

A Cognitive Behavioural-Based Intervention in Reducing Test Anxiety in High School Students: A Pilot Cluster Randomized Controlled Trial

Intervenção de Base Cognitivo-Comportamental na Redução da Ansiedade Perante os Testes em Alunos do Ensino Secundário: Estudo Piloto Aleatorizado e Controlado Por Clusters

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Acta Med Port 2024 Mar;37(3):163-171 ▪ <https://doi.org/10.20344/amp.18876>

ABSTRACT

Introduction: School-age test anxiety is an important risk factor for school performance. Notwithstanding, few studies seek to identify which strategies are effective in improving test anxiety. The aim of this study was to assess whether a cognitive-behavioural intervention for high school students could significantly reduce test anxiety.

Methods: Two-arm, cluster-randomized controlled, unblinded, parallel, trial. Participants were 10th grade students from Alves Martins High School in Viseu, Portugal. Students were randomized at class level to receive a cognitive-behavioural-based intervention combined with mindfulness, psychoeducation, and relaxation techniques, or to a control group with no intervention. Participants' anxiety levels were measured using the Test Anxiety Questionnaire. The analysis of the effect of the intervention was carried out on an intention-to-treat basis at the class level, using multilevel mixed effects models and Bayesian modelling.

Results: The intervention had a significant effect in reducing test anxiety ($d = 0.81$, 95% CI 0.45;1.17, Bayes factor = 31.3). Male gender was an independent risk factor for smaller reductions in anxiety levels. The intervention was more effective in reducing the worry component of test anxiety ($d = 0.76$, 95% CI 0.41;1.11, Bayes factor = 19.9) than the emotionality component ($d = 0.63$, 95% CI 0.31;0.95, Bayes factor = 6.6).

Conclusion: A cognitive-behavioural intervention specifically designed to reduce test anxiety, using a combination of mindfulness, psychoeducation and relaxation techniques, was effective in reducing test anxiety levels.

Trial Registration: Retrospectively registered on clinicaltrials.gov (NCT05481099) in 08/01/2022.

Keywords: Anxiety/psychology; Anxiety Disorders/psychology; Portugal; Students/psychology; Test Anxiety; Test Anxiety Scale

RESUMO

Introdução: A ansiedade face aos testes é um importante fator condicionante da performance escolar. Contudo, são escassos os estudos que procuram identificar quais as estratégias eficazes na sua melhoria. Este estudo teve como objetivo testar a eficácia de uma intervenção cognitivo-comportamental na redução da ansiedade face aos testes em alunos do ensino secundário.

Métodos: Estudo experimental, aleatorizado por *clusters* (turmas), controlado, sem ocultação, com dois grupos paralelos, com alunos do 10.º ano da Escola Secundária Alves Martins em Viseu, Portugal. Os alunos foram aleatorizados ao nível da turma para receber uma combinação de técnicas cognitivas e comportamentais, de *mindfulness*, psicoeducação e técnicas de relaxamento, ou para um grupo controlo sem intervenção. Os níveis de ansiedade dos participantes foram medidos através do Questionário de Ansiedade face aos Testes. A análise do efeito da intervenção foi realizada na base de intenção de tratar ao nível da turma recorrendo a modelos de efeitos mistos multinível e modelação bayesiana.

Resultados: A intervenção teve um efeito significativo na redução da ansiedade face aos testes ($d = 0.81$, IC 95% 0,45;1,17, fator de Bayes = 31,3). Pertencer ao sexo masculino revelou-se um fator de risco independente para uma menor redução nos níveis de ansiedade. O efeito da intervenção foi mais pronunciado na redução da preocupação face aos testes ($d = 0.76$, IC 95% 0,41;1,11, fator de Bayes = 19,9) quando comparado com a emocionalidade ($d = 0.63$, IC 95% 0,31;0,95, fator de Bayes = 6,6).

Conclusão: Uma intervenção especificamente desenhada para reduzir a ansiedade face aos testes, usando uma combinação de técnicas cognitivas e comportamentais de *mindfulness*, psicoeducação e técnicas de relaxamento, foi eficaz na redução dos níveis de ansiedade.

Registo do Estudo: Estudo registado a *posteriori* (registo retrospectivo) em ClinicalTrials.gov com o número NCT05481099 em 01/08/2022.

Palavras-chave: Ansiedade/psicologia; Ansiedade aos Exames; Escala de Ansiedade Frente a Teste; Estudantes/psicologia; Perturbações Ansiosas/psicologia; Portugal

INTRODUCTION

Knowledge assessment in school is crucial in modern society. If, on the one hand, assessment moments (tests) are used to gauge the degree to which students have acquired knowledge, on the other, they are also used as differentiating elements in the access to higher education

and different occupations. Given the importance of tests, it's not surprising that these are mostly described as one of their main sources of worry and stress.¹ An estimated 10-41% prevalence of test anxiety at school age has been found (excluding university students),² peaking in

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Recebido/Received: 22/07/2022 - Aceite/Accepted: 06/01/2023 - Publicado Online/Published Online: 20/03/2023 - Publicado/Publicado: 01/03/2024

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secondary school.¹ Factors such as gender and the type of test have an influence on anxiety levels, which are higher in females and in open response and oral tests when compared to multiple choice tests.^{3,4} Although higher levels of anxiety have been described in female students, there seems to be no influence of gender on school performance.^{3,4} The way in which students manage their level of anxiety determines the impact that anxiety will have on their school performance. Test anxiety is associated with poorer study patterns and lower proficiency in taking tests, with a negative effect on school performance,² in addition to an estimated 12% reduction in school performance and a subsequent reduction in student confidence.¹

The evidence shows some positive effect of school-based programs in the prevention of anxiety.⁵⁻⁷ There seems to be greater effectiveness of programs run by mental health professionals than by teachers, and programs aimed at students at increased risk of anxiety are also more effective than universal programs.⁵ The small effect that has been found refers to anxiety in general and not specifically to test anxiety, and moderate to high heterogeneity and poor overall quality are usually found. In addition, most of the interventions analysed in these studies were based on a single therapeutic approach (for example, cognitive-behavioural therapy), with few combined techniques from different therapeutic approaches. There are no randomised controlled experimental studies carried out in Portugal addressing this issue. Further studies are required to measure this specific component of anxiety in school environment to identify the active ingredients of interventions with an impact on reducing test anxiety.

To fill this gap, our study was aimed at assessing the effectiveness of an intervention specifically designed in reducing test anxiety, using a combination of cognitive and behavioural techniques, mindfulness, psychoeducation, and relaxation techniques, based on the hypothesis that anxiety levels are significantly reduced in the experimental group when compared to the control group.

METHODS

This study is described according to the CONSORT checklist^{8,9} (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/18876/15071>).

Study design

This was an experimental, cluster-randomised, controlled, unblinded study with two parallel groups of 10th grade students at the Alves Martins Secondary School in

Viseu. No changes were made to the initial protocol. Alves Martins Secondary School is the largest public school in the city, located in the centre of Viseu, attended by students from the 7th to the 12th grades, both from the city and from the villages within its catchment area. Students were randomised by class to receive the intervention described below, to avoid contamination of the intervention effect (experimental group) or to be included into a control group that received no intervention. The classes, without restriction by teaching area, were selected by the school management by lot (simple random selection). The study is registered at clinicaltrials.gov with reference number NCT05481099. The study protocol was approved by the Ethics Committee of the *Administração Regional de Saúde do Centro, IP*. Informed consent was obtained from both parents and students. Data were collected in December 2019 (initial assessment) and March 2020 (final assessment).

Participants

The study flowchart is shown in Fig. 1. Participants were recruited following the presentation of the project and approved by the Executive Board of Alves Martins Secondary School. Informed consent forms were given to each head teacher for distribution to the eligible classes. Inclusion criteria regarded students attending the 10th grade and those who gave their informed consent. Those who did not have the cognitive ability to read/interpret/fill in the questionnaire and/or participate in the activities proposed in the intervention group were excluded. Once the informed consents had been received, dates were scheduled for the application of the questionnaires and the intervention to each class.

Intervention

The intervention used in this study is detailed in Appendix 2 (Appendix 2: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/18876/15072>). A psychotherapeutic intervention session was carried out at the beginning of March 2020, including cognitive and behavioural mindfulness strategies, psychoeducation, and relaxation techniques. The session was designed and led by two of the authors, both with experience in training students and dealing with anxiety in this age group. A 90-minute intervention and combined expository and active methodology was used to deliver the content. Students were encouraged to describe their points of view and emotions throughout the session, personal experiences, doubts as well as interactions with colleagues in a constructive way. Participants in the control group received no intervention.

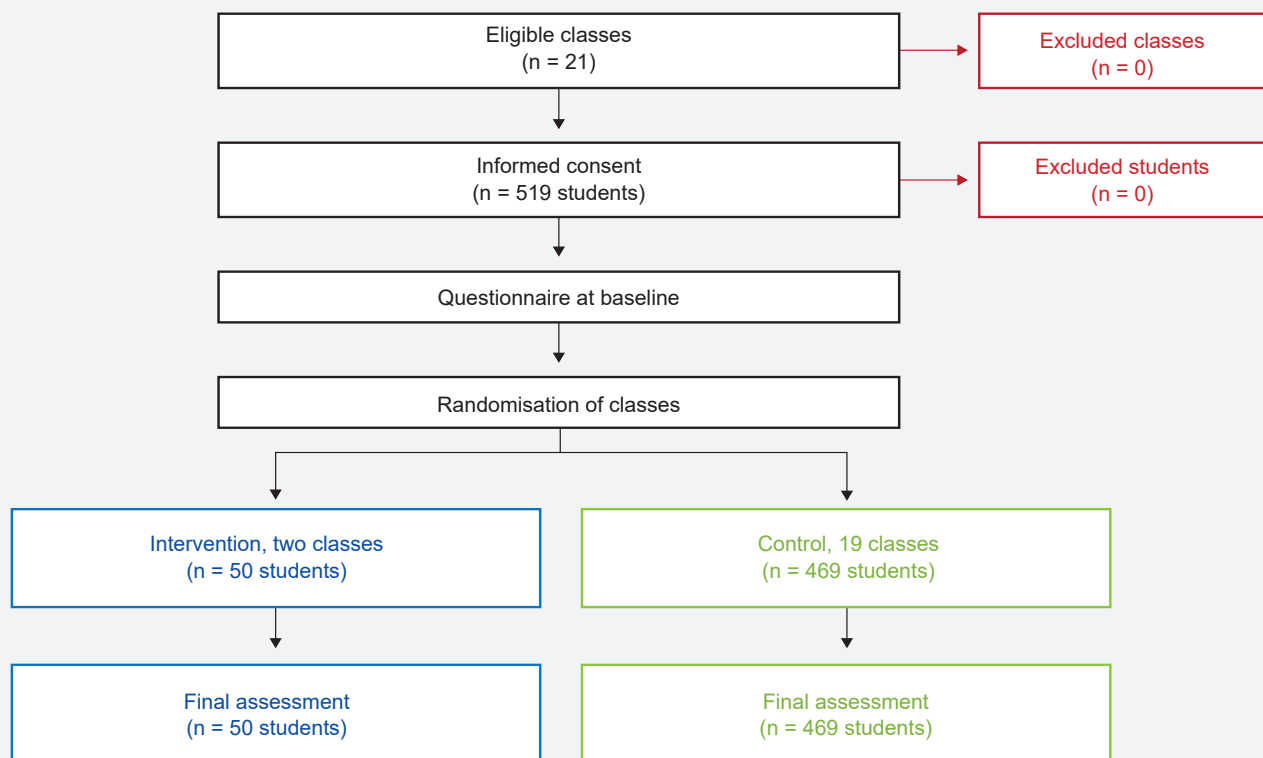


Figure 1 – Study flowchart

Outcome measures

Anxiety levels were measured using the Test Anxiety Questionnaire (TAS)¹⁰ (Appendix 3: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/18876/15073>), showing good internal consistency (Cronbach's $\alpha = 0.8$). The questionnaire has been validated for measuring anxiety levels in 2nd and 3rd cycle elementary school students and has also been used for the same purpose in secondary school students.^{11,12} This was a 10-item questionnaire, each one ranked on a 5-point Likert scale, showing the frequency attributed by the participant to each situation, ranging from 1 (never) to 5 (always). The results of the different items were added in a single scale in which higher results meant higher levels of test anxiety.¹⁰ This scale is divided into two sub-scales measuring the dimensions 'Worry' (items 1 to 5) and 'Emotionality' (items 6 to 10). The 'Worry' subscale refers to thoughts regarding the impact of a possible failure and doubts about self-competence to carry out tasks successfully; the 'Emotionality' subscale refers to the autonomic or physiological reactions evoked by stress and the perception of these reactions.¹³

Main outcome measure

Change in the TAQ score: measured by the difference between the sum of pre- and post-intervention individual responses to each of the 10 items on the scale.

Secondary outcome measures

Change in the 'Worry' subscale: measured by the difference between the sum of pre- and post-intervention individual responses to each of the first five items of the TAQ.

Change in the 'Emotionality' subscale: measured by the difference between the sum of pre- and post-intervention individual responses to each of the last five items of the TAQ.

Sample size

Given that a pilot study was carried out in which no information was available regarding the effect size of the intervention, and that it was aimed at assessing this effect size for future studies, the sample size was not obtained, and we opted to use the rule of including at least 70 participants, as defined by Teare *et al.*¹⁴ As for the minimum difference in clinically significant effect size, to the best of the authors'

knowledge there are no studies addressing this issue.

Randomisation and blinding

After filling in the informed consent form and the questionnaire at baseline, classes were randomly allocated by the school management by drawing lots for the experimental group (two classes) and the control group (19 classes). Due to the nature of the study, no concealment measure was applied.

Statistical analysis

The data collected were entered into Microsoft® Excel® software and checked by members of the research team looking for any inconsistencies and errors. The qualitative characteristics of the participants at baseline were compared at student level using chi-square test, and the quantitative characteristics using Student's t-test. The analysis of the effect of the intervention was carried out on an "intention to treat" basis at class level (randomisation unit) using multilevel mixed effects models (random effects in the ordinate at the origin - 'Intercept'). For modelling purposes and considering that 14 years was the minimum age for the study, this value was subtracted from the age of all the participants to make the interpretation of the models easier. The size of the intervention effect was measured using Cohen's *d* (standardised mean difference), the measure of effect usually used to compare the difference in means between two groups; *d* values between 0.2 and 0.5 meant that the effect size was considered small; between 0.5 and 0.8 medium; and ≥ 0.8 large. Bayesian modelling was also carried out to

obtain the value of the intervention's Bayes factor for each of the outcome measures under study, for a better assessment of the strength of evidence for the intervention tested. The cut-off points defined by Jeffreys were used to interpret the Bayes factor values (Table 1).¹⁵ The analysis was carried out using the R 3.6.3 software.

Table 2 – Participant characteristics at baseline (n = 519)

Characteristic	
Agee (mean \pm SD)	15.3 \pm 0.5
Gender (female)	282 (54.3)
Siblings (yes)	101 (19.5)
Student retention (yes)	53 (10.2)
Follow-up	
Never	367 (70.7)
Psychology	130 (25.0)
Paediatric psychiatry	10 (1.9)
Both	12 (2.3)
Reason	
Unspecified	39 (25.7)
Anxiety	34 (22.4)
Family problems	15 (9.9)
Interpersonal relationships	14 (9.2)
Interpersonal relationships	14 (9.2)
Depression + Anxiety	11 (7.2)
Dyslexia	9 (5.9)
Depression	8 (5.3)
Vocational guidance	4 (2.6)
Motivational support	2 (1.3)
Nutritional problems	1 (0.7)
OCD	1 (0.7)
Medication	
None	477 (91.9)
Methylphenidate	17 (3.3)
Valerian	9 (1.7)
Fluoxetine/Sertraline	5 (1.0)
Risperidone + Fluoxetine	4 (0.8)
Ethyl loflazepate	2 (0.4)
Risperidone	2 (0.4)
Lisdexanfetamine	1 (0.2)
Methylphenidate + Risperidone	1 (0.2)
Methylphenidate + Risperidone + Lisdexanfetamine	1 (0.2)

Results are presented as n (%), unless otherwise stated.

ADHD: attention-deficit/hyperactivity disorder; OCD: obsessive-compulsive disorder

Table 1 – Cut-point for the interpretation of Bayes factor

Bayes factor	Interpretation
> 100	Extremely strong evidence of the experimental hypothesis
30 – 100	Very strong evidence
10 – 30	Strong evidence
3 – 10	Moderate evidence
1 – 3	Weak evidence
1	No evidence
$\frac{1}{3}$ – 1	Weak evidence of the null hypothesis
$\frac{1}{3}$ – 1/10	Moderate evidence
1/10 – 1/30	Strong evidence
1/30 – 1/100	Very strong evidence
< 1/100	Extremely strong evidence of the null hypothesis

RESULTS

The study flowchart is shown in Fig. 1. The participants were recruited throughout December 2019. All 10th grade classes participated in the study and all parents and students in each class have provided their informed consent and were included in the study; 21 classes were included with a median of 25 students per class (minimum 16, maximum 28). Students ($n = 519$) were on average 15.3 ± 0.5 years old, and 282 (54.3%) were female. The characteristics of the participants at baseline are described in Table 2. At baseline, female participants have described higher levels of anxiety than males (32.8 ± 7.2 vs. 27.9 ± 6.9 , $t(517) = 7.87$, $p < 0.001$). This difference was greater in the 'Worry' dimension (17.6 ± 3.9 vs. 14.4 ± 3.8 , $t(517) = 9.61$, $p < 0.001$) than in the 'Emotionality' dimension (15.2 ± 4.5 vs. 13.6 ± 4.2 , $t(517) = 4.23$, $p < 0.001$). Science and Tech-

nology students were included in the intervention group. Apart from this fact, no significant differences were found at baseline as regards the characteristics of the participants by study arm (Table 3).

Main outcome measure: effect of the intervention on the TAQ

The effect of the intervention on test anxiety is shown in Table 4. The intervention had a significant effect on reducing test anxiety ($d = 0.81$, 95% CI 0.45;1.17, BF = 31.3), with an average reduction of 8.4 points on the TAQ expected in students receiving the intervention. Male gender was an independent risk factor for a lower reduction in anxiety levels. Having siblings, attending medical follow-up, student retention and age had no significant effect on the variation in anxiety levels.

Table 3 – Comparison of the characteristics of the participants at baseline (study arm)

Characteristics	Experimental group ($n = 50$)	Control group ($n = 469$)	<i>p</i> -value
Age (mean \pm SD)	15.2 ± 0.4	15.3 ± 0.5	0.30 ^{\$}
Gender (female)	22 (44.0)	260 (55.4)	0.16 ^{\$\$}
Siblings (yes)	11 (22.0)	90 (19.2)	0.77 ^{\$\$}
Student retention (yes)	4 (8.0)	49 (10.4)	0.76 ^{\$\$}
Follow-up (yes)	15 (30.0)	137 (29.2)	1.00 ^{\$\$}

Results are presented as n (%), unless otherwise stated.

\$: Student's *t*-test; \$\$: chi-square test

Table 4 – Effect of the intervention in test anxiety (TAQ scale)

Parameter	Beta	95% CI	<i>p</i> -value
Intercept	-1.5	-2.8; -0.1	0.03
Intervention	-8.4	-12.2; -4.7	< 0.001
Male gender	3.8	2.0; 5.5	< 0.001

Table 5 – Effect of the intervention in subscale scores ('Worry' and 'Emotionality')

Subscale	Parameter	Beta	95% CI	<i>p</i> -value
Worry	Intercept	-1.3	-2.1; -0.6	< 0.001
	Intervention	-4.5	-6.6; -2.5	< 0.001
	Male gender	2.6	1.5; 3.6	< 0.001
Emotionality	Intercept	-1.5	-2.9; -0.04	0.04
	Intervention	-3.8	-5.7; -1.9	< 0.001
	Male gender	1.1	0.0; 2.1	0.03
	Age-14	1.1	0.1 ; 2.1	0.03

Secondary outcome measures: effect of the intervention on 'Worry' and 'Emotionality' subscales

The effect of the intervention on the students' scores on 'Worry' and 'Emotionality' subscales is shown in Table 5.

The intervention had a significant effect on the reduction in worry about tests ($d = 0.76$, 95% CI 0.41;1.11, $BF = 19.9$), with an average reduction of 4.5 points in this subscale being expected in students. Male gender proved to be an independent risk factor for a lower reduction in the levels of worry. As with total scale, no significant effects were found for the other variables studied.

As regards the 'Emotionality' subscale, a significant effect was also found in the reduction of emotionality regarding tests ($d = 0.63$, 95% CI 0.31;0.95, $BF = 6.6$), with an expected 3.8-point average reduction in this subscale. Also, for this subscale, male gender proved to be an independent risk factor for a smaller reduction in the levels of emotionality. A relationship was also found between age and emotionality towards tests, i.e., the older the student, the higher the level of emotionality (on average, 1.1 points more for each year of age from 14 onwards). No significant effects were found regarding the other variables studied.

DISCUSSION

The results of this study suggest that a psychotherapeutic intervention based on cognitive and behavioural mindfulness strategies, psychoeducation and relaxation techniques seems to be effective in reducing test anxiety in tenth grade students.

Primary (QAT scale) and secondary outcome measures ('Worry' and 'Emotionality' dimensions)

The levels of test anxiety were significantly reduced following the intervention tested in this study. The results found are difficult to compare with literature, since the effectiveness of intervention programs is mostly assessed as regards the anxiety in general rather than specifically in relation to tests. Three recent meta-analyses⁵⁻⁷ have found that the interventions tested to reduce anxiety in general had a small positive effect. In comparison, the intervention in our study proved to induce a large effect ($d = 0.81$). This large effect becomes even more relevant since it is considered that interventions with small effect sizes can have substantial practical relevance, provided that low costs are involved, and a large part of the population could be involved.⁷ Only one of the more than 100 studies included in these three meta-analyses specifically measured the effect of the intervention on test anxiety.¹³ Keogh *et al.* tested an

intervention based on cognitive-behavioural therapy on students aged 15-16 vs. a control group with no intervention, and found no effect on test anxiety. However, the study by Keogh *et al.* had important limitations, including a drop-out rate of 50% in the experimental group, the analysis having been carried out by protocol rather than by intention to treat, and the use of body relaxation techniques, which can contribute to the activation of anxiety for some adolescents. In our intervention, in addition to cognitive-behavioural techniques, mindfulness was used (mindfulness training and the use of anchors to focus attention, such as breathing and body sensations), which may have contributed to the positive results found in this study. This suggests that improving the levels of test anxiety may require a combination of strategies.

The analysis of the intervention's effect linked to test anxiety showed that the intervention was effective on both dimensions, mostly in 'Worry'. Given that worrying about tests is mostly associated with lower school performance,^{13,16} these results suggest that the intervention can help improving school performance in students with test anxiety.

Influence of other variables on the levels of test anxiety

Another interesting result of this study was the fact that the intervention led to a smaller reduction in anxiety levels in male participants. This apparently lower effectiveness of the intervention in this population could be explained by the lower level of anxiety in males at baseline, which is in line with literature, showing that these participants consistently have lower levels of anxiety than females.^{3,17-19} Different reasons have been considered to explain this difference in test anxiety levels, including a greater sensitivity to social approval in female participants, leading to a higher level of self-demand, a lower expectation of efficacy, and a greater perception of the threat of assessment moments, which is expressed as fear, difficulty in concentrating and poor self-esteem/academic self-concept.³ Male participants, on the other hand, tend to face the assessment moment as a challenge, and their reaction is more dependent on their perception of competence in dealing with the task. In other words, literature suggests that the higher level of test anxiety in females is more related to vegetative hyperactivation - the physical component of emotionality²⁰ - than to excessive worry - the cognitive component.^{3,19} The results of our study seem to go in the opposite direction, since we found a greater difference between genders in 'Worry' dimension than in 'Emotionality'.

Our data also showed an increasing trend in levels of test anxiety in the 'Emotionality' component but not in 'Worry' with age. These findings could be explained by the different levels of physical development, particularly in terms of brain maturation, since our sample included adolescents at different stages of development. However, as only tenth graders were assessed, age range was not very wide, so the results should be interpreted with caution. Literature shows disparate results regarding the relationship between age and test anxiety. In a cross-sectional study carried out in Spain, Torrano *et al.*³ have found that levels of test anxiety tended to increase with age, with a peak in middle adolescence. On the other hand, a cross-sectional study carried out in Turkey by Sari *et al.*¹⁷ found no relationship between age and test anxiety. Further studies seem to be required to confirm and explain the effect of age on test anxiety.

In the present study, no relationship was found between test anxiety and the other variables tested (having siblings, retention or attending a mental health clinic). Few studies have investigated these possible relationships. Kavakci *et al.*² have carried out a cross-sectional study in Turkey on students facing university admission tests and found a significant correlation between test anxiety scores and depression, anxiety traits and ADHD (attention-deficit/hyperactivity disorder) symptoms, but not with having siblings. The same association between depression and test anxiety was described by Akinsola *et al.*²¹ in an experimental study carried out in Nigeria. Although some studies have emphasized the association between test anxiety and depression², this was not found in our study. However, isolated depression was described by only eight students in our sample, so it's safe assuming that the study had not enough power to find this association.

Strengths and limitations

One of the strengths of this study was its experimental design, specifically assessing test anxiety. Anxiety in general is mostly assessed in literature, so the identification of which components are specifically efficient in this area was not possible. Another strength of the study regarded the intervention tested, combining several strategies to improve levels of test anxiety, compared to interventions reported in the literature that usually used fewer strategies, which may explain the larger effect size found in this study.

Some limitations should be considered when interpreting and generalising the results of this study, including (i) the fact that, even though the intervention group was obtained by simple random selection, two Science and Tech-

nology classes were included, which may have introduced a selection bias. It should be noted that mainly classes in this area are found in most secondary schools; (ii) in addition, it was not an exclusion criterion in this study, as in others, for the participants to present with significant anxiety symptoms or previous psychopathology, which may have contributed to a reduction in the intervention's effect. However, we believe that the inclusion of these participants could give a more specific indication of the program's effect under real conditions; (iii) attending medical follow-up and the reasons for these were measured based on self-report and not on clinical files, which may have contributed to an incorrect measurement of these variables, and, in turn, these may have influenced the association with test anxiety. Even so, no significant bias is to be expected given that in these situations self-reporting is considered as valid as consulting the clinical file;^{22,23} (iv) the use of healthcare professionals in the study is costly if we think in terms of generalising the program and may also raise doubts about whether it is reproducible if applied by professionals other than these. The evidence shows that, with adequate training, supervision and support, teachers or other professionals in the school community can successfully deliver mental health promotion programs, with gains for themselves and the classes they are responsible for, in terms of physical and emotional well-being, concentration and academic performance. There are several successful cases in which, without a single, prolonged intervention such as this one, short mindfulness and relaxation practices have been included in the daily classroom routine;^{24,25} finally, (v) another limitation regarded the evaluation of the short-term effectiveness of the intervention and involving a small number of classes allocated to the experimental group, without measuring its effect on school performance. This was a pilot study with a low budget, preventing any more comprehensive evaluation. Even so, the results of a systematic review suggest that the effect of programs aimed at preventing anxiety is maintained for six to 12 months,⁵ suggesting that the effect of the intervention tested may have had long-term effects, leading to benefits when students took the tests.

Finally, test anxiety levels were measured using a scale validated for 2nd and 3rd cycle students. However, this is the only scale validated in Portugal for this purpose.

CONCLUSION

An intervention specifically designed to reduce test anxiety, using a combination of cognitive and behavioural techniques, mindfulness, psychoeducation, and relaxation

techniques, was effective in reducing the levels of test anxiety. Although further studies are required to assess the impact on school performance of this reduction in anxiety, the effect of this intervention suggests that it could be useful for the academic performance of secondary school students.

STUDY RECORD

This study was recorded at ClinicalTrials.gov with number NCT05481099 on 1 Aug 2022, and was subsequently recorded (retrospective record) as, by mistake, it was not carried out before the study was started.

EDITORIAL DECLARATION

According with the ICMJE recommendation, the Editors declare having accepted this article without any previous prospective record, as this was due to a mistake from the authors and the record was retrospectively done.

AUTHOR CONTRIBUTION

All the authors have contributed equally to writing this manuscript.

HUMAN AND ANIMAL PROTECTION

The authors declare that this project complied with the regulations that were established by the Ethics and Clinical Research Committee, according to the 2013 update of the Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

FINANCIAL SUPPORT

The authors declare that there was no financial support in writing this manuscript.

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