# GEORGIAN MEDICAL NEWS

ISSN 1512-0112 NO 3 (348) Mapt 2024

# ТБИЛИСИ - NEW YORK



# ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии საქართველოს სამედიცინო სიახლენი

# **GEORGIAN MEDICAL NEWS**

Monthly Georgia-US joint scientific journal published both in electronic and paper formats of the Agency of Medical Information of the Georgian Association of Business Press. Published since 1994. Distributed in NIS, EU and USA.

**GMN:** Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

# WEBSITE

www.geomednews.com

# К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

- 1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра. Используемый компьютерный шрифт для текста на русском и английском языках Times New Roman (Кириллица), для текста на грузинском языке следует использовать AcadNusx. Размер шрифта 12. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.
- 2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.
- 3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

- 4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).
- 5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи. Таблицы и графики должны быть озаглавлены.
- 6. Фотографии должны быть контрастными, фотокопии с рентгенограмм в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста в tiff формате.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

- 7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.
- 8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform\_requirements.html В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.
- 9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.
- 10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.
- 11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.
- 12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

# REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

- 1. Articles must be provided with a double copy, in English or Russian languages and typed or computer-printed on a single side of standard typing paper, with the left margin of 3 centimeters width, and 1.5 spacing between the lines, typeface Times New Roman (Cyrillic), print size 12 (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.
- 2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.
- 3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

- 4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.
- 5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles. Tables and graphs must be headed.
- 6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

- 7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.
- 8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform\_requirements.html http://www.icmje.org/urm\_full.pdf
- In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).
- 9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.
- 10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.
- 11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.
- 12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

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რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

- 1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში Times New Roman (Кириллица), ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ AcadNusx. შრიფტის ზომა 12. სტატიას თან უნდა ახლდეს CD სტატიით.
- 2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ,რუსულ და ქართულ ენებზე) ჩათვლით.
- 3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).
- 4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).
- 5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.
- 6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით tiff ფორმატში. მიკროფოტო-სურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სუ-რათის ზედა და ქვედა ნაწილები.
- 7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა უცხოური ტრანსკრიპციით.
- 8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.
- 9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.
- 10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.
- 11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.
- 12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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# CLINICAL SIGNIFICANCE OF CHANGES IN QUALITY OF LIFE INDICATORS AS A METHOD FOR ASSESSING THE EFFECTIVENESS OF ENT HERBAL REMEDIES

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# Abstract.

**Introduction:** Ear, nose, and throat (ENT) diseases cause major disruption in patients' daily lives. Self-medication with conventional and herbal drugs are common in ENT patients. Recent studies reported that the ENT patients' self-medication with conventional medication ranged from 79.1–83.0%. It is also reported that the rate of herbal drug utilization among ENT patients ranges from 2–63% in different nations. The research aims to evaluate the effectiveness of "Herbanoma" as a Phyto preparation for ENT diseases according to the prognostic clinical significance of changes in quality-of-life parameters.

Materials and methods: The study employed the stratified sampling technique to randomly select participants. Five secondary schools of Yerevan were chosen through random selection, followed by the selection of 236 observation units from the selected schools. For the treatment and prevention of diseases of the upper respiratory tract, we used the herbal inhalation mixture "Herbaroma" as an ingredient. The composition of these drops is approved by the Intellectual Property Agency of the Republic of Armenia. SF-36 questionnaire was used to assess the quality of life of adolescents aged 15-17 years who had ENT diseases. Results: The change of the parameters of QL in the experimental group had the greatest clinical significance for the components RP, RE, SF, and Mental Health - MH. The effectiveness of the preventive program was also evaluated according to the main groups of ENT diseases. The clinical significance of the effectiveness of the program for chronic diseases of the nasal cavities was significantly high for almost all components of the quality of life, in particular: Physical health - PH, Mental Health - MH. The program had great effectiveness for this group of ENT diseases. The clinical significance of the effectiveness of prevention programs for chronic inflammatory diseases of the throat was significantly high for the following components of the quality of life: RP, GH, PH, MH. The program has been highly effective for this group of ENT diseases. The clinical significance of the effectiveness of the prevention of chronic inflammatory diseases of the ear was generally assessed as weak. It had reliable average clinical significance for SF, RE, and MH components. Conclusion: Among school-aged children with ENT pathology, the use of the "Herbaroma" drug for prophylactic purposes leads to an improvement in quality-of-life parameters. According to the results of the research, the "Herbaroma" drug had an antiinflammatory, antiseptic effect, contributed to the reduction of the incidence of acute respiratory viral infections, and the prevention of complications. The use of the relatively safe and effective "Herbaroma" preparation in school conditions should be included in the comprehensive program of preventive measures.

**Key words.** ENT pathology, herbal remedies, "Herbaroma", Quality of life, SF-36 questionnaire, clinical significance.

# Introduction.

Ear, nose, and throat (ENT) diseases cause major disruption in patients' daily lives. The prevalence of ENT diseases varies by geography and patient age. Self-practices with conventional and herbal drugs are common in ENT patients. Recent studies reported that the ENT patients' self-practice with conventional medication ranged from 79.1-83%. It is also reported that the rate of herbal drug utilization among ENT patients ranges from 2–63% in different nations. Studies show that early administration of antibiotics for ENT pathology has no advantage compared to placebo either in terms of relieving symptoms or preventing complications [1]. In 33% of children with acute sinusitis, the causative agent of infection is not detected, and in 70% of cases, positive dynamics are observed without the use of an antibiotic [2]. These data increase the importance of pathogenetic therapy aimed at restoring drainage and ventilation of the paranasal sinuses, which in the early stages of the disease can prevent the development of a purulent inflammatory process in the paranasal sinuses. The herbal medicine has a fairly pronounced antiviral effect in children [3,4]. These studies emphasize that limitations in a child's health affect joint family activities, physical activity, general health, behavior, and family emotions. A very strong correlation has also been found between such constraints and limitations on the parents' free time. As an aside, and beyond the scope of this review, it should be noted that studies on patients suffering from sleep apnea syndrome are the focus of many articles looking at the quality of life in ENT patients [5]. With chronic sinusitis, quality of life is limited in areas such as general health, pain, anxiety, the effect of the child's condition/well-being on the parents' emotions, physical fitness, limitations in social functioning, restrictions on the parents' free time, and Patients have long-term nasal obstruction, chronic rhinitis and paranasal sinusitis, where ENT examination shows discharge from the nasal cavities or back of the throat. part Such children experience pain, a feeling of fullness in the face, and a disturbed feeling of odor [5]. Determinants of current and future health and illness among

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adolescents span the social and psychological domains. Healthrelated quality of life (HRQoL) in school-aged adolescents has become a topic of international interest. The term refers to a comprehensive model of subjective health that encompasses the physical, social, psychological, and functional aspects of individual well-being as a multidimensional and subjective construct [6,7]. The purpose of all this interest is to guide the organization of resources and decision-making processes to improve the quality of life of adolescents. To do this, it is necessary to understand the current quality of life of adolescents is important [8,9]. The SF-36 was developed and validated as a universal, short instrument for measuring a person's quality of life; it has been widely used to assess important domains of quality of life [10-13]. Children's perceptions of their illness and their views on treatment are increasingly sought and included in clinical practice [14-17]. The importance of understanding the impact of disease and treatment on health-related quality of life (HRQoL) in children is now recognized. HRQoL is a complex, multidimensional concept that includes social, emotional, and physical functioning or well-being related to a patient's health status. Pediatric clinical research and changing physician-childparent dynamics in clinical practice [18-20]. The use of herbal medicinal products among children and adolescents between the ages of 0 and 17 years in Germany is widely spread. Further research is needed to examine the effectiveness and safety of specific herbal medicines, the potential effects of long-term use, and possible interactions of herbal medicines with concomitantly used traditional medicines [21]. Complementary and alternative medicine (CAM) refers to products that are considered beyond the scope of standard medical care. CAM is commonly used to support or replace traditional treatments and to improve overall well-being [22,23]. CAM use tends to be widespread among children, especially among children with chronic illnesses who may use multiple CAM modalities [24,25]. Non-disclosure of CAM is common among pediatric populations [26] and although CAM has been used as part of traditional health maintenance for many years, few have been rigorously tested for efficacy, reliability, and effectiveness. safety [27]. Failure to disclose information about the use of CAM may increase the risk of side effects [28]. The use of herbal remedies has increased in recent years. It is predicted that this rate will be greater for the COVID-19 pandemic process. It has been reported nearly ~80% of the world's population uses and trusts herbal products for treatment [23]. About 2.9 million American children and teenagers have used herbs or their supplements. In China, the use of herbal medicine is about changing from 30-50% of the total drug consumption. It is estimated that in other developed countries, more than 50% of the population uses herbal products at least once in their life. Herbal medicines account for 60% of treatment at home in developing countries [29]. In children with a chronic illness or among inpatients and outpatients is a higher use of the herbal medicine. The using herbal drugs among children is 85.5% in Germany. Children with neuropsychiatric diseases use herbal medicine about 35.4% [30]. The elementary school-age children in South Korea have epileptic problems ~17.2% and they use herbal medicine at high-range varying from 65.2% to 67.8% [27].

# Materials and Methods.

The research aims to evaluate the effectiveness of "Herbanoma" as a Phyto preparation for ENT diseases according to the prognostic clinical significance of changes in quality-of-life parameters. The study was conducted in 2021-2023. The plan for organizing the study was discussed and guaranteed at a meeting of the Ethics Committee of YSMU. M. Heratsi. The study employed the stratified sampling technique to randomly select participants. Specifically, five secondary schools of Yerevan were chosen through random selection, followed by the selection of 236 observation units from the selected schools. The study of ENT morbidity was carried out in three stages. **Stage I:** a preliminary survey of parents regarding the frequency of acute ENT diseases, and relapses of chronic ENT pathology. Stage II: collection of data from the medical of school-age children records on the frequency of acute respiratory viral infections and tonsillitis. Stage III: clinical examination of the ENT organs of schoolchildren. The following methods were used: anterior and posterior rhinoscopy, pharyngoscopy, otoscopy, and assessment of speech and whisper hearing function.

For the treatment and prevention of diseases of the upper respiratory tract, we used the herbal inhalation mixture "Herbaroma" as an ingredient. Participants in the experimental group received the medication by inhalation once a day for 7 days. The composition of "Herbaroma" is approved by the Intellectual Property Agency of the Republic of Armenia as an invention (Application N AM 20150020). The drug underwent microbiological examination at Arpimed LLC. The drug has anti-inflammatory and antimicrobial effects of plant origin and can be used in the form of inhalations for preventive and therapeutic purposes for diseases of the upper respiratory tract. The collection includes valuable essential oil plants: Flos Matricariae chamomillae, Herba Origani vulgaris, Herba Ziziphorae clinopodioides, and MF Species. The invention was tested on a variety of volunteer patients with various diseases of the upper respiratory tract (alcoholism, sore throat, cough, bronchitis). Tests have shown that the composition has a pronounced antimicrobial, anti-inflammatory, and regenerating effect.

Criteria for inclusion in the study: 1) children of school age 15-17 years old who did not have signs of STIs at the time of examination; 2) written consent of the parents for the inclusion of the child in the study; 3) lack of use of medications to prevent complications of ENT diseases for at least 2 months; 4) Ensuring accessibility of contact with an ENT doctor for a school-age child.

Exclusion criteria from the study: 1) contraindications to the use of the drug for persons with an allergic reaction to herbs and persons who refuse them; 2) lack of written parental consent to include the child in the study or the fact of incomplete and incorrect filling out of documents; 3) the ability to use medications to treat complications of ENT diseases for a period of at least 1 month; 4) difficulties in establishing contact between a school-age child and an ENT doctor.

Groups for comparison were established based on predetermined inclusion criteria through the utilization of a

randomized controlled trial approach. Originally, the ratio of participants in the comparison groups was 1:1. However, after the start of the study, 15 teenagers withdrew from the experimental group due to the challenge of attending the medical facility daily.

The SF-36 tool (The Short Form-36) was used to assess the quality of life of adolescents aged 15-17 years who had ENT diseases. Tools for assessing quality of life are questionnaires developed by experts from the world's leading clinical centers following the principles of evidence-based medicine and Good Clinical Practice (GCP) requirements. One of the most commonly utilized tools is the Medical Outcomes Study Short Form (SF-36), which falls under the category of non-specific questionnaires and is extensively employed for assessing quality of life in both Europe and the USA. This statistical tool comprises 36 questions organized into 8 scales: Physical Functioning (PF), Role-Physical Functioning (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE), and Mental Health (MH). These scales are further delineated into two components: the Physical Health Component (PH), consisting of PF, RP, BP, and GH; and the Psychological Component of Health (Mental Health – MH), consisting of VT, SF, RE, and MH. Each of the eight scales is evaluated on a 100-point scale, where a higher score indicates a higher quality of life. The method utilized to assess the clinical significance of quality-of-life score changes, described by Osoba D. et al. (1998) and Kevin R.M. et al. (2003), was employed to measure the effectiveness of the administered herbal remedy. The scale proposed for interpreting changes in quality-of-life scores is as follows:

- ☐ A change of 5-10 points indicates minimal clinical significance.
- ☐ A change of 10-20 points moderate clinical significance.
- ☐ A change of more than 20 points substantial clinical significance.

The study included 157 adolescents aged 15-17 years, who were divided into 2 clinical groups (Table 1).

To evaluate the clinical efficacy of the "Herbaroma" medication as a preventive measure, the relative risk was computed alongside the construction of a 95% confidence interval. To assess the statistical significance of disparities in quality-of-life parameters among the compared groups following the preventive program, an independent samples t-test was employed.

# Results.

The demographic and clinical characteristics of the patients included in the study are shown in Table 2.

Since the school is an organized collective, it is more appropriate to apply mass preventive and healing measures,

which will ensure not only medical and social efficiency but will be effective from an economic point of view. To evaluate the clinical effectiveness of the Herbaroma drug, as a preventive remedy, the absolute (Table 3) and relative risks were calculated.

Thus, with a probability of 95.0%, the probability of insufficient results as a result of prophylaxis with "Herbaroma" preparation was 2.3 (1.4-3.8) times lower compared to the results of the control group. All parameters of the QL of adolescents included in the preventive program were reliably high. It is necessary to note that the change of the parameters of QL in the G1 group had the greatest clinical significance for the components RP, RE, SF, and Mental Health – MH.

The effectiveness of the preventive program was also evaluated according to the main groups of ENT diseases. The clinical significance of the effectiveness of the program for chronic diseases of the nasal and larynx cavities, according to the QL, was significantly high for almost all components of the quality of life, in particular: Physical health - PH, Mental Health - MH. The clinical significance of the effectiveness of "Herbaroma" in preventing chronic inflammatory throat diseases, as assessed by QL parameters, was notably substantial for such components of the QL, as: RP, GH, PH, MH. The clinical significance of the effectiveness of the remedy in preventing chronic inflammatory ear diseases was generally deemed as modest. However, it exhibited consistent moderate clinical significance for SF, RE, and MH components (Table 4).

We also compared the quality of life of patients included in the experimental group before and after the use of the medication. The results are presented in Table 5. According to the data provided, there was a statistically significant improvement in the quality of life across all parameters, regardless of the type of ENT pathology.

# Discussion.

Children's environment can signal changes in their personalities that manifest themselves more frequent tantrums or conflicts with schoolmates or teachers. Such disorders can occur in connection with the ENT or other conditions such as CNS hypoxia system, poisoning by bacterial toxins in chronic diseases of the upper respiratory tract and ears, hearing loss due to obstruction of the Eustachian tube, and chronic middle ear infections. Health-related quality of life has been found to deteriorate significantly in many areas when children are present suffering from one of the four otolaryngology diseases reviewed. Therefore, further studies on HRQOL also seem appropriate in children treated for other ENT diseases. Using standardized HRQOL questionnaires tailored to specific tasks is important in studies. The child's quality of life should be regularly measured as an element of clinical research [14].

Table 1. Structure of clinical groups by gender.

| Clinical groups $N = \frac{Boys}{n}$  |     | Boys | oys      |    | Girls    |  |
|---|-----|------|----------|----|----------|--|
|   |     | n    | P±SE     | n  | P±SE     |  |
| Main group (chronic ENT patients and frequent sufferers) who received "HERBAROMA" herbal collection in the form of inhalation (G 1) | 71  | 32   | 45.1±5.9 | 39 | 54.9±5.9 |  |
| Control group (chronic ENT patients and frequent patients), who were not included in the program (G 2)                              | 86  | 45   | 52.3±5.4 | 41 | 47.7±5.4 |  |
| Total   | 157 | 77   | 49.0±3.9 | 80 | 51.0±3.9 |  |

**Table 2.** Demographics and Clinical Characteristics of Patients' ENT pathologies.

| Characteristics (N = 157)                            |             |
|--|-------------|
| 1. Gender  |             |
| boys   | 77(49.0%)   |
| girls  | 80(51.0%)   |
| 2. Presence of ENT diseases in different age strata  | 00(31.070)  |
|  | 49(31.2%)   |
| 15 years   | . ,         |
| 16 years   | 53 (33.8%)  |
| 17 years   | 55(35.0%)   |
| 3. Frequency of ENT diseases                         | 50 (27 (0/) |
| Episodic patients                                    | 59 (37.6%)  |
| Frequent sufferers                                   | 98 (62.4%)  |
| 4. Frequency of ENT diseases by gender groups        |             |
| 4.1. Boys  | 45 (50 40/) |
| • Episodic patients                                  | 45 (58.4%)  |
| • Frequent sufferers                                 | 32 (41.6%)  |
| 4.2. Girls   | 20 (40 00/) |
| • Episodic patients                                  | 39 (48.8%)  |
| • Frequent sufferers                                 | 41 (51.2%)  |
| 4. Type of chronic ENT diseases                      | 69(44.2)    |
| Diseases of the throat                               | 85(54.2)    |
| Diseases of the nose and sinuses                     | 3(1.6)      |
| Ear diseases   | 5(110)      |
| 5. The structure of chronic ENT pathology by gender  |             |
| 5.1Boys  |             |
| Diseases of the throat                               | 31(40.3)    |
| <ul> <li>Diseases of the nose and sinuses</li> </ul> | 42(54.5)    |
| Ear diseases   | 4 (5.2)     |
| 5.2Girls   |             |
| Diseases of the throat                               | 38 (47.5)   |
| <ul> <li>Diseases of the nose and sinuses</li> </ul> | 32(40.0)    |
| Ear diseases   | 10(12.5)    |
| 6.Basic nosologies of the throat (n=69)              |             |
| Overgrowth of adenoid tissue                         | 11(15.7%)   |
| Overgrowth of wind parks                             | 14(20.0%)   |
| Chronic tonsillitis                                  | 44(64.3%)   |
| Other throat pathologies                             | -           |
| 7. Diseases of the nose and sinuses (n=85)           |             |
| Allergic rhinitis                                    | 14 (16.5%)  |
| Vasomotor rhinitis                                   | 25(29.4%)   |
| Chronic sinusitis                                    | 41(48.2%)   |
| Other pathologies of the nose                        | 5(5.9%)     |
| 8. Frequency of acute respiratory infections         |             |
| do not get sick                                      | 62(39.5%)   |
| get sick 1-3 times on average                        | 76(48.2%)   |
| get sick 4 or more times                             | 19(12.3%)   |
| 9. The frequency of acute respiratory infections     |             |
| according to the presence of ENT pathology           |             |
| 9.1 Episodic patients(n=59)                          | 59 (37.6%)  |
| ENT pathology is present(n=52)                       | 35 (59.3%)  |
| ENT pathology is absent(n=36)                        | 24 (40.7%)  |
| 9.2 Frequent sufferers(n=98)                         | 98 (62.4%)  |
| ENT pathology is present(n=101)                      | 67(68.4%)   |
| ENT pathology is absent(n=47)                        | 31 (31.6%)  |
| 1 0/ ()  | ( )         |

Table 3. The proportion of poor results in the control and experimental groups.

| Comparison groups | <b>Insufficient results</b> | P±m                     |
|-------------------|-----------------------------|-------------------------|
| G 1 (n=71)        | $N^{G1} = 15$               | $P_{G1} = 21.1 \pm 4.8$ |
| G 2 (n=86)        | $N^{G2} = 42$               | $P_{G2} = 48.8 \pm 5,4$ |
| Total (n=157)     |                             |                         |

 $RR = (n_{G2}/N^{G2})/(n_{GI}/N^{GI}) = (42/86)/(15/71) = 2.3; 95\% CI (1.4-3.8)$ 

One of the main advantages of using the SF-36 is that it allows quality-of-life scores to be compared across groups [10]. However, since the SF-36 was not originally designed to measure important aspects quality of life of adolescents, some studies found that the instrument, particularly the mental component (MCS), is relatively insensitive to changes across populations over time [31]. The study of QL in drug testing has important applicational importance. It should be considered as an additional criterion for evaluating the side effects of a new drug, along with the data of traditional clinical, laboratory, and instrumental studies for the evaluation of drug effectiveness, a tool for selecting a quality drug for clinical practice [6]. The Health Assessment Questionnaire (HAQ) was used to assess the QL. The results of the research allowed us to conclude that the assessment of QL provides an opportunity to obtain specific data on the effect of the drug, and the methodology of the study of QL was the basis for the implementation of the trial of a new drug [32]. It has been proven that the patient's QL parameters have independent predictive value and are the most important factor for evaluating the course of disease treatment. The prognostic possibility of parameters of QL has been proven in various fields of medicine [9]. Many studies investigating the effect of different treatment methods on QL have been performed in various fields of medicine, particularly in ENT [6]. For the assessment of early and long-term consequences after cochlear implantation, QL was used as an important indicator. Assessment of QL is of particular importance in the testing of new drugs [18]. The health-related quality of life has been found to significantly deteriorate in many areas when children are suffering from the four key otolaryngological diseases reviewed. Further studies on the HRQoL thus also appear advisable on those children treated for other diseases of the ear, nose, and larynx/throat. Having standardized HRQoL questionnaires, tailored to specific issues, is important across studies. The quality of life should be an element of the patient's clinical examination [11]. The use of medicinal herbs for the treatment and prevention of diseases has a long tradition throughout the world. Currently, it still plays an important role in health care in many different societies, from developing countries in Asia and Africa to developed Western countries. In countries with highly developed healthcare systems, herbal medicine is often considered as complementary and alternative medicine [33]. Despite their widespread use, many commonly used herbal medicines have not been comprehensively scientifically analyzed through clinical trials for safety and effectiveness [34]. Preclinical and clinical studies on the use of medicinal products in children and adolescents are lacking, regardless of product classification as herbal or chemically defined products. Herbal medicines are often used and considered "natural" products and may cause adverse drug reactions [29]. Most studies are conducted among children with a specific chronic disease [35] or among inpatients and outpatients. Internationally, only a few population-representative studies have examined the use of herbal medicines among children in the general population [36]. Most international studies are conducted among children with specific chronic diseases [32]. This precursor for further surveys indicates that CAM appears to be popular not only among adults in Europe but also among children. The development of a pan-

**Table 4.** Evaluating the effectiveness of the preventive program for ENT diseases according to the clinical significance of the changes in the QL parameters.

| 1. ENT diseases                 |                   |                    |                   |                   |                            |                   |                   |                   |                   |                          |
|---------------------------------|-------------------|--------------------|-------------------|-------------------|----------------------------|-------------------|-------------------|-------------------|-------------------|--------------------------|
| Groups:                         | PF                | RP                 | BP                | GH                | Physical<br>health –<br>PH | VT                | SF                | RE                | МН                | Mental<br>Health –<br>MH |
| G1                              | 96.5              | 55.3               | 59.3              | 55.7              | 62.7                       | 47.8              | 66.5              | 75.7              | 62.2              | 55.8                     |
| G2                              | 86.3              | 34.5               | 56.3              | 46.3              | 45.2                       | 33.5              | 44.2              | 54.2              | 49.5              | 35.6                     |
| The difference in QL parameters | 10.2**            | 20.8***            | 3.0*              | 9.4*              | 17.5**                     | 14.3**            | 22.3***           | 21.5***           | 13.7**            | 20.2***                  |
| t Score, P value                | t=3.0,<br>p=0.003 | t=4.4,<br>p=0.0001 | t=0.67,<br>p=0.5  | t=2.04,<br>p=0.04 | t=1.7,<br>p=0.06           | t=3.0,<br>p=0.003 | t=4.7,<br>p=0.001 | t=4.6,<br>p=0.001 | t=2.9,<br>p=0.004 | t=4.5,<br>p=0.003        |
| 2. Diseases of the no           | se and sinu       | ses                |                   | ·                 |                            |                   |                   |                   |                   |                          |
| Groups:                         | PF                | RP                 | BP                | GH                | Physical<br>health –<br>PH | VT                | SF                | RE                | МН                | Mental<br>Health –<br>MH |
| G1                              | 98.2              | 85.5               | 83.5              | 90.2              | 73.5                       | 70.7              | 85.8              | 80.7              | 85.5              | 73.5                     |
| G2                              | 88.6              | 66.1               | 64.5              | 70.5              | 49.1                       | 58.2              | 69.0              | 66.7              | 62.1              | 47.6                     |
| The difference in QL parameters | 9.6*              | 19.4**             | 18.0**            | 19.7**            | 24.4***                    | 18.5**            | 16.8**            | 18.0**            | 23.6***           | 25.9***                  |
| t Score, P value                | t=2.1,<br>p=0.03  | t=4.3,<br>p=0.000  | t=4.1,<br>p=0.000 | t=4.1,<br>p=0.000 | t=4.9,<br>p=0.000          | t=2.0,<br>p=0.04  | t=2.6,<br>p=0.01  | t=2.1,<br>p=0.04  | t=4.8,<br>p=0.000 | t=3.3,<br>p=0.00         |
| 3. Chronic inflamma             | ntory diseas      | es of the thr      | oat               |                   |                            |                   |                   |                   |                   |                          |
| Groups:                         | PF                | RP                 | BP                | GH                | Physical<br>health –<br>PH | VT                | SF                | RE                | МН                | Mental<br>Health –<br>MH |
| G1                              | 72.5              | 63.8               | 70.8              | 61.7              | 62.7                       | 69.2              | 89.2              | 82.5              | 70.5              | 67.5                     |
| G2                              | 53.8              | 43.8               | 65.0              | 40.5              | 38.6                       | 56.3              | 72.3              | 66.5              | 52.0              | 44.2                     |
| The difference in QL parameters | 18.7**            | 20.0***            | 5.8*              | 21.2***           | 24.1***                    | 12.9**            | 16.9**            | 16.0**            | 18.5**            | 23.3***                  |
| t Score, P value                | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003  | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003          | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003 | t=3.0,<br>p=0.003        |
| 4. Chronic in                   | flammatory        | y ear disease      | s                 |                   |                            |                   |                   |                   |                   |                          |
| Groups:                         | PF                | RP                 | BP                | GH                | Physical<br>health –<br>PH | VT                | SF                | RE                | МН                | MentalHealth – MH        |
| G1                              | 90.5              | 72.9               | 70.5              | 48.8              | 53.4                       | 49.2              | 65.2              | 68.9              | 57.5              | 50.6                     |
| G2                              | 87.5              | 68.8               | 61.8              | 39.3              | 49.3                       | 40.0              | 50.3              | 49.8              | 42.0              | 31.6                     |
| The difference in QL parameters | 3.0*              | 4.1*               | 8.7*              | 9.5*              | 4.1*                       | 9.2*              | 14.9**            | 19.1**            | 15.5**            | 19.0**                   |
| t Score, P value                | t=0.5,<br>p=0.6   | t=0.8,<br>p=0.5    | t=1.4,<br>p=0.2   | t=0.2,<br>p=0.8   | t=0.6,<br>p=0.5            | t=1.5,<br>p=0.1   | t=2.4,<br>p=0.01  | t=3.1,<br>p=0.002 | t=2.4,<br>p=0.02  | t=3.0,<br>p=0.003        |
| * the change has litt           |                   |                    |                   |                   | -                          | -                 | -                 | •                 |                   | *                        |

**Table 5.** Comparison of QL parameters of patients included in the experimental group before and after the use of the medication.

| QL<br>domains | Diseases of the nose and sinuses (1) |      | Ear diseases (2) |      | Diseases | Diseases of the throat (3) |      | Combined ENT pathology (4) |         |
|---------------|--------------------------------------|------|------------------|------|----------|----------------------------|------|----------------------------|---------|
|               | X                                    | SD   | X                | SD   | X        | SD                         | X    | SD                         | <0.0.1  |
| PF            | 88.5                                 | 30.2 | 87.5             | 41.5 | 53.7     | 25.8                       | 86.3 | 32.5                       | < 0.0.1 |
| RP            | 66.0                                 | 25.4 | 68.7             | 39.6 | 43.7     | 22.7                       | 34.5 | 25.4                       | < 0.0.1 |
| BP            | 64.5                                 | 24.5 | 61.7             | 55.3 | 65.0     | 25.3                       | 56.3 | 23.6                       | < 0.0.1 |
| GH            | 70.5                                 | 31.2 | 39.2             | 29.6 | 40.5     | 30.2                       | 46.3 | 27.9                       | < 0.0.1 |
| VT            | 58.2                                 | 29.7 | 40.0             | 30.5 | 56.2     | 29.5                       | 33.5 | 22.1                       | < 0.0.1 |
| SF            | 69.0                                 | 28.9 | 50.2             | 27.5 | 72.2     | 21.5                       | 44.2 | 25.6                       | < 0.0.1 |
| RE            | 66.7                                 | 27.5 | 49.7             | 42.1 | 66.5     | 24.6                       | 54.2 | 22.8                       | < 0.0.1 |
| MH            | 62.1                                 | 28.3 | 42.0             | 39.6 | 52.0     | 28.9                       | 49.5 | 30.5                       | < 0.0.1 |
| PH            | 49.0                                 | 22.8 | 49.2             | 35.6 | 38.6     | 30.5                       | 45.2 | 29.5                       | < 0.0.1 |
| MH            | 47.6                                 | 29.6 | 31.6             | 29.7 | 44.1     | 28.6                       | 35.6 | 22.6                       | < 0.0.1 |

European definition of CAM use and CAM therapies is required to achieve surveys comparable between European countries. Additionally, more research investigating the efficacy and potential adverse effects of CAM therapies is needed because of increasing CAM use by children in Europe [37-39]. The need was emphasized for more and higher quality clinical studies to support naturopathic remedies, which might not be reflected in the latest treatment guidelines. The expert panel also highlighted missed opportunities for physicians and pharmacists to recommend effective naturopathic treatments. The herbal medicine used in children with respiratory illnesses was 59.3%. Parents of children with asthma reported using a range of herbal products (12.8%) for self-care. The most commonly used herbal medicine for pediatric asthmatic patients was linden (21.6%) and ginger (21.2%) [24]. Herbal medicine has traditionally been used in the treatment of symptoms of nocturnal enuresis or urinary incontinence [40,41]. The ginger, chamomile, mint, cardamom, garlic, and onion were used to prevent and treat nausea caused by chemotherapy [38,42]. It has been reported some herbal products are effective in the management of ear pain in Otitis Media. Children with Attention Deficit Hyperactivity Disorder and Anxiety or Depression take herbal products as part of their treatments. The use of CAM in children with medical comorbidities, excessive sleep problems or insomnia is 1.8 times higher than in children without such difficulties [41]. It is reported that herbs significantly decrease body temperature, cough, and breathing difficulties, and improve absorption of pulmonary infiltration and quality of life in severe acute respiratory syndrome (SARS) [27]. The herbal formula (Ma Xin Shi Gan Tang) was claimed to antiviral effect that inhibits the entry of the influenza virus and has the potential to manage seasonal pandemics of influenza infection [25]. The usage of herbal medicines increases day by day. People usually choose herbal products instead of medical drugs. The use of medical plant species in the treatment of children's diseases is a part of traditional knowledge that is handed down by hearsay pieces of advice. Herbal medicine can be unconsciously used as though these products are harmless [3]. The use of herbal products in children is a concern because little information is available on their benefits and risks to this population. This creates a serious problem in the treatment of children, and it can be occurred a serious hazard in clinical care. Since herbal products are available not only in pharmacies but also in food stores and supermarkets there is a serious risk to users and remains a major concern about the herbal drug safety issues. As the global use of herbal products continues to increase and many more new products are introduced into the market the risk will be greater for public health day by day. The risk increases because of by lack of suitable quality controls, inadequate labelling, and the absence of appropriate patient information [23].

# Conclusion.

Among school-aged children with ENT pathology, the use of the "Herbaroma" drug for prevention purposes leads to an improvement in quality-of-life parameters. According to the results of the research, the "Herbaroma" drug had an anti-inflammatory, antiseptic effect, contributed to the reduction of the incidence of acute respiratory viral infections, and the

prevention of complications. The use of the "Herbaroma" preparation in the conditions of the school's health center provides indicators with a positive trend, as it affects the chronic course of the disease. Relatively safe and effective prophylaxis leaves an anti-inflammatory, antiseptic effect. It is guaranteed to be applied in school conditions and included in the comprehensive program of preventive measures.

# Competing interests.

The authors declare that they have no competing interests.

Ethics approval and consent to participate.

According to the Ethics Guidelines of the Yerevan State Medical University, ethical approval was not required (IRB Expert Conclusion No. 2/14, 10/23/2022) and no personal identifiers were included. This work was supported by the Science Committee of the RA (Research project № 22YR-3B014).

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**Резюме.** Заболевания уха, горла и носа вызывают серьезные нарушения в повседневной жизни пациентов. Самолечение ЛОР патологии с использованием традиционных препаратов и фитопрепаратов очень распространено среди пациентов. Согласно результатам последних исследований, процент больных, использующих при самолечении традиционные препараты, колеблется в пределах 79,1-83,0%. Сообщается также, что удельный вес

пациентов с ЛОР патологией, использующих при лечении фитопрепараты, в различных странах варьируется от 2,0 до 63.0%. Целью настоящего исследования явилось изучение эффективности фитопрепарата «Гербарома» в лечении заболеваний ЛОР органов на основе оценки клинической значимости изменений в параметрах качества жизни (КЖ) больных, имеющих указанную патологию.

Материал и методы исследования. Для формирования выборки исследовании использовался стратификационного случайного отбора. Вначале из всех школ г. Ереван случайным образом были отобраны пять средних школ, после чего из выбранных школ методом случайного отбора 236 единиц наблюдения. Для лечения и профилактики заболеваний верхних дыхательных путей использовалась травяная ингалационная смесь «Гербарома». Состав препарата одобрен Агенством интеллектуальной собственности Республики Армения. Для оценки КЖ подростков в возрасте 15-17 лет, страдающих ЛОР патологией, использовался опросник SF-36. Результаты исследования. Изменение параметров КВ в экспериментальной группе имело наибольшую клиническую значимость для таких компонентов КЖ, как ролевое физическое функционирование (РФФ), функционирование ролевое эмоциональное социальное функционирование (СФ) и психологическое здоровье (ПЗ). Эффективность программы профилактики была оценена также по основным группам заболеваний ЛОР органов. Клиническая значимость эффективности программы для хронических заболеваний носовых пазух оказалась значимо высокой почти для всех компонентов качества жизни, в особенности, для физического здоровья (ФЗ) и психического здоровья (ПЗ). Программа имела наибольшую эффективность для указанной группы ЛОР заболеваний. Клиническая значимость эффективности программы для хронических воспалительных заболеваний горла была значимо высокой для таких компонентов КЖ, как ролевое физическое функционирование (РФФ), общее здоровье (ОЗ), а также физическое и психологическое здоровье. Программа имела наибольшую эффективность для указанной группы ЛОР заболеваний. Клиническая значимость эффективности профилактики хронических воспалительных заболеваний уха в целом оказалась низкой. Она имела надежную среднюю клиническую значимость для СФ, РЭФ и ПЗ.

Заключение. Использование с профилактической целью препарата «Гербарома» у школьников с заболеваниями ЛОР органов ведет к улучшению параметров КЖ. Согласно результатам исследования, препарат «Гербарома» дает протововоспалительный, антисептический эффект, что положительно сказывается на снижении первичной заболеваемости острыми вирусными инфекциями и профилактике осложнений. Использование сравнительно безопасного и эффективного препарата «Гербарома» в условиях школы долвно быть включено в программу профилактических мер.

**Ключевые слова:** ЛОР патология, фитопрепараты, «Гербарома», качество жизни, опросник SF-36, клиническая значимость.