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Culturally adapted Turkish version of an internet-based mindfulness intervention for university students: a randomized controlled feasibility trial

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Abstract

Background Studying at university is a stressful time for many, which might result in the development of mental health problems. In the first wave of Covid-19, university students in Turkey reported suffering from an elevated level of stress compared to their peers in other countries. Mindfulness-based interventions could provide the means of successfully decreasing the stress level of university students. Moreover, offering interventions via the Internet could be a scalable option to prevent and treat mental health problems, while offering time/place flexibility, anonymity, and cost-effectiveness.

Method In a randomized controlled trial of parallel design, the feasibility of a culturally adapted internet- and mobile-based intervention (IMI) (StudiCareM-TR) to promote mindfulness among Turkish-speaking university students was tested. Participants ($N=58$) of a public university in Istanbul were randomized into an intervention (IG) vs. waitlist control group (WL). Measurements took place at baseline (t0) and 10 weeks post-randomization (t1). Intervention adherence, acceptance, and potential negative effects were feasibility outcomes. Levels of mindfulness, perceived stress, depression, anxiety, and wellbeing were analyzed in linear regression models to assess the potential efficacy of StudiCareM-TR. All analyses were conducted with the intention-to-treat sample, adjusting for baseline values.

Results Based on participants' feedback, StudiCareM-TR was perceived as acceptable, resulted in few negative effects ($n=7$), and yielded improvements in mindfulness ($\beta=0.70$) and presenteeism ($\beta=-0.61$) compared to WL. Secondary outcomes of depression, anxiety, stress, and wellbeing did not show significant improvements. Assessment dropout was 31% (IG: 50%: WL: 89%), and intervention dropout was 45%.

Conclusions StudiCareM-TR is feasible and acceptable to use among university students in Turkey and has the potential to improve their mindfulness levels. The intervention should be further developed with a focus on engagement-facilitating features in order to reduce intervention dropouts.

Trial registration ID DRKS00024557.

Keywords Ehealth, Cultural adaptation, Internet interventions, Student mental health, Digital health

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Background

University student mental health posits challenges globally. Studying at the higher education level, i.e. at a university and the accompanying demands might be challenging for many students [1, 2]. Apart from the challenges that come along the transition to adulthood [3], studying at a university is related to unique problems such as choosing a major, which in turn leads to a long-time career, navigating studies and private life, socializing, workload and exams [4, 5]. Accordingly, mental health problems may occur frequently around this time [6]. During the global pandemic, students of higher education experienced elevated stress, and in Turkey, students reported having the highest depression level among 26 other countries [7]. Additionally, due to decreased mobility as a prevention measure for COVID-19, online approaches to mental health have become more and more visible and utilized [8, 9].

Although guaranteed by the law, in Turkey the majority of universities do not provide psychological counseling services. There are only 66 out of 208 universities in Turkey that have a student counseling service [10]. Previous literature showed that students who had the highest counseling needs were least likely to seek help from a counseling service [2, 11]. An unpublished master's thesis examined public university students' needs related to academic, personal, professional, and university life in Istanbul. According to the results, half of the students reported having high-level needs related to university life, and 43% of the students reported professional needs. 20 and 14% of the students have high-level needs in academic and personal areas respectively. Surprisingly this study showed that male students have a more positive attitude toward seeking help, compared to their female peers [12], whereas the previous literature from Turkish-speaking students showed an opposite trend [13] as do studies from western countries [14]. Universities in Turkey mostly have obstacles to offering mental health services due to structural issues, e.g. the attitudes of the administration and/or qualification of the staff, and occasionally financial problems [15, 16]. Moreover, when Universities provide any services, students rarely utilize these services [17].

Internet- and mobile-based interventions (IMI) are a cost-effective offer that can reach students without losing their therapeutic value, independent of time and place, and offer anonymity [18, 19]. Issues with IMI are low uptake, acceptability, and security concerns [20, 21]. Human factors, such as user attitudes, ease of use, and perceived usefulness are important in the acceptability and uptake of e-health interventions [22, 23]. Offering IMI may be particularly promising in Turkey, where the wide use of the internet and technological devices (e.g. smartphones, laptops) by the youth in Turkey, 95.7% among the 16–24 age group owns one of these devices, is very high [24]. Moreover, social stigma around seeking mental health continues among university students in Turkey [25], and costs and time constraints might hinder reaching out to psychotherapy in a face-to-face setting [26, 27]. IMI are potentially cost-effective [28, 29] and could be also offered to university students however its cost-effectiveness depends on acceptance and adherence [27]. Therefore, an IMI to improve psychological wellbeing may be a viable option to reach this group and offer psychological health services while ensuring anonymity.

IMI offer scientifically effective ways of psychological help to numerous populations [30] (Bielinski & Berger, 2020) and therefore might address the mental health gap [31]. Moreover, IMI offer benefits for college students with various psychological issues and disorders, e.g. stress [32, 33], depression [34], procrastination [35], and anxiety [36, 37]. Moreover, university students might especially benefit from IMI because of their high internet literacy [20]. IMI could be adapted to the needs of various groups [38] while ensuring appropriate content and delivery to a sample's cultural background and also ensuring ecological validity and efficacy [39]. Culturally adapted IMI, even with a minimal adaption, might yield beneficial effects for student populations [40, 41]. Acceptance Commitment Therapy (ACT) and Mindfulness-based IMI offer improvements in psychological benefits for depression, anxiety, stress, wellbeing, life satisfaction, and academic performance [42] while facilitating psychological flexibility, deliberately accepting the present moment, and taking action in line with one's values [43]. ACT has been shown to be effective in improving various mental health symptoms [42], e.g. depression and anxiety, likely by aiming at increasing psychological flexibility as a core process [44]. Also internet-based ACT (iACT) yielded improvements among university students [45, 46] and might be used in college counseling services [45]. These IMI such as our StudiCare Mindfulness intervention [34, 47] could be culturally adapted to meet even the culturally heterogeneous group of international students' needs [41].

As a rather neglected area in Turkey's university systems, providing a scalable, evidence-based psychological health offer is much needed. Therefore, we conducted a randomized controlled trial (RCT) to assess the feasibility, acceptability, and potential efficacy of a minimally culturally adapted mindfulness IMI for Turkish-speaking students of universities in Istanbul.

Objectives

The trial aimed at answering the following research questions:

1. Is the culturally adapted StudiCare Mindfulness-TR (StudiCareM-TR) feasible and accepted in a Turkish-speaking student population in Istanbul?
    a. What is the level of intervention satisfaction, adherence, and acceptance?
    b. Does StudiCareM-TR cause any negative effects?
2. Does the IMI StudiCareM-TR have a potential effect on increasing Mindfulness and psychological well-being (depression, stress, anxiety, well-being, and quality of life) levels compared to a Waitlist control group?

Method

Study design

We pilot-tested StudiCareM-TR, a culturally adapted version of our StudiCare Mindfulness intervention [34] among Turkish-speaking university students studying in Istanbul. A two-armed, RCT of the parallel design was adopted to compare the guided culturally adapted StudiCareM-TR (IG) with a waitlist control group (WL) receiving the unguided version of the same intervention 10 weeks post-randomization. This study complies with the CONSORT statement for feasibility trials [48]. The ethics committee approval is obtained from the Ethic Commission of Ulm University (Document number: 313/20) and the Scientific Research and Publication Ethics Committee of Turkish German University of Istanbul (Document number: E-19291041-044-1500) and a priori registration was done on 16/02/2021 at the WHO International Clinical Trials Registry Platform via the German Clinical Trials Register (ID: DRKS00024557). This study was conducted based on the guidelines of the Declaration of Helsinki.

Participants

The eligibility criteria for participating in the study were (a) being at least 18 years old, (b) being currently enrolled in a university in Istanbul (Turkey), and c) having a moderate to low level of mindfulness according to a cut-off of < 37 on the Freiburg Mindfulness Inventory (FMI; cut-off represents medium FMI value in the general population [49]) d) not currently undergoing psychotherapy, e) not being currently enrolled in another mindfulness training, e) having sufficient knowledge of the Turkish language (measured by the capability to proceed through enrollment and screening process), f) having internet access, and g) providing written informed consent. Exclusion criteria were currently being in a mindfulness course, having a higher than moderate mindfulness level, and being in psychotherapy.

Recruitment

Participants were recruited from March to May 2021. The recruitment was done via two emails sent out from the Turkish German University in Istanbul, and additionally, university clubs, as well as the informal student groups of other universities in Istanbul, were contacted. The email consisted of a brochure that provided information regarding the Studicare project and an invitation to participate in the training. Potential participants received a direct link to the website where the screening and all the other measurements were taken place. After screening and receiving informed consent, participants were invited to complete the initial survey and then were randomized.

Randomization

Randomization was carried out by an independent researcher, who was not involved in the Studicare Project. A randomization list of 2:4:6 block sizes was created using https://www.sealedenvelope.com/simple-randomiser/v1/lists and an allocation ratio of 1:1 was used.

Intervention

StudiCareM-TR consists of seven weekly modules and two booster sessions; each takes approximately 45 minutes to complete. Modules contain meditation audio files for mindfulness meditation exercises, psychoeducation, weekly assignments, and a mindfulness journal. The entire intervention is offered via the online platform called Minddistrict for interventions. At the end of each module, participants were asked about their comments and recommendations about that module. An overview of the modules is presented in Table 1. Participants were advised to complete one module per week. Participants who completed seven modules had access to booster sessions 1 and 2, 4 and 12 weeks post-intervention, respectively. The intervention was based on Acceptance and Commitment Therapy [43] and stress management principles [50]. Its effectiveness to improve mindfulness has been proved among German-speaking ($d = 1.37$; 95% CI: 1.01 to 1.73) [34] and pilot-tested among English-speaking international students ($\beta = 0.34$, 95% CI [0.06, 0.63]) [41]. StudiCare M-TR was adapted from the original German mindfulness intervention named StudiCare Achtsamkeit [51]. For Turkish-speaking students, intervention content was translated to Turkish, and surface-level modifications [52] were made to the content of the intervention. The translation of the intervention content was done by SB and an independent professional translator, and an independent researcher/psychologist checked the Turkish version and provided feedback on the final version. Stories of the example characters were modified in accordance with student life and stress sources apparent in Turkey, and idioms were added.

Table 1 Overview of the modules

Module names in Turkish (*in English*)	Content	Mindfulness meditation exercises
Bilinçli Farkındalık (*Awareness*)	An introduction to the concept of mindfulness	Body scan, mindful walking exercise
Bedenini dinle (*Mindful body perception*)	Mindful perception of bodily signals	Heart meditation, mindful perception of satiety and hunger
Stres artıran düşünceler (*Stress-aggravating thought*)	Mindful coping strategies to deal with stress and distancing from stressful thoughts	Power of thoughts, mindful straightening the posture
Faydalı bir düşünce (*A beneficial thought*)	Developing a beneficial thought to deal with stress	Inhaling the beneficial thought, short breathing meditation
Hayatın anlamı (*Values in life*)	Discovering what is important and valuable in life	Here and now exercise
Canım kendim (*Self-care*)	Looking at yourself with a loving gaze	Loving and kindness meditation
Zihin ve beden (*Body&mind*)	Enjoying small things in life with mindfulness	Shavasana and mindful yoga
Bilgilerini tazele I&II (*Refresh I&II*)	Review of previous modules	Repeating the previous exercises

Surface-level cultural adaptation refers to altering observable aspects of the intervention, such as language, people, and locations, to match the new target group [52]. Three students were presented as example characters. They were portrayed as a group of students studying in Istanbul in various fields and suffering from problems related to time management, working while studying, adapting to a big city, navigating studies with social life, and relationships with friends, as well as social activities.

All the modifications done for the cultural adaptation are presented in Table 2 in accordance with Spanhel's taxonomy [53]. Modifications included changes to core components and methodological and procedural spheres.

Guidance

At the end of each module, participants received semi-tailored feedback from an e-coach (a trained and supervised psychologist: SB). Each feedback consisted of a review of progress and provided endorsement and motivation to the participants to continue the upcoming modules. Participants were able to contact the e-coach via Minddistrict's message function 24/7 as well. Moreover, two reminder emails were sent to the participants who did not complete the modules in time.

SMS coach

A voluntary text message coach was offered to each IG participant. These motivational SMS messages were set to be sent every 2 days, throughout the intervention. The content of the SMS was related to motivational prompts, and reminders to practice mindfulness and to work on the modules. Four participants signed up for the SMS coach.

Control group

After randomization, WL group participants received a brochure listing other psychological health options as a safety protocol and did not receive instructions against using care-as-usual options. Eight weeks after the randomization, participants of the control group got access to the unguided version of the StudiCareM-TR.

Assessment and outcomes

Assessments were conducted on an online platform, www.unipark.de, at baseline (t0) and 10 weeks post-randomization (t1).

Acceptability

Acceptability was measured via open-ended questions at t1. Moreover, a short voluntary interview regarding the acceptability of the cultural adaptation was conducted by the researcher via Skype and reported descriptively, the interview questions are listed in the Supplementary file. Furthermore, the online platform Minddistrict provided data on usage and engagement (number of completed modules and formative user feedback). Adherence to the intervention was defined as completing five out of seven modules.

Negative effects

Possible negative effects of the intervention were measured via the Negative Effects Questionnaire (NEQ). NEQ consists of 20 questions and shows acceptable item fit and reliability [54]. NEQ has been translated into Turkish and forward and backward translations were consulted and approved by the developer of NEQ. The final version was presented in the Supplementary file.

Outcome data

Mindfulness

The primary outcome of this study is mindfulness, which was measured via 14 items Freiburg Mindfulness Inventory (FMI). It measures mindfulness on a 4-point Likert scale, in which higher scores mean higher

Table 2 Culturally adapted dimensions of the StudiCareM-TR

Core components	Specific components	Example
Content components		
1. Illustrated characters		
	Appearances/ names of characters	changing the names of characters to diverse names (e.g. Ayşe, Mehmet, Havin)
	Content/ stories/ background of characters	added characters from various regions of Turkey who migrated to study in the capital city of Istanbul, who have not just university-related issues, but other problems such as working while studying, adapting to a big city, leaving the family home
2. Illustrated activities		
	Daily life	tutoring, socializing, engaging in physical activity, contacting family
3. Illustrated environment/ burdens		
	Burdens	high level of pressure for academic excellence, social comparison, being away from close family, working while studying, job market
4. Language translation		
	Translating intervention	German to Turkish
5. Language tailoring		
	Simplify text: shortening text passages, simplifying sentences	less technical phrasing, modify wording for easier readability
	Use of concrete terms or informal language	the colloquial form and youth jargon were used
	Milder descriptions of mental health concepts	describing psychological problems in a university context
6. Difference in concepts of mental health and its treatment		
	Stigmatization of mental health problems	framing the goal of the intervention as a mindfulness-based stress management tool instead of mental health intervention in order to reduce the stigma
7. Goals of treatment		
	Increase understanding of treatment possibilities	Informing about the ways of coping with stressors in university life, promoting value-oriented actions
8. Methods of treatment		
	Information/ links to other helpful addresses	psychological help offers which might be available free-of-charge or within the public health system are presented to each participant
9. Illustrated values/traditions	Handling relationships/Values/Importance of family	keeping close contact with family members
Methodological components		
10. Guidance		
	Person used as guide	Guidance by a Turkish-speaking psychologist (SB)
	Format of guidance (tailored feedback)	participants can ask for personal contact in addition to semi-structured feedback, the feedback occasionally included personal touches, such as wishing success for an upcoming exam week
11. Structure	Shorten intervention	Intervention duration per module has been decreased to approximately 30–35 minutes from 50 minutes
Procedural components		
12. Methods used to obtain information		
	Personal interaction (focus groups, interviews, discussions, think-aloud)	received feedback in the form of qualitative data for the process evaluation and further implementation of the program
	Surveys/ questionnaires	assessed acceptance and potential efficacy
	Pilot/ feasibility studies	this trial has been conducted to measure the feasibility to inform a future definitive trial.

Table 2 (continued)

Core components	Specific components	Example
13. Persons involved		
	Target group and associated people	Turkish-speaking students studying at a public university in Istanbul
	Professionals not working with the target group	Student affairs office workers of Turkish German University and university clubs from other universities in Istanbul distributed recruitment emails
14. Theoretical framework		
	Guideline for cultural adaptation of face-to-face treatment	surface structure changes were based on the cultural sensitivity framework by Resnicow [52]

mindfulness. FMI's Turkish version [55] shows good reliability (α = 0.823) and resulted in a similar unidimensional solution, compared to the original version [49].

Anxiety

Anxiety symptoms were measured via the General Anxiety Disorder questionnaire (GAD-7) [56], which has 7 items representing DSM-IV symptom criteria for GAD measured with a 4-point Likert-type rating scale. The Turkish version of GAD-7 shows acceptable reliability (α = 0.852) and resulted in a single-factor solution [57].

Depression

To assess depressive symptoms, the Patient Health Questionnaire depression module (PHQ-9) was used, which uses a 4-point Likert scale, where higher scores correspond to higher depressive symptomology. The Turkish version of the PHQ-9 is a validated instrument with good internal consistency (α = 0.842) [58].

Stress

Stress symptoms were screened via the Perceived Stress Scale (PSS-4) [59], which consists of four items and shows acceptable reliability (α = 0.66) among Turkish students [60]. Each item is presented on a 5-point Likert-type scale, with options from 0 (never) to 4 (very often) [61].

Well-being

The 5-item World Health Organization Well-Being Index (WHO-5) was used to assess wellbeing [62]. The Turkish version of WHO-5 resulted in good internal consistency (α = 0.81) and validity for adult populations [63]. The items are scored between 0 (at no time) and 5 (all of the time), which higher scores mean higher wellbeing.

Presenteeism

Presenteeism was measured via the Presenteeism Scale for Students (PSS) [64]. The subscale for work impairment consists of 10 questions assessing the degree of presenteeism where scores range from 10 to 50 measured with a 5-point Likert scale. The Turkish version of the scale supports the original two-factor structure and shows good reliability (α = 0.88) [65].

Sample size

In order to determine sample size, we used the recommendation by Whitehead et al. [66] for pilot trials: With a statistical power of .90 and a two-sided significance level of 95%, we used a sample size of 15, per arm, for a medium (0.5) effect size. With the previous international version of the StudiCareM-E's 35% dropout [41] in mind, we aimed at reaching a sample size of 54 in total.

Data analysis

The data were analyzed with IBM SPSS v26 and R studio. Descriptive statistics and participants' scores on all outcome variables were reported descriptively. Potential group differences were examined with linear regression models, controlling for baseline values. For each outcome, we reported standardized regression coefficients, 95% confidence intervals (CI), and adjusted R^2 values. All the analyses were based on the intention-to-treat (ITT) principle. Multivariate imputation by chained equations (MICE) [67] algorithm with the predictive mean matching method was used to create 50 complete data sets with 15 iterations. Parameter estimates were pooled based on Rubin's Rule [68] and pooled regression coefficients were reported. We assumed the data were missing at random. Additionally, per protocol (PP) analysis was reported for the primary outcome mindfulness with adherence data (participants that completed at least five modules).

Results

Feasibility

Recruitment and participants

Recruitment was terminated after successfully randomizing the a priori calculated sample size of 58 participants. Out of 178 potential participants screened, 120 were excluded due to the following reasons: not

providing informed consent ($N=70$), having a high level of mindfulness (FMI score > 37) ($N=39$), currently being in psychotherapy ($N=4$), providing a not working email address ($N=3$), changed their mind about attending ($N=2$), currently attending another mindfulness course ($N=1$), and not being a student ($N=1$) (Fig. 1).

Baseline participant characteristics are presented in Table 3. 79.3% of the participants were female, and the mean age was 22.47 (4.08). The majority of the students were full-time students (89.7%), and 20% had psychotherapy experience.

Intervention adherence

Out of 29 participants who were randomized into the IG, five did not finish the first module, and 16 (55.2%) completed the five core modules, which were counted as intervention completers. See Fig. 2 for detailed

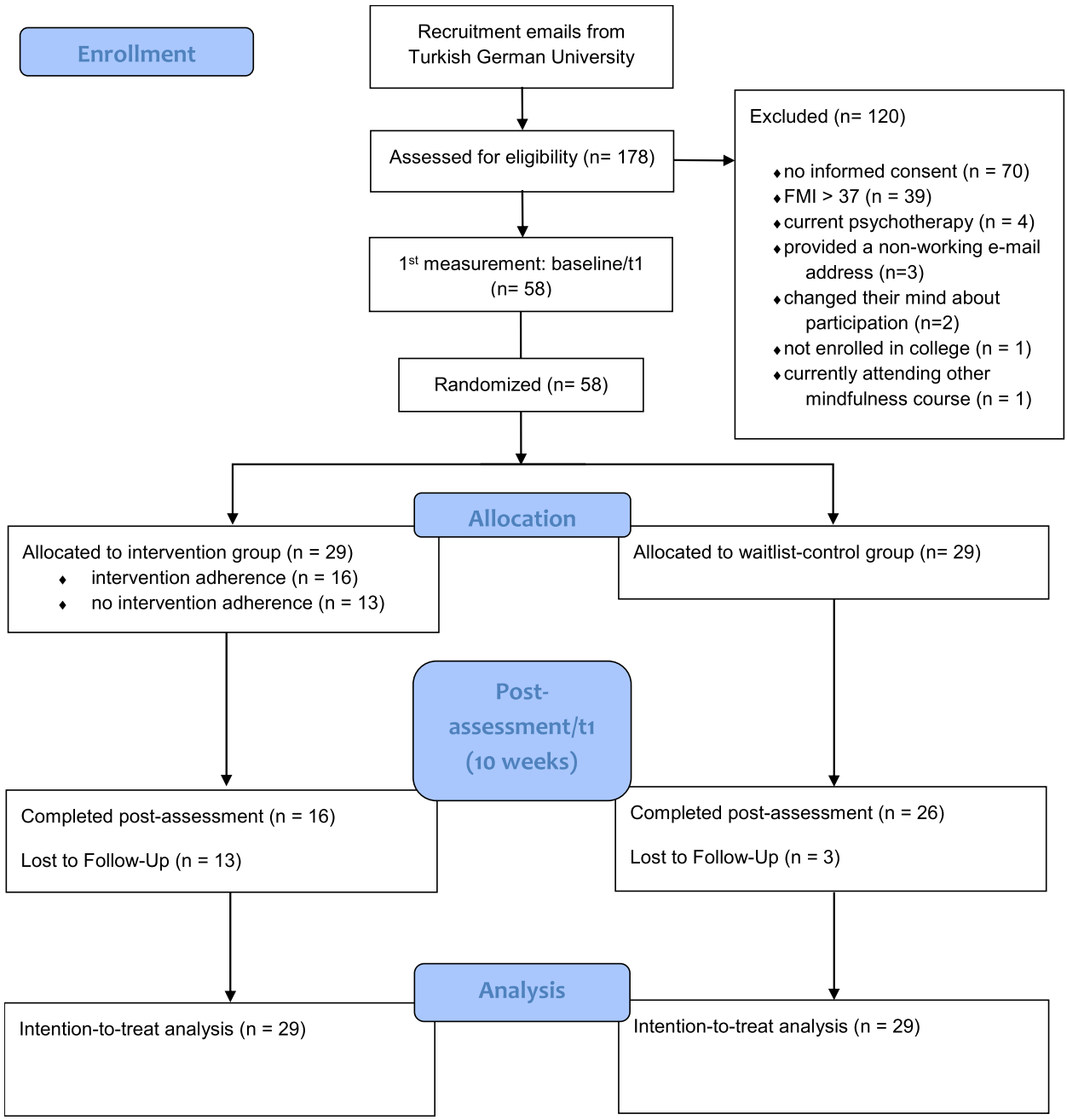

Fig. 1 Study flow diagram

Table 3 Baseline characteristics

	All Participants (*N* = 58)	**IG (*n* = 29)**	**WL (*n* = 29)**
	***N* (%)**	***N* (%)**	***N* (%)**
Sociodemographic characteristics			
Age (M, SD)	22.47 (4.1)	22.10 (4.1)	22.83 (4.1)
Female gender	46 (79.3)	23 (79.3)	23 (79.3)
Single	38(65.5)	19 (65.5)	19 (65.5)
Study characteristics			
Full-time student	52 (89.7)	26 (89.7)	26 (89.7)
Semester (M, SD)	5.6 (2.6)	4.9 (2.7)	6.2 (2.3)
Study subject			
Business & Law	17 (29.3)	9 (31.1)	8 (27.6)
Psychology	16 (27.6)	6 (20.6)	10 (34.5)
Engineering	13 (22.4)	7 (24.1)	6 (20.6)
Medicine & Health	7 (12)	4 (13.8)	3 (10.3)
Religion & Culture	2 (3.4)	–	2 (6.9)
Social Sciences	1 (1.7)	1 (3.4)	–
Other	2 (3.4)	2 (6.9)	–
Treatment utilization			
Psychotherapy experience	12 (20.7)	6 (20.7)	6 (20.7)
	M (SD)	**M (SD)**	**M (SD)**
Outcome measures			
Mindfulness level	29.26 (4.88)	28.28 (4.55)	30.24 (5.09)
Depressive symptoms (PHQ-8)	12.47 (5.53)	13.34 (5.18)	11.59 (5.81)
Anxiety symptoms	16.79 (4.47)	18.38 (4.06)	15.21 (4.35)
Presenteeism level	27.84 (6.48)	26.24 (5.97)	29.45 (6.67)
Well-being	37.72 (15.23)	33.93 (13.46)	41.52 (16.16)
Stress level	19.09 (6.17)	20.62 (5.94)	17.55 (6.11)

M Mean, *SD* Standard Deviation, *IG* Intervention Group, *WL* Waitlist control group, *BFI* Big Five Inventory, *BFI-E* BFI Extraversion, *BFI-N* BFI Neuroticism, *BFI-C* BFI Conscientiousness, *BFI-A* BFI Agreeableness, *BFI-O* BFI Openness for experiences

information on module completion. Except for two participants, 14 intervention completers also completed the t1 assessment. The average intervention duration was 62.56 days for intervention completers. All except for three intervention completers finished the intervention within 2 months post-randomization. About half (51.7%) of the IG and 89% of the WL completed the t1 assessment, which corresponds to an overall assessment dropout rate of 31%. Based on this assessment's results participants practiced mindfulness on average 2.93 days weekly, where they engaged in 12.47 minutes of mindfulness meditation on those days.

Acceptability

Formative user feedback

At the end of each module, we collected acceptability data about that module on the Minddistrict platform, in total we received $N = 123$ feedbacks. According to this feedback, all seven modules received on average a score of 7.5 and higher out of a 10-point scale (1 = did not like it to 10 = love this module). The length of the modules was mostly (77%) described as just about right, while 20% described the modules as long, and 4% as short. Module number six (entitled "Self-care") was the most liked. The majority of the participants said that they could use the learned skills in their daily lives. Mindfulness exercises, such as body scan, and exercises aiming at identifying stress-inducing thoughts were perceived as the most helpful exercises.

Fifteen participants who provided data on t1 reported that in addition to meditation exercises, summaries at the beginning of every module and introduced example characters' stories were perceived as beneficial. Eleven participants reported that the skills they learned in the IMI were mostly adaptable to their daily life. Regarding processing modules within their everyday life on a scale from 1 = not feasible to 10 = completely feasible participants scored on average 6.7; only one participant reported disturbance in their daily life due to what they learned in the IMI. Additionally, they scored 8.7 (1 = never to 10 = absolutely) regarding their likelihood of participating in a mindfulness-based intervention in the future.

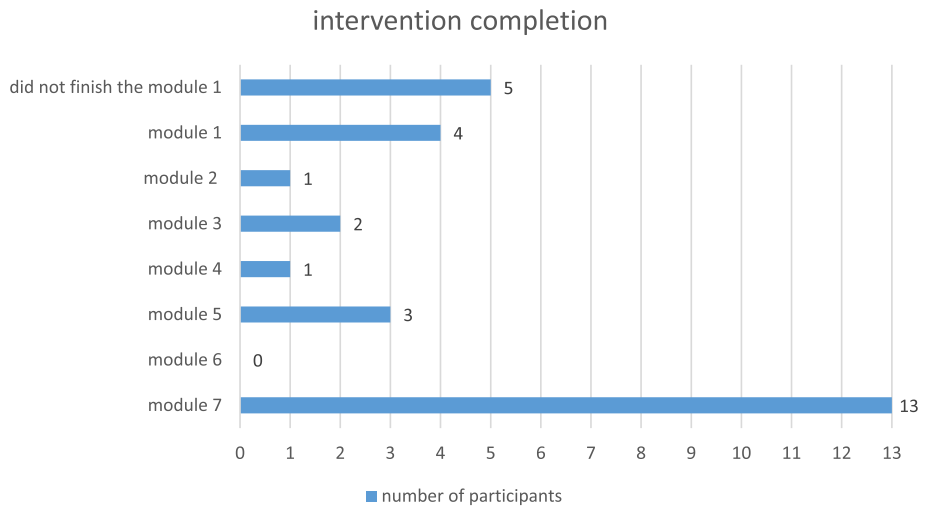

Fig. 2 Intervention completion

Moreover, we conducted voluntary semi-structured interviews with participants who completed the intervention ($N=5$). Regarding the IMI, participants reported finding it helpful, and interesting, moreover flexible access to the intervention and personalized feedback was mentioned as helpful elements. Homework and e-coach were perceived positively by all respondents. All the respondents found the translated and adapted language understandable and there was nothing unfamiliar in terms of introduced concepts. However, most of the respondents ($n=4$) thought that mindfulness could be understood differently by different cultural backgrounds. In the meantime, when asked whether any aspects of the program represented a specific cultural value system, one respondent said no, two mentioned mindfulness belonging to Ancient Asian tradition; whereas the other two referred to diverse example characters presented in the intervention. Moreover, even though our respondents believed that the intervention did not seem to be developed for a specific cultural group, they still mentioned some aspects resembling a specific culture. The following improvements were suggested by the participants: inclusion of more visual representation of the intervention content, simpler formulation of some exercise questions, adding a progress bar on every intervention webpage, and shortening of the length of text fields.

Negative effects

According to the results from the NEQ out of 76 reported negative effects by 16 participants, only 21 of the negative impacts were attributed to the StudiCareM-TR. These negative consequences were related to symptoms from treatment ($N=6$), quality of treatment ($N=12$), stigma from treatment ($N=1$), and hopelessness from treatment ($N=2$). In detail, seven participants reported at least one negative effect attributed to the IMI: one participant reported experiencing more stress than before, two participants reported experiencing more anxiety, two reported being more worried, one felt more hopeless, one had unpleasant memories resurfaced, one reported feeling ashamed in front of others due to having treatment, one thought the issue that person sought help for could not be made any better, two participants reported not always understanding the treatment, one did not always understand the therapist, two did not have confidence in the treatment, four felt that the treatment did not produce any results, and lastly two reported that their expectations of the therapist were not fulfilled.

Efficacy outcomes

According to the analyses of ITT data, controlling for baseline values, in the t1 mindfulness was significantly improved in the IG compared to WL ($\beta=0.70$, 95% CI: 0.26 to 1.14, $p<0.01$; Adjusted $R^2=0.56$). Moreover, StudiCareM-TR resulted in improvements in the presenteeism level ($\beta=-0.61$, 95% CI: -1.14 to -0.06, $p<0.05$; Adjusted $R^2=0.28$). The effect estimates of the remaining outcomes did not reach significance and are tabulated in Table 4. PP analysis showed a similar significant effect in the primary outcome mindfulness at t1, ($n=41$, $\beta=0.82$, 95% CI: 0.38 to 1.27, $p<0.001$; Adjusted $R^2=0.57$).

Discussion

This RCT evaluated the feasibility and potential efficacy of the internet-based mindfulness intervention that is culturally adapted to fit the needs of the Turkish-speaking student population. Our results suggested that culturally-adapted IMI StudiCareM-TR is feasible and

Table 4 Post-randomization between-group differences adjusted for baseline values

	Baseline IG M (SD)	Post-treatment IG M (SD)	Baseline WL M (SD)	Post-treatment WL M (SD)	Standardized coefficient ß	95% CI	*p*-value
Mindfulness (FMI)	28.28 (4.55)	32.79 (6.44)	30.24 (5.09)	30.30 (5.90)	0.70	0.27 to 1.14	0.01
Depression symptoms (PHQ-8)	13.34 (5.18)	12.32 (5.16)	11.59 (5.81)	10.55 (5.66)	0.13	−0.36 to 0.63	0.66
Anxiety symptoms (GAD-7)	18.38 (4.06)	15.72 (5.33)	15.21 (4.35)	14.53 (4.64)	−0.23	−0.79 to 0.33	0.41
Stress level (PSS-4)	20.62 (5.94)	13.08 (2.74)	17.55 (6.11)	12.22 (2.54)	0.09	−0.47 to 0.64	0.75
Wellbeing (WHO-5)	33.93 (13.46)	58.03 (17.52)	41.52 (16.16)	53.26 (14.90)	−0.01	−0.53 to 0.50	0.96
Presenteeism (PSS)	26.24 (5.97)	31.50 (7.45)	29.45 (6.67)	33.82 (5.62)	−0.61	−1.17 to −0.05	0.03

M mean, *SD* Standard deviation, *FMI* Freiburg Mindfulness Inventory *GAD-7* Generalized Anxiety Disorder Questionnaire, *PHQ-8* Patient Health Questionnaire, *PSS* Presenteeism Scale for Students, *PSS-4* Short Form Perceived Stress Scale, *WHO-5* World Health Organization Well-Being Index

acceptable according to formative feedback from the participants. Moreover, recruitment and dropout rates were comparable to previous studies. The intervention caused few negative effects and resulted in improvements in mindfulness and presenteeism, but not mental health in terms of depression, anxiety, stress, and wellbeing. A definitive RCT should ensure the effectiveness of StudiCareM-TR prior to incorporating the intervention into university services in Turkey, where psychological counseling offers for students are mainly absent.

The intervention resulted in good acceptability based on various measures: the formative intervention feedback, where intervention modules received high appreciation and the skills learned were perceived as easy to transfer to real life. Ease of use and perceived usefulness are related to improvements in psychological outcomes in IMI [69].

Surface level changes were done in the cultural adaptation process to increase acceptability. Overall the participants reported that the intervention met their expectations. It is encouraging to know that even with minimal alterations an intervention could be perceived as acceptable and yield positive effects among its target group [70]. This trend was also present in our trial where we adopted minimal changes. Formative research before a feasibility trial where mixed methods, such as community leaders' input and online surveys, can be used to better inform cultural adaptation needs [71, 72]. Yet, culturally adapted interventions are still a neglected and newly developing area of research [73]. Therefore, more research in cultural adaptation studies is needed [74].

Our culturally adapted IMI yielded beneficial effects on mindfulness and presenteeism levels, which is in line with previous research [75]. These skills related to mindfulness and presenteeism could be particularly important in a university setting where academic challenges could be overcome while being mindful and present [42]. More research on the efficacy of the StudiCareM-TR intervention on other psychological variables is still warranted. Based on previous literature, several meta-analyses showed that mindfulness could be taught successfully in online settings [75] and improve quality of life and functioning [76] and showed promising positive effects among student populations [77], also when adapted to varying cultural backgrounds of the students [41].

The negative effects observed among the intervention group were comparable to other reviews concerning participants receiving internet-based cognitive behavioral therapy (ICBT) [78, 79]. According to our results, StudiCareM-TR is a safe intervention for this target group. Although this trial was not targeted at treating a mental disorder, it is still advised to monitor the negative effects of participants in intervention studies and have action protocols in case of adverse events at hand [78]. However, there were discrepancies between the results we acquired from the negative effects questionnaire and interviews at t1: on the one hand interview respondents ($n=5$) stated that the language was easy to understand, introduced concepts were familiar to them, and they benefited from the e-coach, on the other hand, respondents to negative effects questionnaire reported not always understanding the treatment or the therapist ($n=3$) and their expectations not being met by the therapist ($n=2$). This discrepancy might be related to social desirability since the interviews took place via Skype, where participants directly interacted with the researcher. Moreover, in the negative effects questionnaire the questions are formulated more specifically compared to the questions of the interview, which are more broadly formulated in order to receive detailed answers. In the future, the role of therapeutic guidance could be explained in more detail before the trial and the use of technical terms might be avoided as much as possible.

To our knowledge, this was the first internet-based mindfulness intervention offered to university students

in Turkey. Therefore, its novelty aspect might have led to the recruitment taking a very short amount of time and, in the end, mostly receiving positive feedback from participants. However, adherence was still low with only 55% completing the intervention. Possible reasons for non-adherence can be related to the timing of the intervention within the academic year, the length of the intervention, and the nature of guidance. Our study's recruitment finished around the last week of May, which is very close to Spring semester exams, therefore one reason for low adherence may be the fact that students chose to study for their final exams or not to adhere due to summer vacation. Although the individual modules' lengths were perceived as just right, still it might be worthwhile to reduce the number of modules and therefore the intervention duration, since the original German version of this intervention resulted in significant psychological improvements in a German student sample even though on average, only 4 modules were completed [34]. In the future, the mindfulness intervention with the five core modules could be implemented among this population and its results might be compared in terms of intervention adherence and efficacy.

Still, low adherence is a substantial issue in e-health research and implementation [80, 81]. It has been shown in a meta-analysis that adherence is an important predictor of improvement in psychological outcomes [82, 83] and can be bettered with guidance [84]. In order to tackle the adherence threat, we adopted various measures. Our intervention implemented some persuasive design aspects, such as tailoring and reminders, [85, 86], matched the cultural background and mother tongue of the facilitator with the participants, and adapted the original intervention to suit the content and delivery better [87]. Compared to the previous StudiCare Mindfulness trials, our adherence rate, 55%, falls in a similar range. A guided on-demand StudiCare Mindfulness and a guided short version (five modules) of StudiCare Mindfulness found an adherence rate of 27.8% [88] and 70% [34], respectively, meanwhile an adapted version of the same intervention yielded a 40% adherence among international students [41]. Regarding outcomes within group effect sizes our trial (d = .81) results in a similar direction in mindfulness outcome compared to the original StudiCare M trial (d = 1.67.) [34]. Therefore, in StudiCare Mindfulness trials guidance and cultural adaptation might be beneficial in improving adherence, but not necessarily effectiveness. However, please note, that results cannot be compared directly across trials, given the different target groups and study methods. Future research might implement additional measures to improve adherence such as incorporating some therapist behaviors e.g. self-efficacy shaping in the guidance, which might improve treatment outcomes as well [89], gamification, persuasive design aspect implementations, and multimodal delivery [86, 90, 91].

This trial has some limitations. We were only able to collect qualitative data from five participants to further inform acceptability, which is a common problem among student participants of IMI studies [85]. Moreover, only about half of the participants were intervention completers. While this adherence rate is in line with findings from a recent meta-analysis on internet-based mindfulness interventions [75], it might lead to an underestimation of the true effects of the intervention and nevertheless suggests the need for improvement. An internet-based intervention to promote psychotherapy engagement among patients with a Turkish immigration background in Germany resulted in favorable outcomes, however, the participants were significantly older and less educated compared to our population [92]. Therefore, a different set of measures to promote engagement might be appropriate for our sample. We used a WL control group, which might lead to an inflation of between-group effect sizes due to the potential nocebo effects [75]. In order to deal with the potential bias of baseline differences between assessment completers and dropouts, we included baseline values as control variables in regression models.

Conclusions

In conclusion, it seems feasible and acceptable to offer an internet-based mindfulness intervention, specifically StudiCareM-TR, to university students studying in Turkey to improve their mindfulness and presenteeism levels, which might be beneficial in dealing with university-related stressors. Considering high internet access by university students in Turkey and some e-health tools widely available in Turkey's healthcare system, such as the App from the health ministry for enabling making appointments at hospitals or checking medical test results, we might expect societal and governmental e-health readiness [93].

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
SB, AK, DDE, and HB, initiated and contributed to the design of this study. SB adapted the intervention content and assessment. SB is responsible for recruitment, analysis of primary and secondary outcomes and wrote the draft of the manuscript. All authors contributed to the further writing of the manuscript and approved the final version of the manuscript.

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Availability of data and materials
The dataset may be obtained (from S.B.) on request depending on to-be-specified data security and data exchange regulation agreements. To ensure confidentiality, shared data will exclude any identifying participant information.

Declarations

Ethics approval and consent to participate
The ethics committee approval is obtained from the Ethics Committee of Ulm University (Document number: 313/20) and the Scientific Research and Publication Ethics Committee of Turkish German University of Istanbul (Document number: E-19291041-044-1500). Before entering the study, all participants were given written information about the study conditions, data security measures, the voluntary nature of participation, and the freedom to withdraw from the study at any point. To ensure that participants comprehended the provided information, written informed consent was obtained from each participant prior to their inclusion in the study.

Consent for publication
Not applicable.

Competing interests
AK, and HB were involved in the development of StudiCare Mindfulness or its predecessor versions. AK has received fees for lectures/workshops from chambers of psychotherapists and health insurance companies. DDE reports to have received consultancy fees or served in the scientific advisory board from several companies such as Novartis, Sanofi, Lantern, Schön Kliniken, Minddistrict, and German health insurance companies (BARMER, Techniker Krankenkasse). DDE is stakeholder of the Institute for Health Trainings Online (GET.ON), which aims to implement scientific findings related to digital health interventions into routine care. HB reports to have received consultancy fees, fees for lectures or workshops from chambers of psychotherapists and training institutes for psychotherapists and license fees for an Internet-intervention. SB has no conflict of interest to report.

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