**Template for execution of the manuscript containing the results of the original study**

This template is proposed to be used to describe the results of the original study of medical intervention. However, it can be used as a guide for writing a manuscript with different content (analysis of risk factors, evaluation the quality of life, etc.).

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

In case of inapplicability or irrelevancy of any sections of the template for the presentation of the original diagnostic study, it is necessary to give appropriate brief explanations in the section ("not applicable", "irrelevant" or the like).

The numbered names of sections of the manuscript (headlines and subheadlines) are highlighted in green, explanations for authors - in black. Please replace the text of the explanations with the text of the manuscript retaining the names of the sections

**NB!**

* Each statement of the authors, with the exception of those that contain well-known facts, must be accompanied by references to information sources. In general, no more than 3 references per statement should be used. If the statement is based on the authors’ opinion, it is necessary to designate it with such expressions as "in our opinion", "we believe" or the like.
* When discussing unpublished data/research results in the text, use the "unpublished data" indicating the researcher, the year of receipt and the method of obtaining this information (personal message, conference message, etc.) instead of the source reference. In respect to your own unpublished data, use the "unpublished own data" specification.
* In the text of the article, bibliographic references are given consistently, in ascending order, in square brackets in Arabic figures.

**Author(s)**

Name Surname1, Name Surname2, ..., ..., .... (give the full names of the authors in English)

**Affiliation**

1 Place of work of the author 1 (name of university, institute, city, country)

2 Place of work of the author 2 (name of university, institute, city, country)

...

**Article title**

The article title should contain a mention of the study design (for experimental studies – randomized or non-randomized, for observational studies - cohort, cross-sectional or case-control).

**Abstract**

The volume of the abstract in the general case should not exceed 250 words.

**Background:** a short (1-3 sentences) description of the problem that served as the direct cause of the study. As a characteristic of the problem, its scale, mediated effects and /or persisting gaps in this area of knowledge can serve.

**Objective:** description of the main (primary) purpose of the study, research question requiring the conducting a study.

**Methods:** this section of the abstract should contain a brief information about 1) the study design; 2) study subjects (healthy volunteers, patients, data); 3) availability and characteristics of medical intervention; 4) the duration of the study; 5) the primary endpoint of the study (corresponding to its objective) with 6) a description of the methods for its assessment.

**Results:** a brief description of the study participants (the number of participants included in the study the number of participants completed the study, the most significant characteristics of the groups) with an assessment of the outcomes of the study relevant to its objective. It is possible to present the results of the study in subgroups, for example, taking into account the sex, age, severity of the disease, etc. When analyzing multi-criteria relationships (the simplest variant – one dependent variable and several independent ones), the presentation of the results of multivariate analysis is mandatory. The P values must be represented within a third decimal place. If there is evidence of undesirable phenomena associated with medical intervention, their mention is mandatory.

**Conclusion:** a summary (1–3 sentences) of the research results relating to its objective. Avoid excessive generalizations and adhere to a balance in assessing the positive and negative effects of the intervention.

**Key words**

It is necessary to present not more than 5 key words that most fully reflect the subject matter.

**BACKGROUND**

Describe the relevance of the problem that has been the subject of the study, including its scale (prevalence, incidence, etc.), mediated effects (social, economic), and identify resolved and unresolved aspects of the problem with analysis of previously published data (Russian, foreign) with references to primary sources.

*Objective*

Describe the main (primary) purpose of the study, research question requiring the conducting a study.

**METHODS**

***Study design***

The section should give an idea of the study design, who was included in the study and where, duration of the study, the proposed medical intervention (when it was planning), methods of assessment of the results of the study, and methods for the hypothesis testing. For randomized trials, it is mandatory to provide a detailed description of the randomization procedure. It is reasonable to present the study flow-chart in this section.

***Eligibility criteria***

List and, if necessary, characterize (for example, indicating threshold values ​​for quantitative characteristics) preliminary (before the start of the study) formulated criteria for inclusion, non-inclusion and exclusion from the study.

***Conditions***

Identify the centers that participated in the study (including settlements and departmental affiliation and/or ownership). Give explanations about any specific factors (social, economic, cultural) that can influence the external generalizability of the study findings and the possibility of their extrapolation (for example, indicate that the search for participants in the study was conducted only in non-state outpatient healthcare centers, or that patient enrollment in the study was carried out only in the conditions of the polar night, etc.).

***Duration of the study***

Provide data on the planned duration of the enrollment period; the duration of the follow-up period with a description of all intermediate control points (it is highly desirable to have a detailed description of the follow-up protocol for the study participants, linking key events to time points /intervals). It is necessary to note, if there was a shift in the planned time intervals during the study.

***Description of medical intervention***

Indicate what exactly the researchers performed with the participants/their tissues/their data: they prescribed experimental treatment with a new drug, or they took a blood test, or asked to fill out questionnaires, etc. It is necessary to describe the planned doses, the mode of their titration, the routes of administration, the timing of the start and duration of the use of drugs, the conditions for discontinuing therapy. For surgical interventions, describe the features of preoperative preparation, the actual operation, including anesthesia and postoperative management of patients. Also, descriptions are necessary both for non-pharmacological medical interventions and organizational measures studied.

***The main study outcome***

Describe the indicator, without evaluating the values ​​of which the study objective can not be achieved. This can be "true" (deaths, development of life-threatening conditions, severe complications) or "surrogate" endpoint (an indicator of the function of the body's system, a biochemical parameter, an estimation of the quality of life). The main outcome of a medical intervention study should be a characteristic of its safety, efficacy or economic acceptability.

***Additional study outcomes***

Indicate parameters that characterize additional expected results of the study, allowing, for example, to assess other effects or mechanisms of action of medical intervention.

***Subgroup analyses***

Describe the patient groups formed in the study. List the criteria (for example, sex, age, characteristics of the severity of the disease, etc.) used to form subgroups in which or between which the outcome of the study was analyzed.

***Methods for outcome detection***

Describe all the methods and tools used to record the main and additional outcomes of the study.

***Ethical review***

Provide information on the results of consideration of the study protocol by the ethics committee of any level: a) by citing its opinion in this subsection; b) by specifying the document number; c) the date of its signing, and d) the official name of the ethical committee. If there is no protocol, indicate this.

***Statistical analysis***

Principles for calculating the sample size: describe the procedure for calculating the sample size or provide another justification for the sample size (if available). In the absence of such justifications, indicate that the sample size was not previously calculated.

Methods of statistical analysis: a) specify the package of statistical programs used to analyze the results of the study (developer, country of origin); b) note the format for the presentation of quantitative data; c) describe the statistical criteria used in the data analysis.

**RESULTS**

***Study subjects (participants)***

Provide a detailed description of the sample, which should include a description of the initial (recorded at the moment inclusion in the study) characteristics of the study participants. For retrospective studies, the study subjects are data sources (medical records, databases, etc.).

***Main results of the study***

Describe the main endpoint of the study and the related results of statistical analysis. An illustrative (tables, figures) representation of data is welcomed. In this case, duplication of data in tables and figures in the text is not allowed.

***Additional results of the study***

Describe the secondary endpoints of the study, the results of the evaluation of effects in the 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 analyses".

***Adverse events***

Describe all the adverse events that have occurred during the study of medical intervention. Any medical events (illnesses, injuries, unplanned surgical interventions, etc.), whose relationship with the medical intervention (preventive, diagnostic, curative or any other) cannot be ruled out as undesirable should be considered. The absence of adverse events should also be noted.

**DISCUSSION**

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

Present a short (no more than 3–5 sentences) description of the research results relevant to its main purpose (without duplicating the text of the RESULTS section).

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

Present an analytical text containing a discussion of the results relating to the hypothesis (the main endpoint) of the study. The discussion should be conducted in the context of previously known data, opinions and theories (with references to primary sources), and also taking into account the additional results of this study, the results of subgroup analyses. If necessary, discuss the key mechanisms for implementing the effects of medical intervention.

***Study limitations***

Present an analysis of factors that can significantly affect the findings of the study. Limitations can be assigned to each stage of the study, starting with its background, methods (conditions, sample size, used tools for effect assessment) and concluding with interpretation of results (effect size, applicability of research results if use conditions change, etc.).

**CONCLUSION**

Briefly (1–3 sentences) summarize the results of previous studies (preferably based on the systematic assessments presented in the DISCUSSION section) on the problem analyzed; briefly (1-3 sentences) outline the key unsolved aspects of the problem; briefly (5–7 sentences) describe the results obtained with an explanation of their contribution to the solution of the problem. Give a brief rationale for the clinical and/or scientific use of the results of the study. Conclusion must be presented in the form of a single text, not numbered findings. The section should not contain references to literature sources.

**Acknowledgments**

There is an opportunity to express gratitude to those whose contribution to the study was insufficient to recognize them as co-authors (see <http://www.icmje.org/recommendations/translations/russian2016.pdf>for more details), but at the same time it is considered significant by the authors (consultations, technical assistance, translations, etc.).

**Conflict of interest**

Indicate that there is a potential or existing conflict of interest between the authors, i.e. conditions and facts that can affect the conclusions of the submitted manuscript (for example, funding from concerned persons, commercial and non-profit companies, participation of the interested party in the discussion of the results, writing the manuscript, etc.).

The conflict of interests of each author must be stated as follows: “Name Surname - ... (a form of conflict of interest: research grant, lectureship or other with an indication of the interested party). In the absence of a conflict of interest, use the statement “Name Surname confirmed the absence of a conflict of interest, which must be reported“.

**NB!** Each author of the article reveals a conflict of interest over the past 36 months (!). The declaration of a conflict of interest should contain an indication of all (!) forms of cooperation and other actions related to the definition of a conflict of interest for a specified period, and not just actions related to this manuscript. See more here http://vsp.spr-journal.ru/jour/article/view/1687/655.

**ORCID**

It is strongly recommended (in the interest of authors) to indicate the individual code of the researcher, which can be obtained when registering with the ORCID system (<https://orcid.org/>). This will allow authors to avoid possible loss of citation rate.

**References**

The list of references should include only published materials (Internet references are allowed). Self-citation should be avoided, except when it seems necessary (for example, if there are no other sources of information, or the present work is based on or in the continuation of the referent studies).

In the list, all works are listed in the order of citation, and NOT in alphabetical order.

The bibliographic description of each source should include ALL AUTHORS. If there are more than 4 authors of publication, after the third author it is necessary to put the abbreviation "..., etc." or "..., et al.". Indication of the DOI (Digital Object Identifier) of each article cited (if available) is mandatory.

**Contact Information**

Specify the contact information of the corresponding author (responsible for the correspondence with the editorial staff, reviewers, readers). The section should contain the following: full name, academic degree, academic status, organization department and full name of the organization (main place of work), post work address (with postcode), e-mail, work phone number (with city code), mobile number (required for operative communication with the author; is NOT indicated in the published version of the manuscript).

**Additional explanations**

**Permission to re-publishing and license**

The authors must confirm that each graphic object (figure or photograph) presented in the manuscript, and in some cases (at the editor's request) – and the tables are authored and not adopted from other sources. For this purpose, each graphic object must be signed as follows: "Source: Name Surname (first author), co-author, year".

When using adopted graphic objects or tables (including from own previously published works) in the manuscript with the right holder being a third party, the following is required:

* to provide the written permission of the right holder to republish to the editorial office, *or*
* to specify the license type (usually Creative Commons license) in the caption to the graphic object or table, which are governed by this license.

If you have permission to republish from the copyright holder, in the caption to the graphic object/table, specify the following: "Source: reprinted from [reference to the original source] with permission ... (name of the copyright holder)". If the graphic object/table is governed by the Creative Commons license, specify in the caption the following: "Source: reprinted from [reference to the original source]. Distributed under a Creative Commons license ... (license name: for example, Attribution with version number). In the latter case, it is necessary to provide a reference to web-page, where the specified distribution conditions of the adopted graphic object or table are claimed by the copyright holder.

**NB!** If authors use the adopted graphic object (table) translated from a foreign language in the text of the manuscript, the caption to this object must (!) contain an indication of the translation (adaptation). If authors use the adopted derivative (significantly modified) graphic object in the text of the manuscript, it is necessary (!) to use "published with changes" in the caption.