UDC 616-056.52:616.89-008.441.1/616-085
DOI https://doi.org/10.32782/2226-2008-2026-2-6

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CORRECTION OF INCREASED ANXIETY IN CHILDREN WITH OBESITY USING *PASSIFLORA INCARNATA* EXTRACT

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Objective of the study was to evaluate the effectiveness of a standardized *Passiflora incarnata* extract in reducing elevated anxiety levels in children with obesity.

Materials and Methods. A prospective, single-center, controlled study with parallel groups was conducted. A total of 56 adolescents aged 12–17 years with obesity and elevated anxiety were enrolled and allocated into the main group (n = 28) and the control group (n = 28) without randomization. Patients in the main group received a standardized *Passiflora incarnata* extract as part of combination therapy for 30 days. Anxiety levels were assessed using the Spielberger–Khanin scale, with separate evaluation of state and trait anxiety. Treatment effectiveness was analyzed using ROC analysis with determination of the area under the curve (AUC) and 95% confidence intervals.

Results. In the main group, a statistically significant reduction in state anxiety was observed after treatment (AUC = 0.858; 95% CI 0.739–0.937), indicating high discriminative ability of the model and a pronounced therapeutic effect. In the control group, the corresponding value was significantly lower (AUC = 0.581; 95% CI 0.442–0.712), which does not support clinically significant improvement. The effect on trait anxiety was less pronounced (AUC = 0.721; 95% CI 0.585–0.832 vs 0.523; 95% CI 0.385–0.658), consistent with its more stable nature and lower sensitivity to short-term interventions. The use of the extract was associated with reduced emotional tension, improved sleep, and was not associated with clinically significant adverse effects.

Conclusions. The standardized *Passiflora incarnata* extract provides a clinically significant reduction in state anxiety, demonstrates a favorable safety profile, and may be considered a reasonable adjuvant component of comprehensive therapy for psychological and emotional disorders in children with obesity.

Keywords: mental health, children, anxiety, obesity, phytotherapy.

УДК 616-056.52:616.89-008.441.1/616-085

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КОРЕКЦІЯ ПІДВИЩЕНОЇ ТРИВОЖНОСТІ У ДІТЕЙ З ОЖИРІННЯМ ЕКСТРАКТОМ PASSIFLORA INCARNATA

Одеський національний медичний університет, Одеса, Україна

Оцінено ефективність застосування стандартизованого екстракту *Passiflora incarnata* для корекції підвищеної тривожності у дітей з ожирінням. Обстежено 56 підлітків 12–17 років, розподілених на основну (n = 28) та контрольну (n = 28) групи. Пацієнти основної групи протягом 30 днів отримували екстракт *Passiflora incarnata* у складі комплексної терапії. Рівень тривожності визначали за шкалою Спілбергера – Ханіна з використанням ROC-аналізу (AUC; 95% ДІ). Встановлено статистично значуще зниження ситуаційної тривожності (AUC = 0,858; 95% ДІ 0,739–0,937) порівняно з контрольною групою (AUC = 0,581; 95% ДІ 0,442–0,712). Вплив на особистісну тривожність був менш вираженим. Застосування екстракту характеризувалося сприятливим профілем безпеки та клінічно значущим зниженням тривожності.

Ключові слова: діти, ожиріння, тривожність, психічне здоров'я, фітотерапія.

Introduction

Childhood obesity has reached the scale of a global epidemic, combining serious somatic complications with psycho-emotional disorders [1]. For the first time in history, obesity has become more prevalent among school-aged children and adolescents than underweight. If current trends persist, approximately 254 million children and adolescents aged 5–19 years worldwide will have obesity by 2030 [2]. In Ukraine, the results of the first national study conducted according to the WHO methodology (COSI) demonstrated that among children aged 6–8 years, overweight was observed in 22.96%, including 9.13% with obesity and 2.63% with severe obesity [3].

The diagnosis of overweight/obesity requires an integrated assessment, including family history, dietary habits, physical activity level, sleep duration, and mental health status. A key stage is the differentiation between primary obesity (associated with lifestyle and heredity) and secondary obesity (caused by endocrine diseases, genetic syndromes, or medication use) [4].

Childhood obesity leads to psychological stress and the development of behavioral or emotional disorders. A relationship between childhood obesity and an increased risk of anxiety disorders, low self-esteem, depressive symptoms, suicidal ideation, eating disorders, and reduced quality of life has been confirmed. A vicious cycle is formed: low self-esteem and depression may contribute to emotional overeating, which further aggravates weight problems [5]. Children with obesity are significantly more likely to experience stigmatization, teasing, and bullying by peers, already observed in primary school. Obesity can affect socialization, academic performance, and the formation of social relationships, and in the long term may influence adult career opportunities [6].

Effective treatment requires a comprehensive and long-term approach. The only proven effective basis of treatment is family-based behavioral therapy, which includes dietary modification, increased physical activity, sleep correction, and reduction of screen time. For adolescents with severe obesity, when lifestyle modification is insufficient, pharmacotherapy (e.g., GLP-1 analogues) or bariatric surgery may be considered [7].

An important direction of treatment is the correction of psychological and emotional disorders in children with obesity. Psychological consequences are often traumatic for the child and have long-term effects. Considering the limitations of traditional pharmacological methods for correcting psycho-emotional disorders (especially subthreshold or mild ones), interest in alternative approaches such as herbal therapy is increasing [8].

Objective of the study was to evaluate the effectiveness of using *Passiflora incarnata* extract to reduce anxiety in children with obesity.

Materials and Methods

The study was conducted as a prospective single-center controlled study with parallel groups in general secondary schools of Odesa during preventive examinations and at the Center for Mental Health of the municipal non-profit enterprise "Odesa Regional Children's Clinical Hospital" of the Odesa Regional Council (MNE "ORCCH" ORC). Written informed consent was obtained from all participants and their parents. The study was performed in accordance with the standards of Good Clinical Practice (GCP), the principles of the Declaration of Helsinki, and the STROBE recommendations. Study protocol No. 7/22 dated 12.03.2022 was approved by the local ethics committee of MNE "ORCCH" ORC.

All participants and their legal representatives provided written informed consent. Confidentiality of personal data and voluntariness of participation with the possibility of withdrawal at any stage without negative consequences were ensured.

Participants were allocated sequentially on the basis of informed consent without the use of a randomization procedure. The study included 56 adolescents with obesity who had an elevated level of anxiety according to the Spielberger–Khanin scale [9]. Mandatory inclusion criteria were the presence of written informed consent from the child and their legal representative, as well as the absence of decompensated somatic and severe psychiatric diseases, and the use of medications that may affect body weight or psychological status. Participants were divided into: the main group (n = 28) and the control group (n = 28). The mean age of children in the main group was 14.7 ± 1.4 years, in the control group – 14.5 ± 1.6 years. The mean body mass index was 32.5 ± 2.5 kg/m² and 32.1 ± 2.7 kg/m², respectively. Systolic blood pressure values were 119.2 ± 8.4 mmHg in the main group and 117.6 ± 8.8 mmHg in the control group; diastolic – 74.8 ± 6.0 and 73.6 ± 6.3 mmHg, respectively. No statistically significant differences between the groups were found ($p > 0.05$), which confirms their comparability.

For the correction of increased anxiety, as part of complex therapy, children of the main group (n = 28) were prescribed a standardized extract of the medicinal plant Passiflora incarnata in accordance with pharmacopoeial standards, in an oral dosage form at a dose of 1 teaspoon once daily before bedtime for 30 days. Safety assessment was carried out through clinical monitoring throughout the entire treatment period. During observation, no clinically significant adverse events requiring drug discontinuation or changes in therapeutic tactics were registered, which confirms a favorable safety profile of the studied agent. Children of the control group (n = 28) did not receive herbal therapy.

The level of anxiety was determined using the Spielberger–Khanin scale with categorization according to the total score: low level – up to 30 points, moderate – 31–44 points, high – ≥ 45 points. The assessment was performed separately for state anxiety and trait anxiety.

The analysis of therapy effectiveness was performed taking into account the baseline level of anxiety, assessing both the change in the total score and the transition between levels (from high to moderate).

Evaluation of therapy effectiveness was performed using ROC analysis (Receiver Operating Characteristic) with determination of the area under the ROC curve (AUC) and 95% confidence intervals.

Statistical data processing was carried out using STATISTICA 12.0, MedCalc 20.0, Microsoft Excel 2003 with integration of AtteStat 12.5, and the online calculator SISA (Simple Interactive Statistical Analysis – https://-www.quantitativeskills.com/sisa/).

Research results and their discussion

Diagnosis of obesity in children and screening for its complications were performed in accordance with the recommendations of the Ministry of Health of Ukraine and the AAP (American Academy of Pediatrics, USA). In children aged over 2 years and adolescents, overweight was diagnosed when the body mass index (BMI) was ≥ 85th and < 95th percentile for the corresponding age and sex, and obesity – when BMI ≥ 95th percentile. Screening for comorbid conditions in childhood obesity revealed comorbid pathology, including: prediabetes/type 2 diabetes (3.6%), arterial hypertension (5.3%), dyslipidemia (7.1%), non-alcoholic fatty liver disease (1.7%), obstructive sleep apnea (3.6%), polycystic ovary syndrome (3.6%), musculoskeletal disorders (3.6%). Assessment of the psychological state using interviews revealed mild and moderate emotional disturbances associated with obesity, including: feelings of shame and reduced self-esteem (46.4%);

moderate anxiety and episodic depressed mood without pronounced impairment of educational, social, and behavioral activity, emotional overeating and episodes of nocturnal overeating ("stress eating") (21.4%); psychosocial difficulties, including symptoms of depression and anxiety (21.4%), social stigmatization (17.9%) and bullying (12.0%). In the presence of a positive psychological history, children were referred for consultation with a mental health specialist.

A multidisciplinary, family-oriented treatment program included intensive lifestyle modification with the participation of a clinical psychologist (cognitive behavioral therapy), a dietitian (correction of eating behavior, formation of a structured eating regimen, work with overeating triggers), and, if necessary, a pediatric neurologist and an endocrinologist. Herbal therapy was used as a component of comprehensive treatment taking into account the multifactorial etiology of overweight and obesity. Biologically active components of the extract have a moderate sedative effect, reduce the level of nervous excitability, and contribute to sleep normalization. The choice of the herbal preparation for the correction of anxiety manifestations was based on the data of the European Medicines Agency (EMA) regarding the possibility of using medicinal plants in psychological stress, anxiety disorders, and sleep disturbances, in particular Passiflora incarnata [8]. The extract of Passiflora incarnata is officially registered for use in children in EU Member States [10; 11].

In the main group, against the background of therapy with Passiflora incarnata extract, an improvement in the psychological state was noted, which manifested as a decrease in the level of anxiety and emotional tension, as well as normalization of sleep without the development of morning drowsiness phenomena. The mean values of trait anxiety decreased from 50.78 ± 1.82 to 43.57 ± 1.53 points, and state anxiety – from 39.78 ± 1.85 to 32.67 ± 0.66

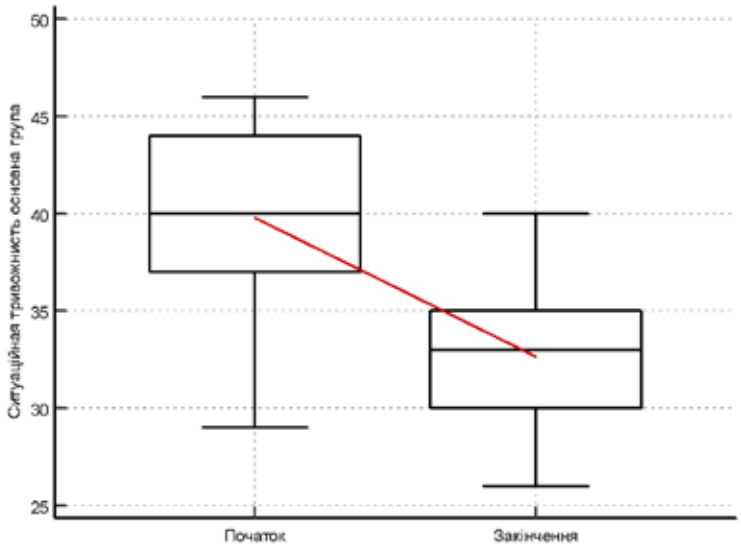

Fig. 1. Comparison of state anxiety in children of the main group

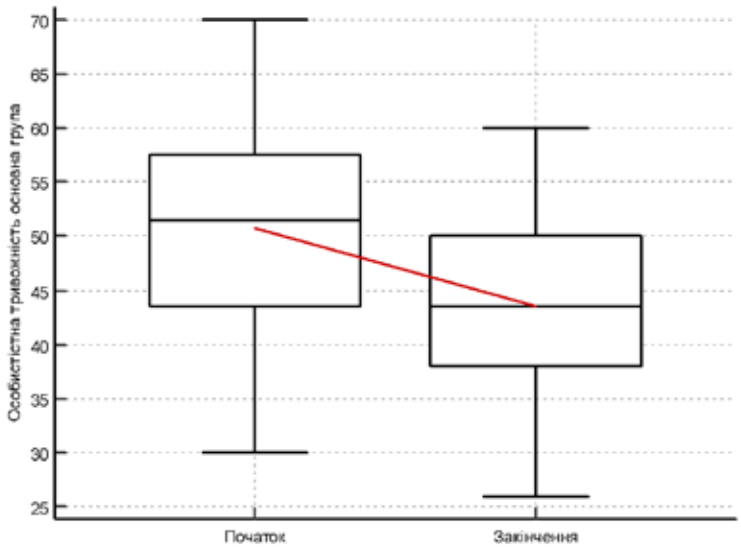

Fig. 2. Comparison of trait anxiety levels in children of the main group

points ($p < 0.05$). The comparison results are presented in Figures 1 and 2.

In the control group, no statistically significant changes of the indicators were found: the level of trait anxiety remained unchanged (49.42 ± 1.82 vs 49.03 ± 0.98 points; $p > 0.05$); the level of state anxiety was 38.10 ± 1.12 vs 36.46 ± 1.00 points ($p > 0.05$). The study results are presented in Figures 3 and 4.

The effectiveness of the performed therapy was evaluated using ROC analysis by comparing the area under the ROC curve (AUC).

Figure 5 presents the results of ROC analysis of intervention effects on state anxiety in children with obesity. In children of the main group who received Passiflora incarnata extract for 30 days, the area under the ROC curve (AUC) was 0.858 (95% CI 0.739–0.937). An AUC value in the range of 0.8–0.9 is considered excellent discriminative ability of the model. At the same time, in children of the control group, the AUC value was only 0.581 (95% CI 0.442–0.712), indicating low predictive value of the model and the absence of clinically significant positive dynamics of state anxiety indicators during the observation period.

Figure 6 presents the ROC analysis of intervention effects on trait anxiety in children with obesity compared with the control group that did not receive pharmacological correction. The effectiveness of therapy was less pronounced in the main group: AUC was 0.721 (95% CI 0.585–0.832), which corresponds to moderate discriminative ability. In the control group, AUC was 0.523 (95% CI 0.385–0.658), indicating the absence of effect.

The most pronounced therapeutic effect was observed in the correction of state anxiety, which is confirmed both by a high proportion of clinical improvement and by the results of ROC analysis.

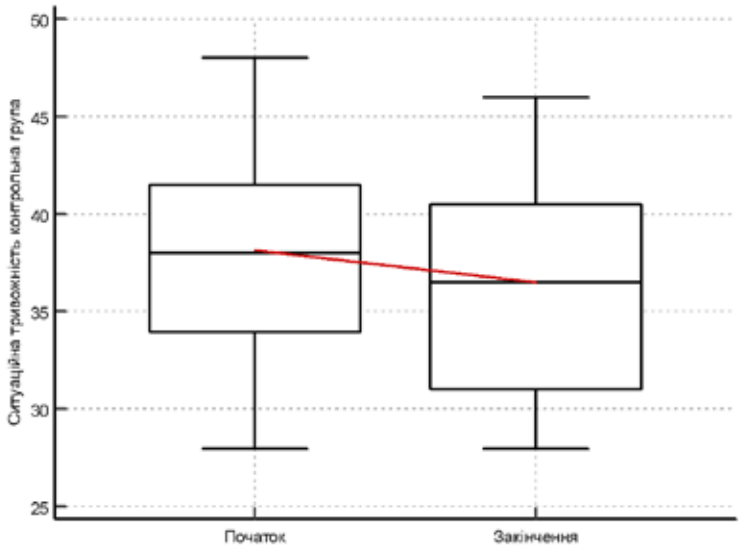

Fig. 3. Comparison of state anxiety in children of the control group

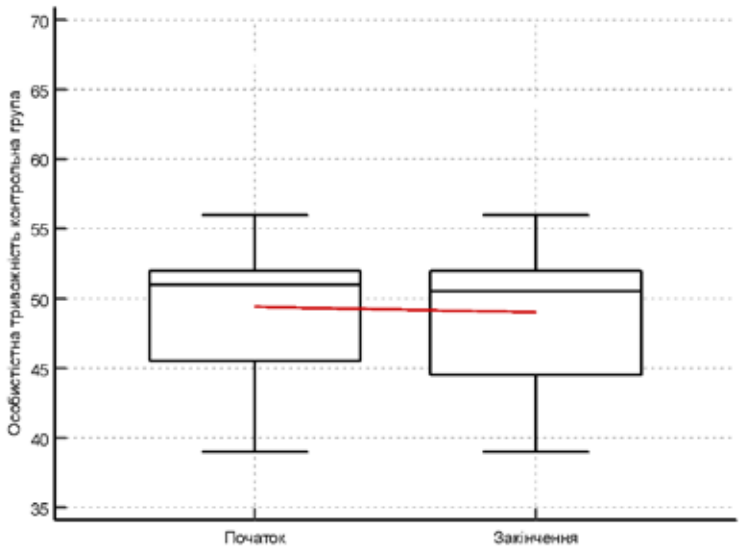

Fig. 4. Comparison of trait anxiety in children of the control group

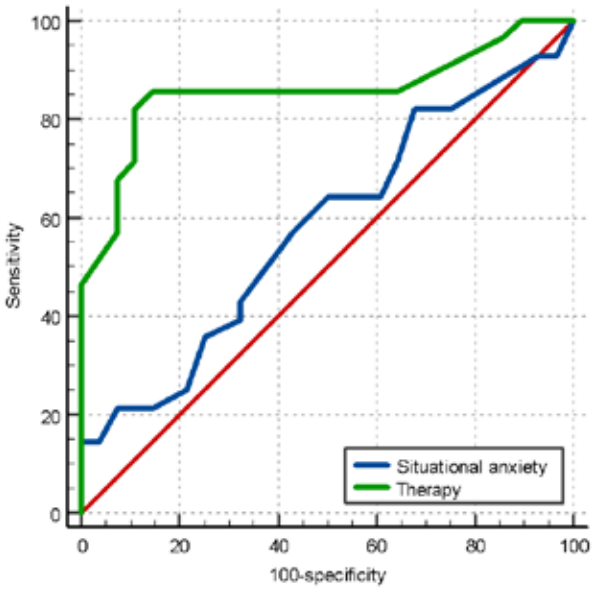

Fig. 5. ROC analysis of intervention effects on state anxiety in children with obesity

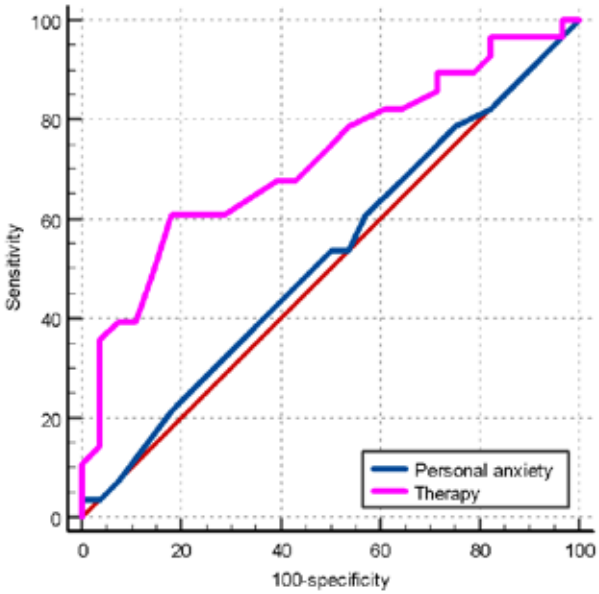

Fig. 6. ROC analysis of intervention effects on trait anxiety in children with obesity

Among children of the main group, a high baseline level of state anxiety (≥ 45 points) was detected in 11 out of 28 patients (39.3%; 95% CI 21.5–59.4), moderate – in 17 children (60.7%; 95% CI 40.6–78.5), and no cases of low level were registered. After therapy, in all patients with a high baseline level of state anxiety (n = 11), a decrease in indicators to a moderate level was observed, corresponding to 100% (95% CI 71.5–100.0) clinical improvement in this subgroup. In patients with a moderate level of state anxiety, a decrease in the total score without transition to a lower category was observed, indicating a less pronounced but stable positive dynamics.

A high baseline level of trait anxiety was detected in 19 out of 28 children (67.9%; 95% CI 47.6–84.1), moderate – in 9 (32.1%; 95% CI 15.9–52.4). After treatment, in patients with a high level of trait anxiety (n = 19), a decrease in indicators without a change in the level category was observed in 12 cases (63.2%; 95% CI 38.4–83.7), whereas a transition to a moderate level – in 7 children (36.8%; 95% CI 16.3–61.6). This indicates a higher sensitivity of state anxiety to therapeutic intervention compared with trait anxiety.

The study was based on the results of our previous work devoted to the assessment of psychological consequences of overweight and obesity in children, in particular increased anxiety and decreased quality of life [12; 13]. The obtained data complement current understanding of the increasing prevalence of subclinical psychological and emotional disturbances among children and adolescents, such as increased anxiety, emotional lability, sleep disorders, and decreased concentration, which, even in the absence of clinically manifested disorders, may negatively affect psychosocial functioning, academic performance, and overall well-being [14; 15].

The impact of herbal therapy on the psychological state of children and adolescents with overweight and obesity has previously been scarcely studied. When selecting a herbal preparation, it was taken into account that the medicinal plant *Passiflora incarnata* is officially included in the European Pharmacopoeia (11th edition) and is recommended for use in mild psychological stress and sleep disturbances [16]. The study demonstrated the clinical effectiveness of the rational use of medicinal plants for the purpose of supporting the mental health of children and adolescents with obesity. The obtained results indicate the feasibility of using herbal preparations and dietary supplements in comprehensive therapy of subclinical psychological and emotional manifestations in pediatric practice, in particular nervousness, anxiety, sleep disturbances, and emotional tension. Such approaches are discussed in contemporary systematic reviews of clinical studies of herbal preparations [8].

Thus, the results of the study expand the spectrum of the use of herbal therapy as an auxiliary tool for supporting mental health in pediatric practice. The obtained data indicate that herbal therapy may be considered as a safe complementary approach to maintaining the mental health of children and adolescents, including in cases of mild or subclinical manifestations of increased anxiety. The use of standardized extracts of medicinal plants, rather than non-certified herbal mixtures, is considered appropriate. In the presence of mild anxiety manifestations, restlessness, sleep disturbances, or psychological tension in a child with obesity, and in the absence of indications for the prescription of psychotropic agents, herbal preparations (in particular, a standardized extract of the medicinal plant *Passiflora incarnata*) may be considered as an auxiliary, "gentle" management strategy. At the same time, they should not be considered as the main method of treatment, but only as a component of a comprehensive management program for children with obesity, which includes psychological support, correction of eating behavior, and lifestyle modification under mandatory medical supervision.

The limitations of the study include the absence of data on long-term outcomes and long-term safety of the use of *Passiflora incarnata* extract. In addition, in the treatment of obesity, it is important to consider the potential impact of any additional agents on metabolic parameters, appetite, and body weight, as they should not be associated with undesirable changes in the metabolic profile. For most herbal preparations, these aspects require further study.

The obtained data indicate the *prospects* of further research into herbal approaches as a component of supporting the mental health of children and adolescents. At the same time, further clinical studies are needed to assess long-term safety, to **determine** optimal dosing regimens, and to develop comprehensive therapeutic strategies taking into account age-related characteristics, metabolic profile, as well as potential drug interactions.

Conclusions

1. The study demonstrated that the use of a standardized extract of *Passiflora incarnata* in children with obesity is accompanied by a significant decrease in the level of state anxiety (AUC = 0.858; 95% CI 0.739–0.937).

2. It was found that the correction of trait anxiety is less pronounced (AUC = 0.721; 95% CI 0.585–0.832) and depends on the baseline level of anxiety.

3. The therapy provides a statistically significant reduction of a high baseline level of state anxiety in all cases, whereas in trait anxiety the effect is variable.

4. A favorable safety profile of the agent was confirmed, and the feasibility of its use as an adjuvant component of **comprehensive** therapy of psychological disorders in children with obesity was substantiated.

Conflict of interest. The authors declare no conflict of interest directly or indirectly related to this work.

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Дата надходження статті до редакції: 21.01.2026.
Прийнята до друку: 07.05.2026.
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