**Template for formatting a manuscript containing the results of the original study**

The template should include all the materials and data that, in your opinion, should be published in the journal (including figures and tables).

The template is proposed to be used to describe the results of an original study of a medical intervention. However, it can be used as a guide when writing a manuscript with other content: analysis of risk factor analysis, study quality of life, etc.

The structure of the template should be reproduced in the final version of the manuscript.

If any of the sections of the template are not applicable or irrelevant to the original study being presented, it is necessary to provide appropriate brief explanations (“not applicable”, “irrelevant”, etc.) in the section.

The names of the sections of the manuscript (headings and subheadings) are highlighted in **blue**, explanations for authors – in **black** color. Please, while preserving the names of the sections, replace the text of the explanations with the text of the manuscript.

The [Rules for Authors](https://en.therapy-journal.ru/pages/for-authors.html#rules) must also be followed when preparing the article.

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* When writing original articles, we recommend that you follow the current versions of international recommendations for describing the relevant type of researches, posted on the [EQUATOR](https://www.equator-network.org/reporting-guidelines/) (Enhancing the Quality and Transparency of Health Research) resource.
* Each statement by the authors, with the exception of those containing generally known facts, should be accompanied by references to the sources of information. In general, no more than 3 references should be used for each statement. If the statement is based on the opinion of the authors, this should be indicated by expressions such as “in our opinion”, “we believe” or similar.
* In the text of the article, bibliographic references are given sequentially, in ascending order, in square brackets using Arabic numerals.

**ORIGINAL STUDIES**

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**ARTICLE TITLE**

The title of the article should be as specific as possible and include a mention of the study design (randomized or non-randomized for experimental studies, cohort, cross-sectional, or “case-control” for observational studies). It is also recommended to include an indication of the target patient population and medical intervention (if used) in the title.

**Author(s)**

Surname N.N. 1, Surname N.N.2 , …, …, …

**Affiliation**

1Author’s 1 place of work (full official name of the institution, city, country)

2Author’s 2 place of work (full official name of the institution, city, country)

**Summary**

The summary should generally not exceed 2000 characters with spaces. The summary should not contain references to literature sources.

***Annotation*.** A brief (1–3 sentences) description of the problem that served as the immediate reason for performing the study. The characteristics of the problem may include its scale, indirect effects, and/or remaining gaps in this area of knowledge.

***Aim*** – a description of the main (primary, primary) aim of the study, the research question that required performing the study. The aim is given in verb form: “The aim is to determine the risk / evaluate the features / make a comparative analysis / evaluate and compare the effectiveness”, etc.

***Material and methods.*** This section of the summary should contain brief information:

– about the study design;

– subjects of the study (healthy, sick, data);

– the presence and characteristics of medical intervention;

– duration of the study;

– the primary endpoint of the study (corresponding to its objective) with a description of the methods for its assessment.

***Results.*** A brief description of the study participants (the number included in the study, those who completed it, the most significant characteristics of the formed groups) with an assessment of the outcomes of the study related to its goal. It is permissible to present the results of the study in subgroups formed, for example, taking into account gender, age, severity of the disease, etc. When analyzing multicriteria correlations (the simplest option is one dependent variable and several independent ones), the presentation of the results of the multivariate analysis is mandatory. The p values should be presented with an accuracy of up to three decimal places. If there are any data on adverse events associated with medical intervention, their mention is mandatory.

***Conclusion.*** That is a summary (1–3 sentences) of the results of the study relatively to its purpose. Discussion of the results and excessive generalizations should be avoided, and a balance in assessing positive and negative effects of the intervention should be maintained.

***Key words***

Indicate 3–10 words/phrases that most fully reflect the essence of the presented work.

**Conflict of interests**

Please indicate any potential or actual conflict of interests of the authors, i.e. conditions and facts that may affect the conclusions of the submitted manuscript (e.g. funding from interested parties, commercial and non-commercial companies, participation of an interested party in discussing the results, writing the manuscript, etc.).

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You should indicate the source of funding for both the research work and the publication of the article: the title of the planned research work carried out on a state assignment, grant number and name of the foundation, commercial or state organization, private individual, etc. Indication of the amount of funding is not required.

If there is no funding source, note: “Source of funding: None.”

**INTRODUCTION**

In this section, you should justify the relevance of the problem that has become the subject of the study, including its scale (prevalence, morbidity, mortality, quality of life, etc.), indirect effects (social, economic), and also identify resolved and unresolved aspects of the problem with an analysis of previously published data (Russian, foreign) with links to primary sources.

***Aim of the study***

Formulate as briefly as possible the main (primary, fundamental) aim of the study, research question, solution of which was required by the study.

Formulating of the aim in the main text and in the summary should match.

**MATERIAL AND METHODS**

***Design of the study***

This section should provide an idea of the study plan (design), who was included in the study and where (full official name of the institution, including locality and departmental affiliation and/or form of ownership), its duration, proposed medical intervention (if planned), how the study results were assessed, how the study hypothesis was tested. For randomized studies, it is necessary to provide a detailed description of the randomization procedure. It is also advisable to describe the design of the study in this section.

***Eligibility criteria***

List and, if necessary, characterize (e.g., specifying threshold values for quantitative characteristics) the preliminary (before the study) criteria for inclusion, non-inclusion, and exclusion from the study.

Specify the methods for determining these criteria. For example, if patients with any pathology were excluded, indicate on the basis of which documents or examinations this was done.

***Testing facilities***

List the institutions that took part in the study (full official names of institutions, including localities and departmental affiliation and/or form of ownership). Provide explanations regarding any specific factors (social, economic, cultural) that could affect the external generalizability of the study findings and the possibility of their extrapolation (for example, indicate that the search for study participants was performed only in non-governmental outpatient medical and preventive institutions or that patients were recruited for the study only in polar night conditions, etc.).

***Duration of the study***

Provide information on the planned duration of the study inclusion period, the duration of the observation period with a description of all intermediate control points (it is highly desirable to describe in detail the protocol for observing study participants with reference of key events to time points/intervals). Be sure to note if there was a shift in the planned time intervals during the study.

***Description of the medical intervention***

Indicate what exactly the investigators did with the participants / their tissues / their data: administering an experimental treatment with a new drug, taking a blood sample, asking them to fill out questionnaires, etc. The planned doses to be used, titration schedule, ways of administration, timing of the start and duration of drug use, and the conditions for stopping therapy should be described. For surgical interventions, describe the features of the preoperative preparation, surgery itself, including pain relief, and postoperative care. Non-drug medical interventions (e.g., questionnaires) and studied organizational measures (e.g., patient routing) also require descriptions.

***Main outcome of the study***

Describe the index that must be assessed to achieve the aim of the study. This may be a “true” endpoint (death, life-threatening conditions, severe complications) or a “surrogate” endpoint (an index of body system function, biochemical parameter, or an assessment of life quality). The main outcome of a medical intervention study should be a measure of its safety, efficacy, or economic acceptability.

***Additional outcomes of the study***

Show the indexes that characterize additional expected results of the study, which, for example, allow to estimate other effects or mechanisms of medical intervention’s action.

***Analysis in subgroups***

Describe the patient groups formed in the study. List the criteria (e.g., gender, age, disease severity characteristics, etc.) used to form the subgroups in or between which the outcome analysis was performed.

***Outcome recording methods***

Describe all methods and tools used to record the primary and secondary outcomes of the study.

***Ethical review***

Provide information on the results of the review of the study protocol by the ethics committee at any level:

– citing its conclusion in this subsection;

– specifying the document number and the date of its signing, the full official name of the ethics committee and the institution where it functions. If the protocol is not available, indicate this.

***Informed consent***

Provide information about the availability of written informed consent from patients to participate in the study.

***Statistical analysis***

Describe the procedure for calculating the sample size or provide another justification for its size (if any). If there is no such justification, indicate that the sample size was not pre-calculated.

List the methods of statistical data analysis:

– specify the statistical software package (including its version number) that was used to analyze the study results (developer, country of origin);

– mark the format for presenting quantitative data;

– describe the statistical criteria used in the data analysis.

**RESULTS**

***Objects (participants) of the study***

Provide a detailed description of the studied sample, which should include a list of the baseline (recorded upon inclusion in the study) characteristics of the study participants. For retrospective studies, the objects of study are data sources (medical records, databases, etc.).

***Main results of the study***

Describe the main outcome of the study and the related results of the statistical analysis of the data. Illustrative presentation of data (tables, illustrations) is welcome. However, duplication of data from tables and illustrations in the text is not allowed.

***Additional results of the study***

Describe additional outcomes of the study, the results of the assessment of effects in subgroups and (or) the mechanisms of the described effects. The analysis should be limited only to those subgroups that were listed in the subsection “Subgroup analysis”.

***Adverse events***

Describe all adverse events that occurred during the study of the medical intervention. Any medical events (diseases, injuries, unplanned surgeries, etc.), the connection of which with the medical intervention (preventive, diagnostic, therapeutic or any other) cannot be excluded, should be considered adverse events. The absence of adverse events should also be noted.

The “Results” section should not contain a discussion of the results or an expression of the opinions of the authors.

**DISCUSSION**

***Summary of the main result of the study***

Provide a brief (no more than 3–5 sentences) description of the results of the study related to its main aim (without duplicating the text of the Results section).

***Discussion of the main result of the study***

Provide an analytical text containing a discussion of the results related to the hypothesis (main aim) of the study. The discussion should be held in the context of previously known data, opinions and theories (with references to primary sources), as well as taking into account additional results of the present study, the results of the analysis in subgroups. If necessary, resort to a discussion of the key mechanisms for implementing the effects of medical intervention.

***Limitations of the study***

Provide an analysis of factors that can significantly affect the conclusions of the study. Limitations can be related to each stage of the study, starting with its substantiation, methods (conditions of the study, sample size, methods and methods of assessing the indexes) and ending with the interpretation of the results (clinical significance of the effect, applicability of the study results when the conditions of its use change, etc.).

**CONCLUSION**

Briefly (1–3 sentences) summarize the results of previous studies (preferably based on systematic evaluations presented in the Discussion section) on the problem being analyzed; briefly (1–3 sentences) outline the key unresolved aspects of the identified problem; briefly (5–7 sentences) describe the obtained results and explain their contribution to solving the problem. Provide a brief substantiation for the clinical and/or scientific use of the study results.

Discussion of the results and any generalizations should be avoided.

The conclusion should be presented as a complete text, not as numbered conclusions. The section should not contain references to sources of literature.

***Acknowledgments***

The authors may express gratitude to those whose contribution to the study was insufficient to be recognized as co-authors (for more details, see [here](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)), but is considered significant by the authors (consultations, technical assistance, translations, etc.).

**REFERENCES**

Only published materials are included in the list of references (references to Internet resources are allowed). Self-citation should be avoided unless it is absolutely necessary (for example, if there are no other sources of information or the present work is based on or continues the cited studies). Self-citation should preferably be limited to 3 references.

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Detailed rules for formatting references are available [here](https://en.therapy-journal.ru/pages/for-authors.html#references).

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For groups of authors, it is necessary to indicate the contribution of each author to the research and creation of the article. The following participation options may be available: article concept, research concept and design, writing the text, collecting and processing material, literature review, material analysis, statistical processing, editing, approval of the final version of the article, etc.

**Example:**

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Petrov B.B.: collecting and processing materials.

Sidorov V.V.: analysis of the obtained data, writing the text.

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**Sample of information about the author:**

**Ivan I. Ivanov**, MD, PhD (Medicine), professor of the Department of clinical pharmacology, N.N. Burdenko Voronezh state medical university of the Ministry of Healthcare of Russia. Address: 394036, Voronezh, 10 Studencheskaya St.

E-mail: ivan-ivanov@example.ru

ORCID: https://orcid.org/0000-0000-000-00XX. Scopus ID: 565XXXXXXXX. eLibrary SPIN: 5724-XXXX

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