

Instructions to the Authors

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» GENERAL

Indian Journal of Pharmacology (IJP), an official publication of the Indian Pharmacological Society, is published by the Medknow Publications, Mumbai, India, bimonthly in February, April, June, August, October and December each year. The URL of the journal website is: www.ijp-online.com. The e-mail ID is ijp@ijp-online.com

» SCOPE

Indian Journal of Pharmacology accepts, in English, review articles, articles for educational forum, original research articles (full length and short communications), letter to editor, case reports and interesting fillers. Articles concerning all aspects of pharmacology will be considered. Articles of general interest (e.g. methods, therapeutics, medical education, interesting websites, new drug information and commentary on a recent topic) are also welcome.

» EDITORIAL POLICY

Indian Journal of Pharmacology considers only original communications/articles/write-ups submitted exclusively to the journal. Prior and duplicate publications are not allowed. Publication of abstract under conference proceedings will not be considered as prior publication. It is the duty of the authors to inform the IJP about all submissions and previous reports that might be regarded as prior or duplicate publication.

Manuscripts for publication will be considered on their individual merits. All manuscripts will be subjected to peer review. Normally manuscripts will be sent to at least two reviewers and their comments along with the editorial board's decision will be forwarded to the contributor for further action. The authors may suggest referees working in the same area for evaluating the manuscript.

The IJP insists on ethical practices in both human and animal experiments. Evidence for approval by a local Ethics Committee must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of anaesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA (animal) and ICMR (human). The journal will not consider any paper which is ethically unacceptable. A statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Authors must be careful when they reproduce text, tables or illustrations from other sources. Plagiarism will be viewed seriously. Please see instructions below on this subject. All accepted papers are subject to editorial changes.

Copyright:

Any article accepted for publication/published in the Indian Journal of Pharmacology will be the copyright of the journal. The journal has the right to publish the accepted articles in any media (print, electronic or any other) any number of times. The authors should agree to transfer copyright and sign a declaration to this effect.

» SUBMISSION OF MANUSCRIPTS

IJP uses Manuscript Management System (MMS) for submission of manuscripts. Log on to website, www.journalonweb.com/ijp, and click 'Manuscript submission'

and follow the instructions. Authors are advised to follow up the manuscripts through the same system.

Undertaking

The manuscript must be submitted with a statement, signed by all the authors, regarding the originality, authorship and transfer of copyright as per the format given in Annexure I.

Mailing address

Dr. Bikash Medhi

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Department of Pharmacology,
Post Graduate Institute of Medical Education & Research,
Chandigarh 160012, India.

Email: editor@ijp-online.com

Websites:

www.ijp-online.com

www.journalonweb.com/ijp (for submission of manuscripts)

>> PREPARATION OF THE MANUSCRIPT



Authors should keep their manuscripts as short as possible. Manuscripts should be typed double spaced in a single column in A4 size only. It should be paginated on the upper right hand corner of each page, beginning with the title page. The language of manuscript must be simple and explicit. If needed, the authors should consult those experienced in scientific writing and communication. Recent issues of the Indian Journal of Pharmacology should be reviewed for the general format adopted in respect to various elements of a paper. Identity of the author(s) must NOT appear anywhere in the manuscript (except on the first page file).

(A) Review Articles and (B) Educational Forum

Reviews are written by researchers of considerable experience in the field concerned. The authors should review the recent trends or advances in that field in the light of their own work. However, when an author has not done enough original work on a topic but wants to share the knowledge on recent advances/trends which may be useful for post-graduate students or junior members of faculty, one may do so by writing for Educational Forum.

The major portion of the above articles should deal with the up-to-date developments in the field in the last 3-5 years. Authors are advised to search Medline and other databases on the Internet, apart from collecting information using conventional methods.

These articles should contain a covering letter, title page, summary (need not be structured) and key words. They should be written under appropriate sub-headings. The authors are encouraged to use flowcharts, boxes, cartoons, tables and figures for better presentation. Some of the other details are given below.

(C) Original Research Articles

These may either be a full length research article or a short communication. These papers should be arranged into the following sections:

1. Covering letter
2. Title page
3. Abstract and key words
4. Introduction
5. Materials and Methods

6. Results
7. Discussion
8. Acknowledgment
9. References
10. Tables
11. Figures

1) Covering Letter

In addition to the general details (name, address, contact details including mobile number of the corresponding author), it should mention in brief what is already known about this subject and what new is added by the submitted work.

2) Title page

It should be paginated as page 1 of the paper. It should include the title, authors' names and affiliations, running title, address for correspondence including e-mail address and also the total number of pages, figures and tables.

Title:

Must be informative, specific and short. It should not exceed 150 characters.

Authors and affiliations:

The names of authors and their affiliations should be given. It should be made clear which address relates to which author.

Running title:

It is a short title printed in the journal at the right top corner of right hand page of the article (except the lead page). It should be not more than 50 characters in length.

Address for correspondence:

The corresponding author's address should be given on the title page. The e-mail ID of the corresponding author or the contact e-mail ID must also be provided.

3) Abstract and key words

Abstract:

It must start on a new page carrying the following information: (a) Title (without authors' names or affiliations), (b) Abstract, (c) Key words, (d) Running title. It should not exceed 250 words excluding the title and the key words. The abstract must be concise, clear and informative rather than indicative.

The abstract must be in a structured form (OBJECTIVES, METHODS, RESULTS and CONCLUSIONS) and explain briefly what was intended, done, observed and concluded. The conclusions and recommendations not found in the text of the article should not be given in the abstract.

Key words:

Provide 3-5 keywords which will help readers or indexing agencies in cross-indexing the study. The words found in title need not be given as key words. Use terms from the latest Medical Subject Headings (MeSH) list of Index Medicus. A more general term may be used if a suitable MeSH term is not available.

4) Introduction

It should start on a new page. Essentially this section must introduce the subject and briefly say how the idea for research originated. Give a concise background of the study. Do not review literature extensively but provide the most recent work that has a direct bearing on the subject. Justification for research aims and objectives must be clearly mentioned without any ambiguity. The purpose of the study should be stated at the end.

5) Materials and Methods

This section should deal with the materials used and the methodology (how the work was carried out). The procedure adopted should be described in sufficient details to allow the experiment to be interpreted and repeated by the readers, if desired. The number of subjects, the number of groups, the study design, sources of drugs with dosage regimen or instruments used, statistical methods and ethical aspects must be mentioned under the section. The data collection procedure must be described. If a procedure is a commonly used, giving a previously published reference would suffice. If a method is not well known (though previously published) it is better to describe it briefly. Give explicit descriptions of modifications or new methods so that the readers can judge their accuracy, reproducibility and reliability.

The nomenclature, the source of material and equipment used, with details of the manufacturer in parentheses, should be clearly mentioned. Drugs and chemicals should be precisely identified using their non-proprietary names or generic names. If necessary, the proprietary or commercial name may be inserted once in parentheses. The first letter of the drug name should be small for generic name (e.g., dipyridamole, propranolol) but capitalized for proprietary names (e.g., Persantin, Inderal). New or uncommon drug should be identified by the chemical name and structural formula.

The doses of drugs should be given as unit weight per kilogram body weight e.g., mg/kg and the concentrations should be given in terms of molarity e.g., nm or mM. The routes of administration may be abbreviated, e.g., intra-arterial (i.a.), intracerebroventricular (i.c.v.), intra-gastric gavage (i.g.), intramuscular (i.m.), intraperitoneal (i.p.), intravenous (i.v.), per os (p.o.), subcutaneous (s.c.), transdermal (t.d.) etc.

Statistical Methods: The variation of data should be expressed in terms of the standard error of mean (SEM) or the standard deviation (SD), along with the number of observations (n). The details of statistical tests used and the level of significance should be stated. If more than one test is used it is important to indicate which groups and parameters have been subjected to which test.

6) Results

The results should be stated concisely without comments. They should be presented in logical sequence in the text with appropriate reference to tables and/or figures. The data given in tables or figures should not be repeated in the text. The same data should not be presented in both tabular and graphic forms. Simple data may be given in the text itself instead of figures or tables. Avoid discussions and conclusions in the results section.

7) Discussion

This section should deal with the interpretation, rather than recapitulation of results. It is important to discuss the new and significant observations in the light of previous work. Discuss also the weaknesses or pitfalls in the study. New hypotheses or recommendations can be put forth.

Avoid unqualified statements and conclusions not completely supported by the data. Repetition of information given under Introduction and Results should be avoided. Conclusions must be drawn considering the strengths and weaknesses of the study. They must be conveyed in the last paragraph under Discussion. Make sure conclusions drawn should tally with the objectives stated under Introduction.

8) Acknowledgements

These should be typed on a new page. Acknowledge only those who have contributed to the scientific content or provided technical support. Sources of financial support may be mentioned.

9) References

It should begin on a new page. The number of references should normally be restricted to a maximum of 25 for a full paper. Majority of them should preferably be of articles published in the last 5 years.

Papers which have been submitted and accepted but not yet published may be included in the list of references with the name of the journal and indicated as "In press". A photocopy of the acceptance letter should be submitted with the manuscript. Information from manuscript "submitted" but "not yet accepted" should not be included. Avoid using abstracts as references. The "unpublished observations" and "personal communications" may not be used as references but may be inserted (in parentheses) in the text.

References are to be cited in the text by superscribed number and should be in the order in which they appear. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or illustration. As far as possible mentioning names of author(s) for reference should be avoided in the text.

The references must be verified by the author(s) against the original documents. The list of references should be typed double spaced in the Vancouver style. Examples are given in Annexure II. Please refer to a [PowerPoint presentation](#) on common reference styles and using the reference checking facility on the manuscript submission site.

10) Check list for Tables

- Serially numbered in Arabic numerals?
- Short self explanatory heading given?
- Columns have headings?
- Units of data given?
- 'n' mentioned?
- Mean \pm SD or Mean \pm SEM given?
- Statistical significance of groups indicated by asterisks or other markers?
- P values given?
- Rows and columns properly aligned?
- Appropriate position in the text indicated?

11) Figures

Each figure must be numbered and a short descriptive caption must be provided. A computer drawn figure with good contrast is acceptable. Sometimes, raw data for graphs may be required in Excel sheet when the article is accepted for publication. Graphic files for diagrams and figures may be converted to *.pcx, *.tiff, *.jpg format. These files should not exceed 2 MB in size.

Check list for Figures

- Serially numbered? Self explanatory caption given?
- X and Y axes graduated?
- X and Y axes titled (legend)?
- Units mentioned (if necessary)?
- Different symbols/markers for different groups given?
- SD or SEM represented (graphically)?
- Statistical significance indicated?
- Approximate position in the text marked?

Checklist for RCT

The authors reporting randomized controlled trial (RCT) should refer the checklist (Annexure III). The relevant items of the checklist may be referred for reporting other trials.

(D) Short communications

While other things remain the same as described above, these papers should be considerably small in contents.

(E) Letter to Editor/Correspondence

This may either be a small research communication or a commentary on a contemporary issue or remarks/queries on a recently published article in IJP.

(F) Case Reports

Interesting clinical cases (with pharmacologic significance) may be considered for publication. Those with photographs stand a better chance. The case reports should have an unstructured abstract, introduction, case history and a brief discussion.

(G) Fillers

The write-up must be brief. Interesting pictures and photographs may be submitted.

For all other items, please contact the Chief Editor.

Specific requirements for various types of articles are given below:

	Review article	Educational Forum	Full length Research paper	Short Communication	Letter to Editor	Case Report
Abstract	Unstructured Less than 250 words	Unstructured Less than 250 words	Structured Less than 250 words	Unstructured Less than 150 words	None	Unstructured Less than 150 words
Keywords	3-5	3-5	3-5	3-5	None	3-5
Running Title	Less than 50 characters	Less than 50 characters	Less than 50 characters	Less than 50 characters	None	Less than 50 characters
Word Limit	6400	5000	3200	1600	800	1000
Tables and Figures	Upto 6	Upto 4	Upto 6	Upto 3	Upto 1	Upto 2
References	Upto 60	Upto 40	Upto 30	Upto 20	Upto 5	Upto 5

» PROTECTION OF PATIENTS' RIGHT TO PRIVACY

Identifying information should not be published in written descriptions, photographs, sonograms, CT scans, etc., and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian, wherever applicable) gives informed consent for publication. Authors should remove patients' names from figures unless they have obtained informed consent from the patients. The journal abides by ICMJE guidelines:

- 1) Authors, not the journals nor the publisher, need to obtain the patient consent form before the publication and have the form properly archived. The consent forms are not to be uploaded with the cover letter or sent through email to editorial or publisher offices.
- 2) If the manuscript contains patient images that preclude anonymity, or a description that has obvious indication to the identity of the patient, a statement about obtaining informed patient consent should be indicated in the manuscript.

» REVISED MANUSCRIPT

The authors should revise the manuscript immediately after receipt of the comments from the IJP. A note mentioning the changes incorporated in the revised text as per referee's comments (point by point) should be sent. The revised manuscript has to be submitted online within the stipulated time. Calling for revision does not guarantee acceptance. A revised manuscript which underwent major changes is likely to be sent to referees for re-review. If the authors have substantial reasons that their manuscript was rejected unjustifiably, they may request for reconsideration.

» PROOFS

Proofs will be sent to the corresponding author for final checking. It is the authors' responsibility to go through the proof meticulously and correct errors if any. Corrections should be restricted to printer's error only and no substantial addition/deletion should be made.

» REPRINTS

Reprints must be ordered while returning the corrected page proofs. The charges will be very high for late orders.

» PLAGIARISM

Authors should note that :

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3. if a few lines of text are to be reproduced from any source, 'the author' and 'the source' must be clearly indicated in the text. The reproduced lines must be in italics and given within quotes. If it is a paragraph it must be slightly indented also. To reproduce large portions of text, permission from the copyright owner(s) must be obtained and submitted to the IJP.
4. to reproduce tables or illustrations, permission from the copyright owner(s) must be obtained and a copy of the permission letter must be submitted to the journal. The source must be clearly acknowledged below the table or illustration as required by the copyright owner(s).
5. According to UGC guidelines the plagiarism or similarity index should be less than 10%.

» ANNEXURE I

**INDIAN JOURNAL OF PHARMACOLOGY
DEPARTMENT OF PHARMACOLOGY, PGIMER,**

Chandigarh 160012, INDIA

DECLARATION AND COPYRIGHT TRANSFER FORM: TO BE SIGNED BY ALL AUTHORS

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I/we give consent for publication in the IJP in any media (print, electronic or any other) and transfer copyright to the IJP in the event of its publication in the IJP.

I/we do not have any conflict of interest (financial or other) other than those declared*.

I/we have read the final version of the manuscript and am/are responsible for the contents. The work described in the manuscript is my/our own and my/our individual contribution to this work is significant enough to qualify for authorship.

No one who has contributed significantly to the work has been denied authorship and those who helped have been duly acknowledged.

I/we also agree to the authorship of the article in the following sequence:

Author's name(s)	Signatures
1.-----	1. -----
2.-----	2.-----
3.-----	3.-----
4.-----	4.-----
5.-----	5.-----

Note:

- All authors are required to sign this form.
- No addition, deletion or change in the sequence of authors is allowed at a later stage without valid reasons.
- If the authorship is contested before publication the manuscript will be either returned or kept in abeyance till the issue is resolved.
- This form may be photocopied and used.

Authorship responsibilities:

- Anyone who makes significant intellectual contribution must be given authorship.
- Every author must be involved in planning, implementation and analysis of the research study and its presentation in the form of the manuscript.
- In case some clarification is sought, they should be able to reply to the queries.
- Authors should be ready to take public responsibility for the content of the paper.
- All the authors in a manuscript are responsible for the technical information communicated. For this reason it is necessary that all authors must read and approve the final version of the manuscript before signing the consent and declaration form.

* Conflict of interest, if any, must be declared on a separate sheet.

>> ANNEXURE II



EXAMPLES OF REFERENCES - VANCOUVER STYLE

(from Uniform Requirements for Manuscripts, www.icmje.org)

Articles in Journals

1. Standard journal article

List the first six authors followed by et al. (Note: NLM now lists up through 25 authors; if there are more than 25 authors, NLM lists the first 24, then the last author, then et al.)

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996 Jun 1;124(11):980-3.

As an option, if a journal carries continuous pagination throughout a volume (as many medical journals do) the month and issue number may be omitted. (Note: For consistency, the option is used throughout the examples in Uniform Requirements. NLM does not use the option.)

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124: 980-3.

More than six authors:

Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood leukaemia in Europe after Chernobyl: 5 year follow-up. *Br J Cancer* 1996;73:1006-12.

2. Organization as author

The Cardiac Society of Australia and New Zealand. Clinical exercise stress testing. Safety and performance guidelines. *Med J Aust* 1996; 164: 282-4.

3. No author given

Cancer in South Africa [editorial]. *S Afr Med J* 1994;84:15.

4. Article not in English

(Note: NLM translates the title to English, encloses the translation in square brackets, and adds an abbreviated language designator.) Ryder TE, Haukeland EA, Solhaug JH. Bilateral infrapatellar seneruptur hostidligere frisk kvinne. *Tidsskr Nor Laegeforen* 1996;116:41-2.

5. Volume with supplement

Shen HM, Zhang QF. Risk assess-ment of nickel carcinogenicity and occupational lung cancer. *Environ Health Perspect* 1994;102 Suppl 1:275-82.

6. Issue with supplement

Payne DK, Sullivan MD, Massie MJ. Women's psychological reactions to breast cancer. *Semin Oncol* 1996; 23(1 Suppl 2):89-97.

7. Volume with part

Ozben T, Nacitarhan S, Tuncer N. Plasma and urine sialic acid in non-insulin dependent diabetes mellitus. *Ann Clin Biochem* 1995;32(Pt 3):303-6.

8. Issue with part

Poole GH, Mills SM. One hundred consecutive cases of flap lacerations of the leg in ageing patients. *N Z Med J* 1994;107(986 Pt 1):377-8.

9. Issue with no volume

Turan I, Wredmark T, Fellander-Tsai L. Arthroscopic ankle arthrodesis in rheumatoid arthritis. *Clin Orthop* 1995;(320):110-4.

10. No issue or volume

Browell DA, Lennard TW. Immuno-logic status of the cancer patient and the effects of blood transfusion on antitumor responses. *Curr Opin Gen Surg* 1993:325-33.

11. Pagination in Roman numerals

Fisher GA, Sikic BI. Drug resistance in clinical oncology and hematology. Introduction. *Hematol Oncol Clin North Am* 1995 Apr;9(2):xi-xii.

12. Type of article indicated as needed

Enzensberger W, Fischer PA. Metronome in Parkinson's disease [letter]. *Lancet* 1996;347:1337. Clement J, De Bock R. Hematological complications of hantavirus nephro-pathy (HVN) [abstract]. *Kidney Int* 1992;42:1285.

13. Article containing retraction

Garey CE, Schwarzman AL, Rise ML, Seyfried TN. Ceruloplasmin gene defect associated with epilepsy in EL mice [retraction of Garey CE, Schwarzman AL, Rise ML, Seyfried TN. In: *Nat Genet* 1994;6:426-31]. *Nat Genet* 1995;11:104.

14. Article retracted

Liou GI, Wang M, Matragoon S. Precocious IRBP gene expression during mouse development [retracted in *Invest Ophthalmol Vis Sci* 1994; 35:3127]. *Invest Ophthalmol Vis Sci* 1994;35:1083-8.

15. Article with published erratum

Hamlin JA, Kahn AM. Herniography in symptomatic patients following inguinal hernia repair [published erratum appears in *West J Med* 1995;162:278]. *West J Med* 1995;162: 28-31. Books and Other Monographs (Note: Previous Vancouver style incorrectly had a comma rather than a semicolon between the publisher and the date.)

16. Personal author(s)

Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996.

17. Editor(s), compiler(s) as author

Norman IJ, Redfern SJ, editors. Mental health care for elderly people. New York: Churchill Livingstone; 1996.

18. Organization as author and publisher

Institute of Medicine (US). Looking at the future of the Medicaid program. Washington: The Institute; 1992.

19. Chapter in a book

(Note: Previous Vancouver style had a colon rather than a p before pagination.) Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, editors. Hypertension: pathophysiology, diagnosis, and management. 2nd ed. New York: Raven Press; 1995. p. 465-78.

20. Conference proceedings

Kimura J, Shibasaki H, editors. Recent advances in clinical neuro-physiology. Proceedings of the 10th International Congress of EMG and Clinical Neurophysiology; 1995 Oct 15-19; Kyoto, Japan. Amsterdam: Elsevier; 1996.

21. Conference paper

Bengtsson S, Solheim BG. Enforcement of data protection, privacy and security in medical informatics. In: Lun KC, Degoulet P, Piemme TE, Rienhoff O, editors. MEDINFO 92. Proceedings of the 7th World Congress on Medical Informatics; 1992 Sep 6-10; Geneva, Switzerland. Amsterdam: North-Holland; 1992. p. 1561-5.

22. Scientific or technical report

Issued by funding/sponsoring agency: Smith P, Golladay K. Payment for durable medical equipment billed during skilled nursing facility stays. Final report. Dallas (TX): Dept. of Health and Human Services (US), Office of Evaluation and Inspections; 1994 Oct. Report No.: HHSIGOEI69200860. Issued by performing agency: Field MJ, Tranquada RE, Feasley JC, editors. Health services research: work force and educational issues. Washington: National Academy Press; 1995. Contract No.: AH CPR282942008. Sponsored by the Agency for Health Care Policy and Research.

23. Dissertation

Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis (MO): Washington Univ.; 1995.

24. Patent

Larsen CE, Trip R, Johnson CR, inventors; Novoste Corporation, assignee. Methods for procedures related to the electrophysiology of the heart. US patent 5,529,067. 1995 Jun 25. Other Published Material

25. Newspaper article

Lee G. Hospitalizations tied to ozone pollution: study estimates 50,000 admissions annually. The Washington Post 1996 Jun 21;Sect. A:3 (col. 5).

26. Audiovisual material

HIV+/AIDS: the facts and the future [videocassette]. St. Louis (MO): Mosby-Year Book; 1995.

27. Legal material

Public law: Preventive Health Amendments of 1993, Pub. L. No. 103-183, 107 Stat. 2226 (Dec. 14, 1993).

Unenacted bill: Medical Records Confidentiality Act of 1995, S. 1360, 104th Cong., 1st Sess. (1995).

Code of Federal Regulations:

Informed Consent, 42 C.F.R. Sect. 441.257 (1995).

Hearing: Increased Drug Abuse: the Impact on the Nation's Emergency Rooms: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Operations, 103rd Cong., 1st Sess. (May 26, 1993).

28. Map

North Carolina. Tuberculosis rates per 100,000 population, 1990 [demo-graphic map]. Raleigh: North Carolina Dept. of Environment, Health, and Natural Resources, Div. of Epidemiology; 1991.

29. Book of the Bible

The Holy Bible. King James version. Grand Rapids (MI): Zondervan Publishing House; 1995. Ruth 3:1-18.

30. Dictionary and similar references

Stedman's medical dictionary. 26th ed. Baltimore: Williams & Wilkins; 1995. Apraxia; p. 119-20.

31. Classical material

The Winter's Tale: act 5, scene 1, lines 13-16. The complete works of William Shakespeare. London: Rex; 1973. Unpublished Material

32. In press

(Note: NLM prefers "forthcoming" because not all items will be printed.) Leshner AI. Molecular mechanisms of cocaine addiction. N Engl J Med. In press 1996.

Electronic Material

33. Journal article in electronic format

Schimdt D, Lynch, J. Evaluation of the reproducibility of parallel artificial membrane permeation assays (PAMPA). Millipore Corporation; USA [Serial online] 2002 [cited in 2002]. Available from: <http://www.millipore.com/techpublications/tech1/ANI728EN00>

>> ANNEXURE III



Checklist for reporting RCT (from www.consort-statement.org)

PAPER SECTION and topic	Item	Description Reported on	Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objective	5	Specific objectives and hypotheses.	
		Clearly defined primary and secondary outcome measures and, when applicable, any methods used to	

Outcomes	6	enhance the quality of measurements (e.g., multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization-- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	
Randomization-- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization-- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	

Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	



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