

Frequency-Modulated Auditory Stimulation in Anxiety and Depression: A Controlled Trial in Primary Care

Ravi Kumar^{1*}, Neha Sharma¹, Aniket Deshmukh², Arjun Nair¹, Meera Pillai²

¹Department of Clinical Research and Healthcare Systems, IIT Delhi Health Sciences Unit, New Delhi, India.

²Department of Medical Innovation and Translational Medicine, IIT Bombay Medical Center, Mumbai, India.

Abstract

The clinical trial titled “Effect of Modulated Auditory Stimulation on Interaural Auditory Perception” (NCT0544189) sought to determine whether a specific auditory intervention, “Bérard in 10,” could enhance the benefits of routine treatments for patients experiencing anxiety and/or depression. Unblinded, randomized, controlled clinical trial. Mejerada del Campo Health Center, Madrid (Primary Care). A total of 233 patients were selected via systematic sampling and met the following inclusion criteria: being legally adult and free of severe acute illness or an unstable chronic condition. All participants underwent assessment with the Goldberg and Hamilton scales and were assigned either to the Emotional Well-Being group (EWB, n = 86) or the Anxiety and/or Depression group (AD, n = 147). Precisely half the members of each group underwent the auditory intervention. Participants listened to classical music altered by a frequency modulator (Earducator) designed to dampen irregular frequencies for 30 min per session, delivered twice daily across 5 consecutive days. Scores on the Hamilton Anxiety Scale and Hamilton Depression Scale, recorded at the 3-month and 6-month follow-up points. According to the per-protocol analysis, participants in the EWB group who received the auditory intervention (n = 14) recorded markedly reduced anxiety and depression scores at both 3 and 6 months relative to those in the EWB group who did not receive it (n = 36) (p < 0.05), producing large and moderate effect sizes respectively; similarly, members of the AD group receiving the intervention (n = 31) achieved lower anxiety and depression scores at 3 months and reduced anxiety scores at 6 months compared with the AD group without the intervention (n = 52) (p < 0.05), showing a small effect size. No harmful effects were observed. The auditory intervention “Bérard in 10” proved effective at substantially lowering the risk of developing anxiety and depression symptoms while also providing a modest improvement to the results of standard primary care treatments.

Keywords: Auditory perception, Anxiety-depression, Emotional well-being, Auditory intervention, Bérard method

Corresponding author: Ravi Kumar

E-mail: ravi.kumar@outlook.com

Received: 10 November 2025

Revised: 05 February 2026

Accepted: 05 February 2026

How to Cite This Article: Kumar R, Sharma N, Deshmukh A, Nair A, Pillai M. Frequency-Modulated Auditory Stimulation in Anxiety and Depression: A Controlled Trial in Primary Care. Bull Pioneer Res Med Clin Sci. 2026;6(1):56-69. <https://doi.org/10.51847/B0JvDLGXD5>

Introduction

Mental health conditions pose one of the largest global challenges because of the heavy economic, social, and personal burdens they impose [1]. Roughly 10% of people worldwide are affected. Furthermore, these conditions

have surged by nearly 50% in recent years [2], with the COVID-19 pandemic causing particularly widespread harm in this domain [3].

Rates of mental illness throughout Europe fluctuate depending on the country and the period studied [1, 4], as does access to primary care services [5, 6]. Within Spain,

approximately 49.2% of individuals who seek care at primary health facilities suffer from some form of mental disorder [7]. Primary care is the most suitable setting for addressing the bulk of mental health concerns, thanks to its broad availability, continuous therapeutic relationships, holistic biopsychosocial framework, and capacity to connect patients with external support services when needed [2].

Among all mental health issues, anxiety disorders and depression stand out as the most prevalent [8]. These two conditions frequently co-occur in primary care settings, although it remains uncertain whether the overlap reflects two distinct disorders or a shared underlying pathology [9].

Anxiety can be addressed through psychological methods, pharmacological agents, or a combination of both [10]. Psychological treatment rests mainly on cognitive-behavioral therapy (CBT), while medication options typically involve selective serotonin reuptake inhibitors, noradrenaline reuptake inhibitors, and mirtazapine. Using both modalities together generally delivers the best outcomes [10]. A range of non-drug supportive therapies with varying levels of research support is also suggested when they carry no notable side effects; examples include relaxation exercises, mindfulness practices, yoga, aromatherapy, guided imagery, and digital technologies [11]. However, the improvements achieved with these approaches tend to be modest [12-16].

Management of depression relies on psychotherapeutic techniques, psychosocial support, and drug-based interventions [17, 18]. Cognitive-behavioral therapy is the primary psychological strategy, whereas pharmacological options include selective serotonin reuptake inhibitors, monoamine oxidase inhibitors, and agents targeting norepinephrine and dopamine reuptake. Pairing CBT with antidepressant medication consistently produces stronger results [17, 18]. Certain non-pharmacological strategies—such as naturopathic remedies, biological therapies, and exercise programs—may contribute to symptom relief when added to conventional care. Yet, high-quality evidence supporting their use remains sparse [19].

More recently, music has gained attention as a tool for treating several psychiatric conditions, including schizophrenia, bipolar disorder, generalized anxiety disorder, major depressive disorder, and post-traumatic stress disorder [20]. It appears capable of diminishing symptoms of anxiety and depression, likely by modulating neural networks responsible for reward, arousal, emotion control, learning processes, and neuroplastic changes [21]. Positive influences have also been documented in non-clinical populations through strengthened connections between brain hemispheres [15]. Additionally, studies have reported associations between specific emotional states and deviations in typical auditory processing. In anxiety, hearing thresholds rise at low frequencies and fall

at high frequencies [22, 23]; in depression, thresholds increase especially in the upper frequency range [23, 24]. As a result, the difference in hearing sensitivity between the two ears is typically larger among those with anxiety-depression than among those experiencing good emotional health. These auditory shifts are ear-specific: anxiety-related loss occurs mainly in the right ear, whereas depression tends to impair hearing in both ears [23]. An auditory intervention (AI) may therefore correct interaural imbalances (discrepancies in hearing thresholds between the right and left ears) and adjust overall auditory sensitivity [25]. The intervention reduced overemphasis on high frequencies and helped equalize hearing performance across ears. Still, it remains unclear whether such auditory adjustments translate into clinical benefits for anxiety and/or depression.

The goal of this investigation was to test whether the described auditory intervention could amplify the benefits of existing therapies for patients with anxiety and/or depression who attend a primary care health center. Because stopping patients' ongoing pharmacological or psychological treatments would have been unethical, the auditory intervention was delivered as a supplementary component. This approach enabled exploration of whether the intervention works through pathways distinct from those of standard therapies. The study also explored demographic and clinical characteristics linked to stronger positive responses.

Materials and Methods

Study type

This investigation took the form of an open-label, randomized, controlled clinical trial registered under the title “Effect of Modulated Auditory Stimulation on Interaural Auditory Perception,” identification number NCT05441891. The trial assessed the effects of applying an auditory intervention against a no-intervention control in participants who had normal emotional well-being as well as in those displaying symptoms of anxiety and/or depression [25].

Approval for the protocol was granted by the Ethics Committee of Hospital la Princesa, Madrid, on 8 March 2012 (project code: 05/11). Further authorization was later obtained from the Local Research Committee of Southeast Madrid [25].

All procedures complied with current Good Clinical Practice standards. Written informed consent was obtained from each individual before enrolment, and the study adhered to the ethical principles of the Declaration of Helsinki in its most recent revision.

Sample size determination

The target sample size was set at 124 participants, evenly divided between the emotional well-being group and the

anxiety and/or depression group. Calculations were performed using a two-tailed test at the 95% confidence level, with 80% power and an expected 15% loss to follow-up.

Population

A total of 327 people were drawn from appointment records at the Centro de Salud Mejorada del Campo (Madrid, Spain) through systematic sampling. Selection involved taking the first person from every five attendees across six family medicine clinics, with three in the morning and three in the afternoon. Eligible participants had to be adults who provided signed informed consent. Individuals were excluded if they were pregnant, had deafness, suffered from severe or psychotic mental illness, or reported active substance or alcohol use [23]. A family physician confirmed eligibility through a direct interview. Before testing, each person's ears were checked, and any earwax buildup was removed. The Goldberg Scale was then used as a screening measure for anxiety and depression symptoms. Participants scoring low on the GADS were placed in the Emotional Well-Being group (EWB). Those with elevated scores continued to the Hamilton Rating Scales and were assigned to the Anxiety and/or Depression group (AD). All participants also completed a form collecting sociodemographic and clinical information [23].

Assignment to study groups

Each emotional state category was further split into an intervention arm and a no-intervention arm using stratified block randomization [25].

Personnel handling the randomization had no role in delivering the intervention, collecting outcome measures, or performing data analysis. Randomization occurred only after confirmation that participants met all eligibility criteria and had given informed consent.

Auditory intervention (AI)

The auditory intervention followed a shortened adaptation of the Bérard method [26], reducing the total from 20 sessions down to 10 ("Bérard in ten"). It consisted of 10 sessions lasting 30 minutes each, during which participants listened to music processed with a frequency equalizer (Earducator). These sessions were scheduled in pairs, separated by at least 3 hours. Detailed technical aspects of the procedure have been reported elsewhere [25].

Absence of hearing intervention

Participants assigned to the control condition received no form of auditory stimulation.

Study variables

The Goldberg Anxiety and Depression Scale functioned as the initial screening tool for emotional difficulties [27].

Symptom severity and frequency were measured with the Hamilton Scale for Anxiety (HAS) and the Hamilton Scale for Depression (HAMD) [28]. Validated Spanish editions of these instruments were applied [29, 30]. Evaluations covered the participant's state over the previous 3 weeks.

Hamilton anxiety scale—total anxiety

This measure summed the 14 items from the Hamilton Anxiety Scale. Scores could range from 0 to 56 points.

Hamilton anxiety scale—psychological anxiety

This component included only items 1–6 of the Hamilton Anxiety Scale. Scores could range from 0 to 24 points.

Hamilton anxiety scale—somatic anxiety

This component included items 7–14 of the Hamilton Anxiety Scale. Scores could range from 0 to 32 points.

Hamilton depression scale

The total was calculated from 17 items of the Hamilton Depression Scale. Scores could range from 0 to 52 points.

Sociodemographic variables

Information was recorded for each participant on nationality, gender, age, education level, employment status, history of noise exposure, use of hearing protection, and medical background.

Sociodemographic details were gathered at the initial visit (baseline). The Hamilton Anxiety and Depression Scales were administered at baseline, after 3 months, and after 6 months for every participant.

Response quantification

Treatment success was classified as a reduction of at least 50% in the baseline scale score. A moderate improvement was defined as a drop of 25% to 49%, and a lack of response was noted when the score decreased by less than 25%.

Statistical analysis

All statistical calculations were restricted to participants who finished the full study protocol and received their assigned intervention. Data distribution was checked for normality with the Shapiro–Wilk test. Equality of variances was assessed using the Levene test, which showed no significant deviation. Comparisons of mean values were performed using a two-way ANOVA, with the Bonferroni post hoc test for multiple comparisons.

Associations between the auditory intervention and various baseline factors (for example, analgesic consumption and similar conditions) were examined using contingency tables and Fisher's exact test. The threshold for statistical significance was set at $P < 0.05$.

The entire analysis was conducted with GraphPad Prism software for Windows, version 9.0.0 (GraphPad Software, San Diego, CA, USA).

Results and Discussion

The movement of participants through the various stages of the trial is presented in **Figure 1**.

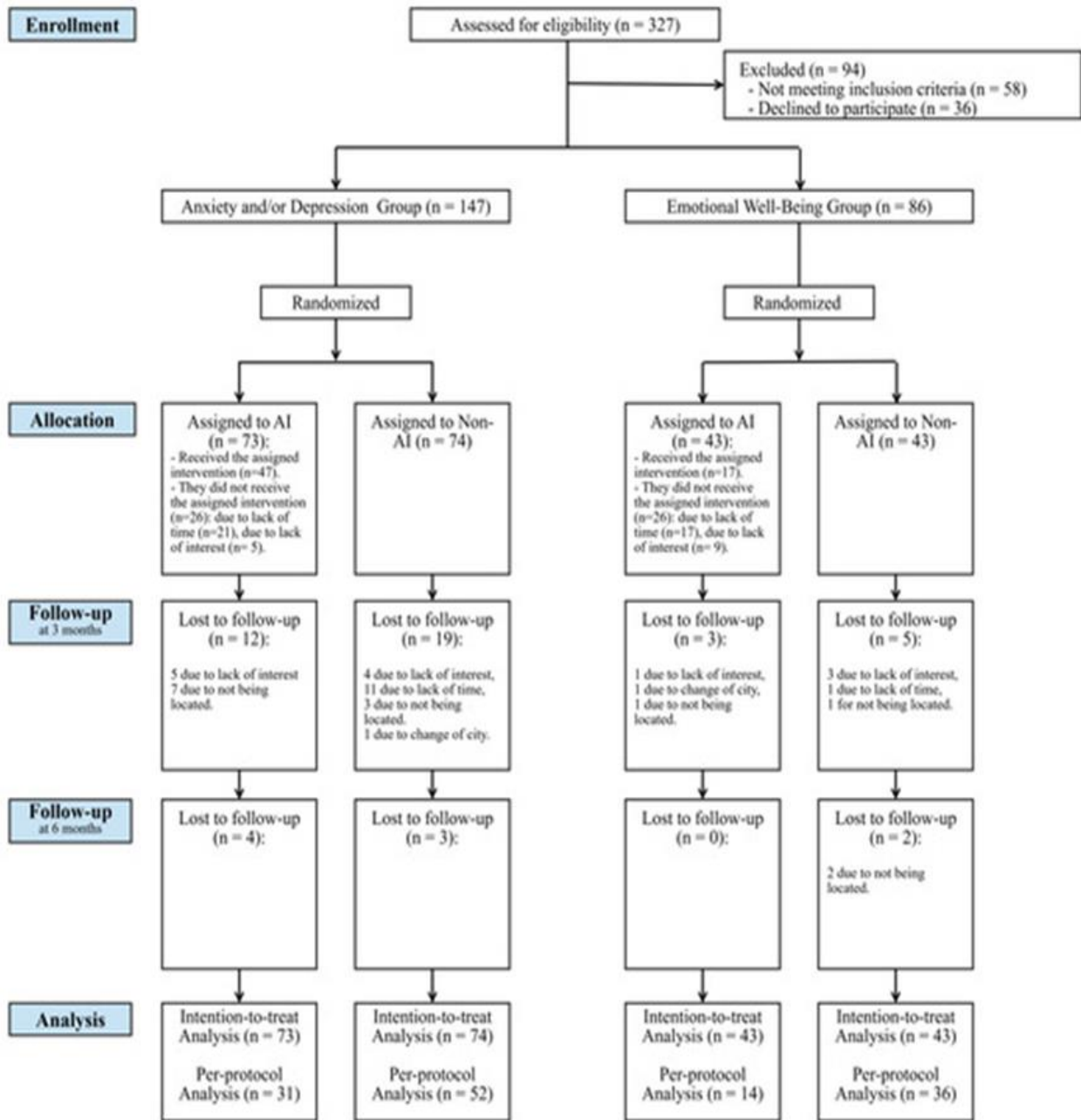


Figure 1. Flowchart of the clinical trial. An unblinded, randomized, controlled clinical trial. Abbreviation: AI = auditory intervention.

Given that mental health states can change spontaneously, the study investigated the frequency of such shifts within the study arms at the three-month and six-month time points.

Among participants in the emotional well-being group who did not receive the auditory intervention, 37% had shifted into the Anxiety and/or Depression category after three months. This proportion increased to 45.7% by the six-month follow-up. In the Anxiety and/or Depression group, only 6.8% moved toward Emotional Well-being at

both the three-month and six-month evaluations. Notably, cases of isolated depression were extremely rare throughout the observation period.

A total of 14 individuals completed the 10 auditory intervention sessions in the Emotional Well-being group and 31 in the Anxiety and/or Depression group.

Demographic and health characteristics according to the intervention group

Key features of the participant groups are summarized in **Table 1.**

Table 1. Demographic and health characteristics by intervention groups.

Variable	Auditory intervention (n = 31)	Non-intervention (n = 52)	Auditory intervention (n = 14)	Non-intervention (n = 36)
Age (years)	50.40 (11.30)	42.49 (12.02)	40.33 (22.50)	46 (12.91)
Gender (female)	23 (74.19%)	39 (75%)	5 (35.71%)	17 (47.22%)
Nationality				
Spanish	29 (93.54%)	45 (86.53%)	14 (100%)	33 (91.66%)
Rest of Europe	1 (3.22%)	4 (7.69%)	0 (0%)	3 (8.33%)
African	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hispanic American	1 (3.22%)	3 (5.76%)	0 (0%)	0 (0%)
Education level				
No studies	0 (0%)	3 (5.76%)	1 (7.14%)	0 (0%)
Primary studies	6 (19.35%)	27 (51.92%)	10 (71.43%)	16 (44.44%)
Secondary studies	0 (0%)	12 (23.07%)	0 (0%)	6 (16.66%)
Professional training	13 (41.93%)	7 (13.46%)	3 (21.43%)	12 (33.33%)
University studies	12 (38.7%)	3 (5.76%)	0 (0%)	2 (5.55%)
Employment situation				
Student	0 (0%)	3 (5.77%)	1 (7.14%)	0 (0%)
Active	7 (22.64%)	25 (48.08%)	4 (28.57%)	23 (63.88%)
Unemployed	18 (58.01%)	23 (44.23%)	8 (57.15%)	11 (30.56%)
Retired	6 (19.35%)	1 (1.92%)	1 (7.14%)	2 (5.56%)
Noise exposure				
No	28 (90.33%)	28 (53.85%)	13 (92.86%)	18 (50%)
Yes, only in the past	0 (0%)	15 (28.85%)	1 (7.14%)	8 (22.22%)
Yes, currently	3 (9.67%)	9 (17.30%)	0 (0%)	10 (27.78%)
Use of hearing protectors				
No	29 (93.55%)	45 (86.54%)	10 (71.43%)	31 (86.11%)
Yes, partially	2 (6.45%)	5 (9.62%)	4 (28.57%)	5 (13.89%)
Yes, always	0 (0%)	2 (3.84%)	0 (0%)	0 (0%)
Family history of depression	2 (6.45%)	9 (17.3%)	1 (7.14%)	4 (11.11%)
Family history of early deafness	1 (3.22%)	10 (19.23%)	1 (7.14%)	4 (11.11%)
Right laterality	31 (100%)	46 (88.46%)	14 (100%)	34 (94.44%)
Personal history of significant pain				
No	18 (58.07%)	26 (50%)	9 (64.29%)	19 (52.77%)
Yes, only in the past	7 (22.58%)	6 (11.54%)	5 (35.71%)	14 (38.88%)
Yes, currently	6 (19.35%)	20 (38.46%)	0 (0%)	3 (8.33%)
Personal history of immunological alteration				
No	18 (58.07%)	35 (67.30%)	9 (64.29%)	25 (69.44%)
Yes, only in the past	7 (22.58%)	5 (9.62%)	0 (0%)	4 (11.11%)
Yes, currently	6 (19.35%)	12 (23.08%)	5 (35.71%)	7 (19.45%)
Personal history of significant ENT pathology				
No	31 (100%)	49 (94.23%)	14 (100%)	33 (91.67%)
Yes, only in the past	0 (0%)	3 (5.77%)	0 (0%)	3 (8.33%)
Personal history of mental pathology				
No	11 (35.48%)	26 (50%)	8 (57.14%)	17 (47.22%)
Yes, only in the past	20 (64.52%)	20 (38.46%)	6 (42.86%)	17 (47.22%)
Yes, currently	0 (0%)	6 (11.53%)	0 (0%)	2 (5.56%)
Analgesics treatment				
No	19 (61.29%)	36 (69.23%)	13 (92.86%)	31 (86.11%)
Yes, only in the past	0 (0%)	2 (3.85%)	0 (0%)	2 (5.55%)
Yes, currently	12 (38.71%)	14 (26.92%)	1 (7.14%)	3 (8.34%)
Immune treatment				
No	31 (100%)	49 (94.23%)	14 (100%)	33 (91.67%)
Yes, only in the past	0 (0%)	0 (0%)	0 (0%)	1 (2.77%)
Yes, currently	0 (0%)	3 (5.77%)	0 (0%)	2 (5.55%)

Anxiolytics treatment				
No	18 (58.07%)	37 (71.15%)	12 (85.71%)	32 (88.88%)
Yes, only in the past	3 (9.68%)	3 (5.77%)	0 (0%)	2 (5.56%)
Yes, currently	10 (32.25%)	12 (23.08%)	2 (14.29%)	2 (5.56%)
Antidepressants treatment				
No	21 (67.74%)	37 (71.15%)	14 (100%)	30 (83.32%)
Yes, only in the past	3 (9.68%)	5 (9.62%)	0 (0%)	3 (8.34%)
Yes, currently	7 (22.58%)	10 (19.23%)	0 (0%)	3 (8.34%)
Psychological treatment				
No	25 (80.65%)	35 (67.31%)	9 (64.29%)	30 (83.33%)
Yes, only in the past	6 (19.35%)	11 (21.15%)	5 (35.71%)	6 (16.66%)
Yes, currently	0 (0%)	6 (11.54%)	0 (0%)	0 (0%)
Taste in music				
No	0 (0%)	10 (19.23%)	0 (0%)	4 (11.11%)
Yes, listening regularly	24 (77.42%)	30 (57.69%)	10 (71.43%)	22 (61.11%)
Yes, but not listening regularly	7 (22.58%)	12 (23.08%)	4 (28.57%)	10 (27.78%)

Age is expressed as a mean (standard deviation). The remaining variables are expressed as sample sizes (n) and percentages (%). Abbreviation: Interv. = intervention.; F.H. = family history; P.H. = personal history; ENT = ear nose throat.

When potential connections were explored between receiving the auditory intervention and several pre-existing conditions (such as use of pain relievers, immune-related issues, anxiolytic or antidepressant medication, psychological therapy, and personal enjoyment of music), only enjoyment of music was linked to a statistically meaningful outcome in the A/D group ($P = 0.0113$).

Internal consistency of the psychometric scales

Statistical examination confirmed that the reliability coefficients measuring internal consistency (Cronbach's alpha) stood at 0.87 for the Hamilton Total Anxiety Scale, 0.86 for the Psychological Anxiety Scale, 0.84 for the Somatic Anxiety Scale, and 0.79 for the Hamilton Depression Scale. Overall, these outcomes reflect solid internal consistency within the administered questionnaires.

Effect of hearing intervention on anxiety and depression in the two emotional groups

Given that the variables displayed normal distribution, the data were examined using repeated-measures two-way ANOVA supplemented by Bonferroni post-hoc testing.

To explore the preventive role AI might play against the emergence of anxiety or depressive conditions, researchers contrasted the anxiety and depression assessment variables in the Emotional Well-being group across time points for participants who underwent the intervention versus those who did not. Similarly, to gauge the therapeutic role of AI, parallel comparisons were conducted within the Anxiety and/or Depression group between the intervention recipients and non-recipients. These psychological measures were collected at the start (T0), after 3 months (T3m), and after 6 months (T6m).

Comparison of means at different time milestones

Average scores on the HAS-Total, HAS-Psychological, HAS-Somatic, and HAMD variables were evaluated at the initial assessment and at the 3- and 6-month follow-ups for each intervention subgroup in both the EWB and AD categories.

Within the EWB group, every scale yielded statistically significant outcomes at both the 3-month and 6-month intervals. The extent of improvement proved more pronounced after 3 months. Across all scales, the subgroup registering the lowest scores—signaling diminished vulnerability to anxiety and depression—was consistently the one provided with the AI (**Figure 2**).

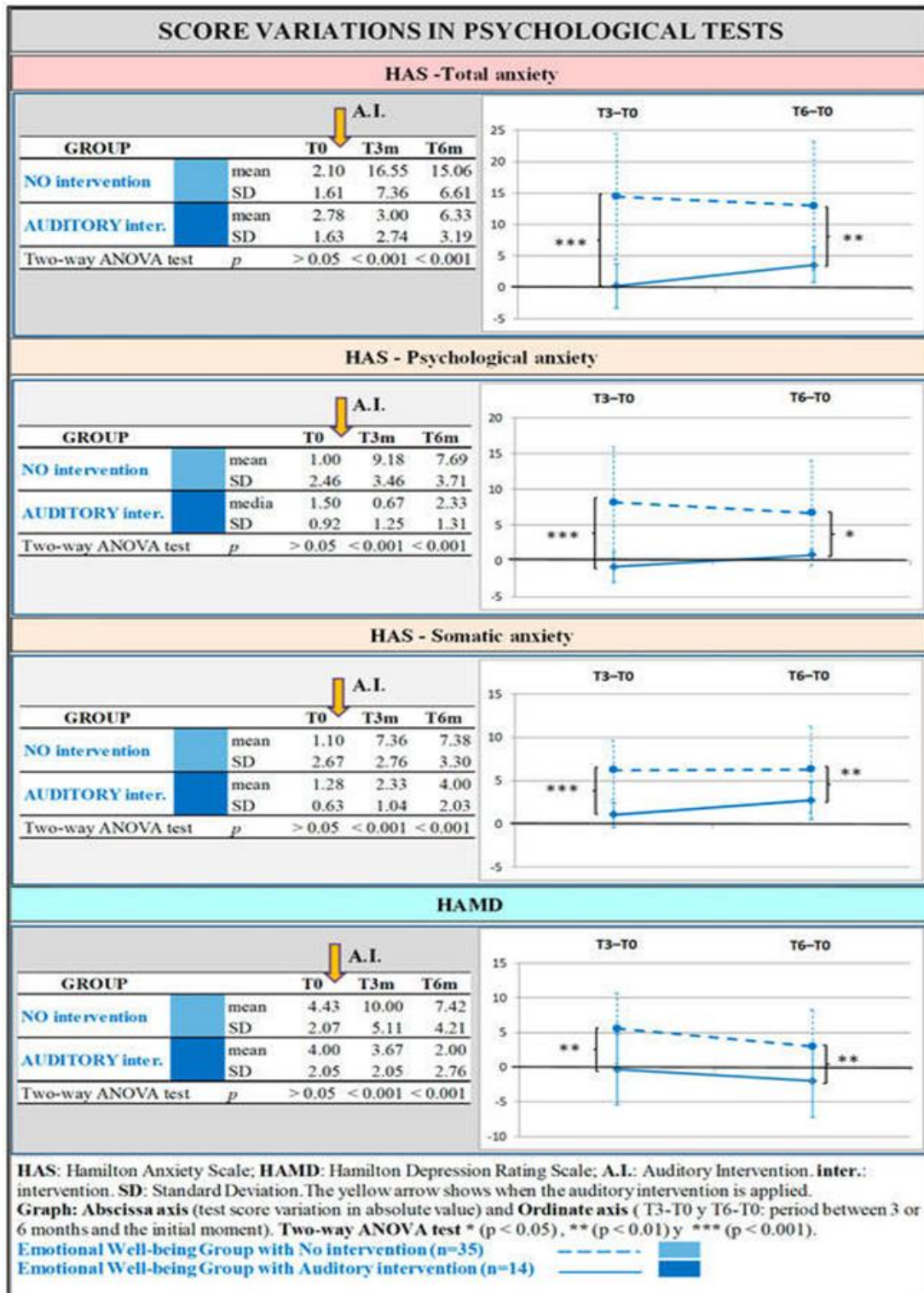


Figure 2. Emotional Well-being group: Evaluation of anxiety and depression in the subgroups with and without auditory intervention using the Hamilton test for anxiety and depression. The tables in the left column correspond to the absolute values obtained in the psychological tests. The figures in the right column compare, for the two groups (with and without AI), the differences between time 3 months and time 0, and between time 6 months and time 0.

In the AD group, notable differences appeared on all examined scales three months following the intervention. By the six-month mark, however, significance remained

only on the HAS-Som scale. The subgroup attaining the most positive results in the AD category was likewise the one that received the AI (**Figure 3**).

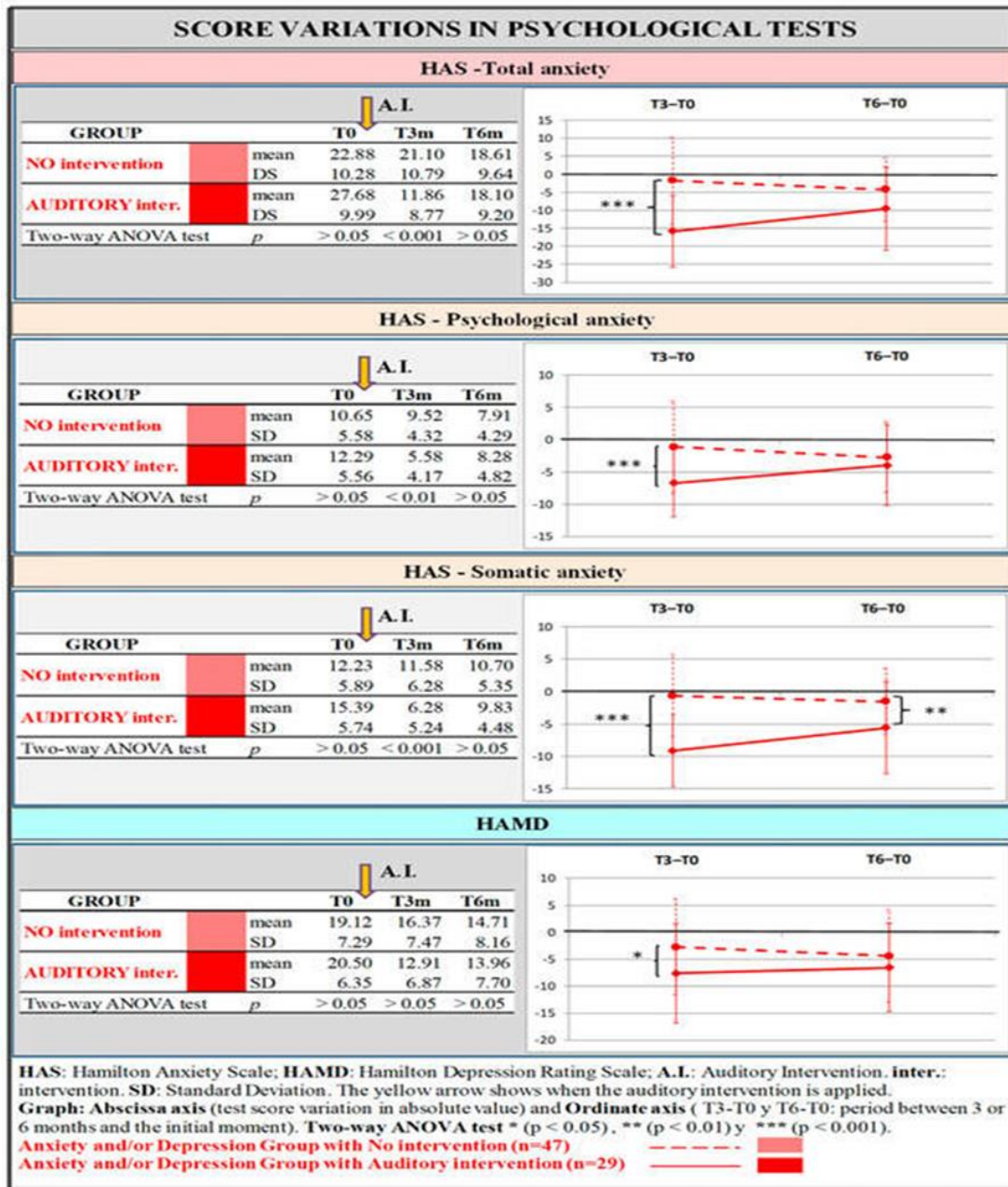


Figure 3. Anxiety and/or depression group: evaluation of anxiety and depression in the subgroups with and without Auditory Intervention using the Hamilton test for anxiety and depression. The tables in the left column correspond to the absolute values obtained in the psychological tests. The figures in the right column compare, for the two groups (with and without AI), the differences between time 3 months and time 0, and between time 6 months and time 0.

Response to treatment

Table 2 summarizes the response categories observed in the study groups following the Hearing intervention.

Table 2. Responses to the auditory intervention of the different groups.

Participant group	Measures showing total response	Measures showing partial response
Emotional well-being group	HAS-psychological score (3 months) HAMD score (6 months)	None reported
Anxiety and/or depression group	HAS-total score (3 months) HAS-psychological score (3 months) HAS-somatic score (3 months) HAS-total score (6 months) HAS-somatic score (6 months) HAMD score (3 months) HAMD score (6 months)	None reported

Total Response: decrease $\geq 50\%$ of the initial scale score; Partial Response: decrease between 25%–49% of the initial scale score. The results show a statistically significant difference between those exposed to the auditory intervention and those not exposed ($P < 0.05$).

Standardized mean difference

To quantify the effect size and facilitate comparisons with alternative approaches, Cohen’s d, also known as the Standardized Mean Difference, was computed (Table 3). Calculations relied on the combined standard deviation to accommodate groups of unequal sample sizes. Standardized mean differences of 0.2, 0.5, and 0.8 are conventionally interpreted as small, medium, and large effect sizes, respectively.

Table 3. Standardized mean differences between the groups.

Participant group	T3m–HAS-total	T3m–HAMD	T6m–HAS-Total	T6m–HAMD
Emotional well-being groups (with and without auditory intervention)	-1.16	-0.74	-0.68	-0.51
Anxiety and/or depression groups (with and without auditory intervention)	-0.20	-0.09	-0.01	-0.02

Cohen’s D, calculated with the combined standard deviation for groups of different sizes. T3m: three months after the start; T6m: six months after the start; HAS: Hamilton anxiety scale; HAMD: Hamilton depression rating scale.

The auditory intervention delivered over 10 sessions produced a large preventive effect against anxiety at the 3-month point, which diminished to moderate by 6 months. Prevention of depression registered a moderate effect at both 3 months and 6 months (Table 3). When viewed through a treatment lens, AI exerted only a small influence on anxiety reduction in the AD group at the 3-month evaluation (Table 3).

Epidemiological factors associated with a better response after auditory intervention

The influence of various epidemiological factors on the studied groups following the hearing intervention is presented in Table 4.

Table 4. Demographic and clinical factors that predict a better or worse evolution of anxiety and depression symptoms over time, with and without auditory intervention.

Scale/Group	After 3 months	After 6 months
HAS:		
Psychological anxiety (Ω)	No findings	No findings
HAS: Somatic anxiety (Ω)	No findings	No findings
HAS: Total anxiety (*)		
Group without intervention	Better results: Having university studies compared to other education levels. Worse results: Age range 51–65 years old. Being retired. History of pain. History of mental pathology. Having taken antidepressants in the past. Having taken analgesics in the past. Having followed psychological treatment in the past.	Better results: — Worse results: Being retired. Family history of depression.
Group with auditory intervention	Better results: Being unemployed is better than working for someone else. The age range 31–50 years is better than 51–65 years. Worse results: Having taken anti-anxiety or antidepressants in the past. Having a basic education is worse than having a higher level of education.	Better results: — Worse results: Having taken anti-anxiety or antidepressants in the past.
HAMD (*)		
Group without intervention	Better results: — Worse results: History of chronic pain. Having taken analgesics in the past. Having followed psychological treatment in the past. Being retired.	Better results: — Worse results: —

Group with
auditory
intervention

Better results: Being unemployed is better than working for someone else. **Worse results:** Current history of mental pathology presents a worse outcome than having had it in the past or not having had it at all.

Better results: — **Worse results:** —

Two-way ANOVA with repeated measures in a single factor and Bonferroni post-test, (*) $P < 0.05$. (Ω) $P > 0.05$. Abbreviations: HAS = Hamilton anxiety scale; HAMD = Hamilton depression rating scale; Psychol. = psychological.

In patients who did not receive hearing intervention, the factors linked to a more favorable progression included being aged 18 to 51 years, having university-level education, not being retired, lacking a family history of depression, and having no chronic pain, mental disorders, or prior use of analgesics, antidepressants, or psychological therapy. These patterns held at both 3 and 6 months. Among patients who underwent hearing intervention, the strongest outcomes were observed in individuals in their forties or fifties, those with education beyond primary level, unemployed individuals, those without any history of mental illness, and those who had not used anxiolytics or antidepressants in the past and were not currently taking pain medication.

Adverse effects

No adverse effects were observed either during or after the hearing intervention.

The auditory intervention successfully prevented the development of anxiety and depression symptoms at both the 3-month and 6-month follow-ups in the EWB group. By comparison, the AD group experienced a reduction in these symptoms at 3 months, but by 6 months, only somatic anxiety had improved.

Even in the groups that received no hearing intervention, some degree of change was noticeable over time. This shift was markedly more pronounced in the Emotional Well-being group, which makes sense because these participants were individuals already seeking care at a health center for various health concerns.

A range of musical approaches has previously been applied in the treatment of anxiety and depression [20, 31, 32], although the benefits observed have generally been modest and supported by only moderate evidence. Similarly, our AD group displayed only a modest impact on anxiety and depression control. This limited outcome may stem in part from the greater heterogeneity of this group, which lowered the overall statistical power. An additional factor could be that symptom intensity and duration were not taken into account. Earlier research has indicated that music-based interventions tend to produce somewhat greater improvements in depressive symptoms than in anxiety [20], with most data coming from hospital environments. In contrast, our primary care study revealed the opposite pattern: anxious symptoms decreased more noticeably than depressive ones. This finding likely reflects the higher prevalence of anxiety relative to

depression among patients typically seen in health centers [8, 9].

The present results indicate that the “Bérard in ten” hearing intervention functions more as a preventive measure than as a curative one, consistent with earlier reports [33]. Importantly, this study is the first to demonstrate in a novel way that a musical intervention can exert a preventive influence on anxiety and depression symptoms. Moreover, this preventive benefit surpassed the effect previously reported for physical exercise among healthy young adults [13].

Both the study’s methodology and its potential implementation in primary care settings represent new contributions. It is also worth noting that no side effects were reported at any point. However, the dropout rate was relatively high, comparable to those seen with both short-term treatments, such as antibiotics, and long-term therapies, such as antihypertensives or antidiabetic medications, in primary care [34]. The overall loss to follow-up reached 29.6%, exceeding the anticipated 15%. This higher-than-expected attrition may be linked to the extended 6-month study period, which was longer than the 3-month duration used in prior investigations [26]. Dropout was lower in the EWB group (19.77%) than in the AD group (35.37%), possibly because individuals experiencing anxiety and/or depression tend to expect rapid relief with minimal effort.

Several justifications exist for grouping patients with anxiety and/or depression symptoms together. Both disorders involve similar functional changes in the locus coeruleus, raphe nuclei, and limbic system. These disruptions often lead to distorted perceptions, especially in the auditory and visual domains, mediated by the amygdala [35]. Epidemiologically, anxiety and depression frequently co-occur [36, 37]. In primary care, treatment focuses on a broad biopsychosocial framework rather than on establishing a specific diagnosis [38-40].

Examination of epidemiological characteristics within the Anxiety and/or Depression group revealed a predominance of women with an average age of 45 years, primary-level education, and current employment. These features align closely with patterns described in other research [41, 42]. The group also contained a larger share of retired individuals and showed elevated ongoing use of painkillers. Additional relevant elements include the role of pain [42] and early retirement as potential triggers for depression.

The hearing intervention produced stronger positive outcomes among unemployed participants. This is particularly encouraging in light of the well-documented link between unemployment and anxiety-depression [43, 44]. One likely explanation is that unemployed individuals had more time available to complete the therapy consistently. Moreover, the absence of previous anxiolytic or antidepressant use was associated with better anxiety control, possibly indicating milder or less chronic symptoms and a lack of lasting neurological changes from earlier episodes. Control of depressive symptoms at 6 months was also enhanced when no active mental health disorder was present, given that such disorders themselves generate substantial anxiety and depression [36, 45].

In contrast, ongoing analgesic use negatively affected anxiety outcomes after the intervention, perhaps because pain or the medication itself interferes with the auditory intervention's influence on relevant brain pathways or auditory processing. This observation is supported by known adverse effects of anti-inflammatory drugs on hearing [46] and the impact of chronic pain on central nervous system function [47]. Regarding age, anxiety control was superior in the 31–50 years age range compared with the 51–65 range, which may relate to shorter symptom duration in younger adults. Lastly, completion of university-level education was linked to improved socioeconomic status and, in turn, to a reduced likelihood of anxiety disorders [48].

Every other element examined (including family background and personal medical history) appeared to promote the early appearance of anxiety and/or depression symptoms. In turn, this would likely lead to enduring functional modifications in the brain circuits that regulate these disorders. The pattern matches results reported in prior investigations [49, 50].

The Bérard method first attracted notice in the 1980s. At that time, it was mainly applied to autism spectrum conditions and used in educational settings to assist schoolchildren struggling with learning problems [51]. While the earliest trials produced many encouraging outcomes, later systematic reviews concluded that the supporting evidence was insufficient [52, 53]. Key shortcomings in study design, such as inadequate statistical power and missing control groups, were largely responsible. As a result, the method gradually fell out of widespread use. In the area of mental health, its application has been limited to a few case reports on depression, which nevertheless showed promising signs [51]. Given the well-documented connection between music and emotional regulation, we set out to test the Bérard method specifically for reducing anxiety-depressive symptoms. We therefore included a proper control group and aimed for a sample size large enough to deliver solid statistical power. Unfortunately, the number

of participants who withdrew during the trial weakened this aim.

A variety of theoretical models have been developed to clarify how auditory interventions based on the Bérard approach produce their effects [26]. Most of these models concentrate on different parts of the auditory processing pathway. Music listening is known to engage elaborate networks of brain regions that go far beyond the auditory cortex itself, involving broad areas of the temporal, frontal, parietal, subcortical, and cerebellar structures [15]. Even so, the exact processes by which a structured auditory intervention can reshape these networks remain poorly understood. We suggest that the “Bérard in ten” auditory intervention works by counteracting the right hemisphere's overemphasis on high-frequency sounds. It does so through repeated exposure to strong, irregular, and rapidly switching auditory stimuli that eventually fatigue and reduce the overall state of heightened auditory alertness [25].

Among the study's notable strengths are its randomized controlled trial design, which made it possible to examine both therapeutic and preventive outcomes of the auditory intervention; the extended follow-up period reaching 6 months, far longer than the 3-month maximum evaluated in previous work; and its conduct in primary care, a setting where anxiety and depression are highly prevalent and where interventions can be delivered and monitored with relative ease. On the limitation side, the trial was open-label and not blinded, so it cannot rule out a placebo contribution from the intervention itself. The AD group was also quite mixed, bringing together patients who had only anxiety symptoms, only depressive symptoms, or a combination of both. In addition, the study did not classify whether symptoms were recent, long-standing, or currently in a quiet phase. Finally, many participants were receiving other drug treatments or psychological therapies at the same time, which makes it difficult to isolate the specific contribution of the auditory intervention.

Regarding directions for future research, the auditory protocol used here was based on the classic Bérard method and comprised 20 sessions. Doubling the number of sessions while ensuring an adequately powered sample might yield greater, longer-lasting improvements. It would be worthwhile to develop modified versions of the “Bérard in ten” program that patients could apply independently at home. Including assessments of musical preferences and abilities might also allow for more tailored insights into how music influences anxiety and depression in different people. Lastly, investigating the method's potential effects on memory formation or habituation processes — and testing structured combinations with approaches such as cognitive-behavioral therapy — could shed light on its value for managing anxiety-depressive symptoms over both short- and medium-term time frames.

Conclusion

The auditory intervention proves capable of preventing anxiety and/or depression among individuals who start with good emotional well-being, while also offering a modest symptom-relieving effect for those already in the anxiety and/or depression group. Therefore, the auditory intervention (“Bérard in ten”) stands out as an effective, time-efficient, and completely safe preventive strategy that deserves consideration when addressing anxiety and/or depression, above all in primary care environments.

Acknowledgments: None

Conflict of interest: None

Financial support: None

Ethics statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Hospital la Princesa, Madrid (Protocol code: 05/11; 8 March 2012).

Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

References

1. GBD 2019 Mental Disorders Collaborators. Global, regional, and national burden of 12 mental disorders in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet Psychiatry*. 2022;9(2):137–50.
2. World Health Organization. Comprehensive mental health action plan 2013–2030. 1st ed. Geneva: World Health Organization; 2021. ISBN 978-92-4-003102-9.
3. COVID-19 Mental Disorders Collaborators. Global prevalence and burden of depressive and anxiety disorders in 204 countries and territories in 2020 due to the COVID-19 pandemic. *Lancet*. 2021;398(15):1700–12.
4. de la Torre J-A, Vilagut G, Ronaldson A, Serrano-Blanco A, Martín V, Peters M, et al. Prevalence and variability of current depressive disorder in 27 European countries: a population-based study. *Lancet Public Health*. 2021;6(10):e729–38.
5. Ghebreyesus TA, Fore H, Birtanov Y, Jakab Z. Primary health care for the 21st century, universal health coverage, and the sustainable development goals. *Lancet*. 2018;392(10156):1371–2.
6. Koppner J, Chatziarzenis M, Faresjö T, Theodorsson E, Thorsell A, Nilsson S, et al. Stress and perceived health among primary care visitors in two corners of Europe: Scandinavia and Greece. *Int J Health Geogr*. 2020;19(1):55.
7. Ruiz-Rodríguez P, Cano-Vindel A, Muñoz Navarro R, Medrano L, Moriana JA, Buiza Aguado C, et al. Impacto económico y carga de los trastornos mentales comunes en España: una revisión sistemática y crítica. *Ansiedad Estrés*. 2017;23(2):118–23.
8. Reneses B, Garrido S, Navalón A, Martín O, Ramos I, Fuentes M, et al. Psychiatric morbidity and predisposing factors in a primary care population in Madrid. *Int J Soc Psychiatry*. 2015;61(4):275–86.
9. Wiegner L, Hange D, Björkelund C, Ahlborg G. Prevalence of perceived stress and associations to symptoms of exhaustion, depression and anxiety in a working age population seeking primary care—an observational study. *BMC Fam Pract*. 2015;16:38.
10. National Institute for Health and Care Excellence (NICE). Generalised anxiety disorder and panic disorder in adults: management. London: NICE; 2019.
11. Rodríguez Tejada A, Torres Tejera ME. Estrategias no farmacológicas en el tratamiento de la ansiedad. *Aten Primaria Pract*. 2024;6(1):100193.
12. Miró Barrachina MT, Perestelo Pérez L, Pérez Ramos J, Rivero Santana A, González Lorenzo M, de la Fuente Portero JA, et al. Eficacia de los tratamientos psicológicos basados en mindfulness para los trastornos de ansiedad y depresión: una revisión sistemática. *Rev Psicopatol Psicol Clin*. 2011;16(1):1–14.
13. Larun L, Nordheim LV, Ekeland E, Hagen KB, Heian F. Exercise in prevention and treatment of anxiety and depression among children and young people. *Cochrane Database Syst Rev*. 2006;2006(3):CD004691.
14. Mera-Posligua M, Arredondo-Aldana K, Ponce Alencastro J. Trastorno de ansiedad generalizada abordado desde la terapia de aceptación y compromiso: caso clínico. *Rev Cient Investig Salud GESTAR*. 2021;4(2):73–85.
15. Zaatar MT, Alhakim K, Enayeh M, Tamer R. The transformative power of music: insights into neuroplasticity, health, and disease. *Brain Behav Immun Health*. 2024;35:100716.
16. Kushner MG, Maurer EW, Thuras P, Donahue C, Frye B, Menary KR, et al. Hybrid cognitive behavioral therapy versus relaxation training for co-occurring anxiety and alcohol disorder: a randomized clinical trial. *J Consult Clin Psychol*. 2013;81(3):429–42.
17. National Institute for Health and Care Excellence (NICE). Depression in adults: treatment and management. London: NICE; 2022.

18. Grupo de Trabajo de Revisión de la Guía de Práctica Clínica sobre el Manejo de la Depresión en el Adulto. Revisión de la guía de práctica clínica sobre el manejo de la depresión en el adulto (2014). Santiago de Compostela: Ministerio de Sanidad; 2023.
19. Farah WH, Alsawas M, Mainou M, Alahdab F, Farah MH, Ahmed AT, et al. Non-pharmacological treatment of depression: a systematic review and evidence map. *Evid Based Med*. 2016;21(3):214–21.
20. Golden TL, Springs S, Kimmel HJ, Gupta S, Tiedemann A, Sandu CC, et al. The use of music in the treatment and management of serious mental illness: a global scoping review of the literature. *Front Psychol*. 2021;12:649840.
21. Chen WG, Iversen JR, Kao MH, Loui P, Patel AD, Zatorre RJ, et al. Music and brain circuitry: strategies for strengthening evidence-based research for music-based interventions. *J Neurosci*. 2022;42(35):8498–507.
22. Guest M, Boggess M, D'Este C, Attia J, Brown A. An observed relationship between vestibular function and auditory thresholds in aircraft-maintenance workers. *J Occup Environ Med*. 2011;53(2):146–52.
23. Estalayo-Gutiérrez B, Álvarez-Pasquín MJ, Germain F. Modulation of auditory perception laterality under anxiety and depression conditions. *Symmetry*. 2022;14(1):24.
24. Yovell Y, Sackeim HA, Epstein DG, Prudic J, Devanand DP, McElhiney MC, et al. Hearing loss and asymmetry in major depression. *J Neuropsychiatry Clin Neurosci*. 1995;7(2):82–9.
25. Estalayo-Gutiérrez B, Álvarez-Pasquín MJ, Germain F. Modulation of asymmetry in auditory perception through a bilateral auditory intervention. *Symmetry*. 2022;14(12):2490.
26. Bérard G, Brockett S. Hearing equals behavior: updated and expanded. Schaumburg (IL): eBooks2go; 2014.
27. Goldberg D, Bridges K, Duncan-Jones P, Grayson D. Detecting anxiety and depression in general medical settings. *BMJ*. 1988;297(8600):897–9.
28. Carrobes J, Costa M, Del Ser T, Bartolomé P. La práctica de la terapia de conducta. Valencia: Promolibro; 1986.
29. Montón C, Pérez Echeverría MJ, Campos R, García Campayo J, Lobo A. Escalas de ansiedad y depresión de Goldberg: una guía de entrevista eficaz para la detección del malestar psíquico. *Aten Primaria*. 1993;12(6):345–9.
30. Ramos-Brieva JA, Cordero Villafáfila A. Validación de la versión castellana de la escala de Hamilton para la depresión. *Actas Luso Esp Neurol Psiquiatr Cienc Afines*. 1986;14(4):324–34.
31. Bradt J, Dileo C, Magill L, Teague A. Music interventions for improving psychological and physical outcomes in cancer patients. *Cochrane Database Syst Rev*. 2016;(8):CD006911.
32. Aalbers S, Fusar-Poli L, Freeman RE, Spreen M, Ket JC, Vink AC, et al. Music therapy for depression. *Cochrane Database Syst Rev*. 2017;(11):CD004517.
33. Woolf SH. The power of prevention and what it requires. *JAMA*. 2008;299(17):2437–9.
34. Orueta R, Toledano P, Gómez-Calcerrada RM. Cumplimiento terapéutico. *Med Fam SEMERGEN*. 2008;34(3):235–43.
35. Hall JE. Mecanismos encefálicos del comportamiento y la motivación. In: Guyton y Hall. Tratado de fisiología médica. Elsevier; 2016. p. 38958–9466.
36. Sadock VA, Sadock BJ, Ruiz P. Comorbilidad de los trastornos del estado de ánimo. In: Kaplan & Sadock. Sinopsis de psiquiatría. Wolters Kluwer; 2015.
37. Aragonès E, Piñol JL, Labad A. Comorbilidad de la depresión mayor con otros trastornos mentales comunes. *Aten Primaria*. 2009;41(8):545–51.
38. Pérez-Franco B, Turabián-Fernández JL. ¿Es válido el abordaje ortodoxo de la depresión en atención primaria? *Aten Primaria*. 2006;37(1):37–9.
39. Salazar Fraile J, Sempere Verdú E. Malestar emocional: manual práctico para una respuesta en atención primaria. Valencia: Generalitat Valenciana; 2012.
40. Aragonès E. Desacuerdos diagnósticos entre médicos generales y psiquiatras. *Aten Primaria*. 2008;40(12):644.
41. Sadock VA, Sadock BJ, Ruiz P. Anxiety disorders. In: Kaplan & Sadock's synopsis of psychiatry. Wolters Kluwer; 2015.
42. Sadock VA, Sadock BJ, Ruiz P. Mood disorders. In: Kaplan & Sadock's synopsis of psychiatry. Wolters Kluwer; 2015.
43. Kim TJ, von dem Knesebeck O. Is an insecure job better for health than having no job at all? *BMC Public Health*. 2015;15:985.
44. Deniel Rosanas J, Bosch Molas M, Culí Borràs N, Olmeda Brea C. Influencia del paro sobre los problemas de salud mental. *Aten Primaria*. 1996;18(5):379–82.
45. Haro JM, Palacín C, Vilagut G, Martínez M, Bernal M, Luque I, et al. Prevalencia de los trastornos mentales y factores asociados. *Med Clin (Barc)*. 2006;126(12):445–51.
46. Kyle ME, Wang JC, Shin JJ. Impact of nonaspirin NSAIDs and acetaminophen on sensorineural hearing loss. *Otolaryngol Head Neck Surg*. 2015;152(3):393–409.

47. Thorp SL, Suchy T, Vadivelu N, Helander EM, Urman RD, Kaye AD. Functional connectivity alterations. *Pain Physician*. 2018;21(3):E207–14.
48. Sadock VA, Sadock BJ, Ruiz P. Trastornos de ansiedad. In: Kaplan & Sadock. *Sinopsis de psiquiatría*. Wolters Kluwer; 2015.
49. Wittchen HU, Kessler RC, Pfister H, Lieb M. Why do people with anxiety disorders become depressed? *Acta Psychiatr Scand Suppl*. 2000;102(406):14–23.
50. Bittner A, Goodwin RD, Wittchen HU, Beesdo K, Höfler M, Lieb R. What characteristics of anxiety disorders predict depression? *J Clin Psychiatry*. 2004;65(4):618–26.
51. Bérard G. *Audition égale comportement*. Sainte-Ruffine: Maisonneuve; 1982.
52. Sinha Y, Silove N, Wheeler D, Williams K. Auditory integration training for autism spectrum disorders. *Arch Dis Child*. 2006;91(11):1018–22.
53. Sinha Y, Silove N, Hayen A, Williams K. Auditory integration training for ASD. *Cochrane Database Syst Rev*. 2011;2011(12):CD003681.