that received the intervention was protected.

Mindfulness and stress

The analyses of the results indicated a significant impact of the time factor on many of the variables studied, suggesting, for example, decreases in stress levels throughout the study for the intervention group, as well as an increase throughout the intervention of the total mindfulness score and the subscales Acting with awareness and non-judging in the participants of the online program.

Limitations and Conclusion

The first limitation that can be mentioned is the absence of an active control group since a waiting list control group was used in this work. Therefore, there was no control over, for example, the placebo effect that could result from the use of an active condition (Turner et al., 1994). Accordingly, it is recommended that, in future studies, researchers try to test the effect of the intervention in comparison to active control conditions.

A second limitation would be the high rate of attrition that occurred throughout the study. Although this is common in studies of this modality (Cavanagh et al., 2013), the pandemic may also have contributed to the increase in this factor. However, all analyses were conducted considering the intention-to-treat analysis (McCoy, 2017) according to the conservative carry forward method (Hollis & Campbell, 1999), which is considered a method that underestimates the effect of the intervention, therefore maintaining more reliable results (Liu-Seifert et al., 2010).

Another limitation concerns the weekly assessment methods of adherence to the program and the frequency of mindfulness practices throughout the program. Even trying to access this information through weekly questionnaires, this type of access proved to be inefficient, since many of the participants did not respond to these questionnaires throughout the study, reducing its effectiveness. Therefore, subsequent programs should seek alternatives for collecting data on the frequency and performance of the practices, such as including automated tools for measuring usage in the application itself.

Finally, the fact that most of the stages of the study were carried out by a single researcher made it impossible for the researcher and participants to be blinded. Despite this, the present study is believed to provide important information about the feasibility of a four-week online mindfulness intervention via mobile application. It is recommended that in future work a greater segmentation of the steps to be performed by each researcher is made, preserving important factors such as blinding (Carvalho & Silva, 2013).

The results suggest that the 4-week online intervention made available through the *Neurosaúde* application was able to act as a protective factor against anxiety developed by university students during the COVID-19 pandemic. The protective effect of the intervention

became more intense and reached a high level of significance one month after the end of the intervention (at follow-up) coinciding with the height of the first wave of the pandemic in Brazil.

Through the analysis of the qualitative results, it can be inferred that the mobile application worked adequately throughout the intervention and was well accepted by the users, who considered it useful and easy to understand. In conclusion, the *Neurosaúde* application is a useful tool to help prevent anxiety in university students.

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