N-of-1 Journal
ATTN: Editor-in-Chief
1020 SW Taylor St., Ste. 340
Portland, OR 97205

n-of-1
CLINICAL CASE REPORTS

Submission Guidelines

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Aim and Scope

N-of-1: Clinical Case Studies (hereafter referred to as *N-of-1*), aims to be a cutting-edge peer-reviewed resource of high quality case reports, case studies, case series, and *n*-of-1 clinical trials, with the intention of providing baseline evidence for future clinical research.

N-of-1 an official journal of Whole Systems Research Institute (hereafter referred to as WSRI), a research collaborative aimed at supporting the holistic, systems-based research initiatives of Whole Systems Healthcare (hereafter referred to as WSHC). *N-of-1* will be comprehensive and integrative by reporting potential novel treatments and outcomes for conditions from across the spectrum of healthcare.

To be consistent in these aims, manuscripts submitted to *N-of-1* should demonstrate at least one of the following:

- Novel or additional perspective on the understanding of health conditions in the clinical setting.
- Novel or additional perspective on understanding social impacts of health on the individual, and on managing those situations.
- Demonstrate efficacy or inefficacy of treatments or modalities in clinical situations.
- Document efficacy or inefficacy of less understood treatments or modalities.
- Document the efficacy or inefficacy of less understood medical professions.
- Describe an integrative approach to patient care.

Inquiries and Submissions

a. Inquiries regarding submissions may be sent to info@nof1journal.org.
b. Submissions should be sent to submissions@nof1journal.org with the following format:
    i. Subject must be in the format "Submission: [Article Title]"
    ii. Body of the email should contain an abstract and a short paragraph or cover letter explaining how this manuscript contributes to *N-of-1* aims and scope.
    iii. Manuscript should be an attachment in *.doc* or *.docx* format only. Files in *.pdf* format will not be accepted.
c. Before manuscripts will be considered for editing, a $27.50 submission fee must be paid. Submission fee may be paid at nof1journal.com by selecting "Submissions," and following the prompts to make payment. All payments must be made with credit, debit, or online payment method. Cash or check payment will not be accepted.
d. Manuscript Type: Only case reports, case studies, case series, *n*-of-1 clinical trials, and letters to the editor will be considered for editing and publishing. Letters to the editor will be a maximum of 300 words, and will serve two main purposes: post-publication peer-review and

sharing experiences with fellow readers. Both are equally important in maintaining the journal's high standards.

e. All submissions must include a release of information (ROI) form signed by the patient(s) included in each study. The form should specifically state that the patient(s) discussed in the study or article consents to their case information being used in the context of medical research for the purpose of this case study and any future case series study that may include their case information. The ROI form must also delineate the specific terms of information related to their case to be released, including mental health or sexual-health related information.

Submission Guidelines: Case Report, Case Study, and Case Series

1. Formatting

a. Manuscripts must adhere to CARE Guidelines detailed in Section 3.
b. Manuscripts must be submitted with a cover page that includes the following:
    i. Manuscript title.
    ii. Manuscript running title, if indicated (i.e., a short version of your title, five words or fewer).
    iii. Authors should be listed below the manuscript title.
        1. **NOTE:** Only include authors on the cover page of your manuscript in order to facilitate double-blind peer-review process.
    iv. Author affiliations should be listed numerically below the author section and referenced numerically after each author in superscripted text.
    v. Article type.
    vi. Keywords: two to five keywords representing the main content of the article. There is a maximum of seven keywords allowed.
    vii. Number of figures and tables.
c. Manuscripts must be submitted in 12-point Times New Roman font, double-spaced, with 1-inch margins.
d. Page numbers should be located on the bottom right of each page.
e. Title of the article must be centered in the header of each page.
f. Manuscripts may be a maximum of 3,000 words.
    i. Manuscript length excludes abstracts, figures and table captions, footnotes, citations, and section titles.
g. Citations must be in AMA format.
h. Figures and tables should be attached as separate attachments in the submission email. File sizes should be less than 25MB.

i. Manuscripts must be written in American English.

2. CARE Guidelines

Case report, case study, or case series submissions must follow the CARE Guidelines format as outlined at https://www.care-statement.org/ . Submissions that do not include the below sections in each case study or case series will be rejected for editing:

a. **Title:** Titles should reflect the intervention or primary focus of the case study in question. It is recommended that the title contain "case report", "case study" or "case series" as applicable.
b. **Keywords**: Please list keywords that reflect the topic of the case(s) in question. These may include diagnoses, treatment modalities, systems, etc. two to five keywords are encouraged. There is a maximum of seven keywords allowed.
c. **Abstract:** Abstract must reflect a summary of the case study and include a section summarizing the introduction, diagnoses, treatment, and any pertinent conclusions. Abstracts must be 300 words or less.
d. **Introduction:** Introductions should include an overview of pertinent evidence-based background regarding the case. This includes current knowledge on the condition or treatment modality that is being discussed.
e. **Patient Information**: Patient information must be de-identified and include the primary concerns and presenting symptoms of the patient. Pertinent medical, social and family history may also be reviewed here as well as any past interventions.
    i. De-identifying patient data: Any explicit mention of the following 18 identifiers that are considered PHI should not be present in any document submitted to *N-of-1*. Any inclusion of these will result in rejection of the submission.
        1. Patient Name
        2. Date of Birth
        3. Telephone or Fax Numbers
        4. Any geographic data
        5. Social Security Numbers
        6. Email Addresses
        7. Medical Record Numbers
        8. Account Numbers
        9. Health Plan Beneficiary Numbers or IDs
        10. Certificate or License Numbers
        11. Vehicle License Plate Numbers
        12. Website URLs
        13. Medical Device ID Numbers or Serial Numbers
        14. IP Addresses

15. Full-face photos or photos with identifying tattoos (Photos of tattoos approved with patient explicitly signed consent).
16. Biometric Identifiers
17. Any unique or identifying number or code.
18. Genetic Codes, not including descriptions of genetic alleles that are non-identifying.

f. **Clinical Findings:** Pertinent physical exam results should be reviewed.
g. **Diagnostic Assessment**: Pertinent lab results, radiology or other testing should be discussed here.
h. **Timeline:** Symptom presentation, diagnostic and treatment information should be organized in a timeline. A variety of formats for this are accepted.
i. **Therapeutic Intervention**: Discussion of the therapeutic intervention(s) undergone for this patient to be reviewed here. Additional background on what is currently known about the intervention may also be included here. Specifics about the treatment, including dosage, tapering schedules and any procedures should be discussed in detail here.
j. **Follow-up and Outcomes**: All patient and clinician-assessed outcomes should be described. This includes any follow-up diagnostic testing, adverse or unanticipated events, notes on tolerability of the intervention or other pertinent outcomes of treatment.
k. **Discussion**: This section should include an evidence-based discussion regarding the primary lessons of this case report or case series. Relevant literature should be included as well as a description of how this case study or case series adds to the current known literature. Discussion on any rationale for the outcome of treatment should also be discussed here.
l. **Patient Perspective and Informed Consent:** Patient perspective should be discussed briefly here, as well as confirmation of written informed consent to the treatment, interventions described. Their informed consent to have their case published should also be stated in this section.
m. **Author Acknowledgments:** All authors must disclose any funding and educational sources that are relevant to the case study or case series. This includes clinical employers, educational institutions and companies involved in the manufacture of any treatment modalities such as supplement, pharmaceutical or medical device companies.
n. **References**: Any resources referenced in any of the above sections must be listed in this section in AMA Format.
o. **Policy for figures and tables:** Any figures or tables included in each submission must be an original figure from the authors or otherwise referenced appropriately in AMA Format. Figures and Tables must include axis labels that are clear. Captions must be included below the figure or table that outline the meaning and pertinent takeaways. Confidence Intervals must be included, if applicable. Any figure or table must be clear to the reader without having read the entirety of the article.

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Submission Guidelines: *n*-of-1 Clinical Trial

1. Formatting

a. Manuscripts must adhere to CONSORT Guidelines detailed in Section 4.
b. Manuscripts must be submitted with a cover page that includes the following:
    i. Manuscript title.
    ii. Manuscript running title, if indicated (i.e., a short version of your title, five words or fewer).
    iii. Authors should be listed below the manuscript title.
        1. **NOTE:** Only include authors on the cover page of your manuscript in order to facilitate double-blind peer-review process.
    iv. Author affiliations should be listed numerically below the author section and referenced numerically after each author in superscripted text.
    v. Article type.
    vi. Keywords: two to five keywords representing the main content of the article. There is a maximum of seven keywords allowed.
    vii. Number of figures and tables.
c. Manuscripts must be submitted in 12-point Times New Roman font, double-spaced, with 1-inch margins.
d. Page numbers should be located on the bottom right of each page.
e. Title of the article must be centered in the header of each page.
f. Manuscripts may be a maximum of 3,000 words.
    i. Manuscript length excludes abstracts, figures and table captions, footnotes, citations, and section titles.
g. Citations must be in AMA format.
h. Figures and tables should be attached as separate attachments in the submission email.
i. Manuscripts must be written in American English.

2. Institutional Review Board Registration

a. All submissions should include institutional IRB Registration Number and Statement from IRB issuing approval for trial.

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3. CONSORT Guidelines

N-of-1 clinical trial submissions must follow the CONSORT Extension for Reporting N-of-1 Trials (CENT) Guidelines format, available for download at http://www.consort-statement.org/extensions?ContentWidgetId=47627.

The list below highlights relevant sections of CENT guidelines, but the full checklist should be consulted before submission. Submissions that do not include the below sections will be rejected for editing:

a. **Title:** Titles should identify the trial as an *n*-of-1 trial.
b. **Abstract:** Structured summary of trial design, methods, results, and conclusions (for specific guidance see CENT guidance for abstracts)
c. **Introduction:** Introductions should include an overview of pertinent evidence-based background, specific objectives, and hypotheses. The introduction should include rationale for using *n*-of-1 approach.
d. **Methods:** Describe trial design, planned number of periods, and duration of each period (including run-in and wash out, if applicable). Should also include important changes to methods after trial start (such as eligibility criteria), with reasons.
e. **Participants:** Should include diagnosis or disorder, diagnostic criteria, comorbid conditions, and concurrent therapies. If a research study, whether institutional ethics approval was obtained.
f. **Interventions:** Interventions for each period with sufficient details to allow replication, including how and when they were actually administered.
g. **Outcomes:** Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed, as well as description and measurement properties (validity and reliability) of outcome assessment tools. Should report any changes to trial outcomes after the trial commenced, with reasons.
h. **Sample Size:** How sample size was determined and, when applicable, explanation of any interim analyses and stopping guidelines.
i. **Randomisation:** Whether the order of treatment periods was randomised, with rationale, and method used to generate allocation sequence. When applicable, type of randomisation; details of any restrictions (such as pairs, blocking) and full, intended sequence of periods.
j. **Statistical Methods:** Methods used to summarize data and compare interventions for primary and secondary outcomes. Statistical methods used to account for carryover effect, period effects, and intra-subject correlation.
k. **Results:** number and sequence of periods completed, and any changes from original plan with reasons. Whether any periods were stopped early and/or whether trial was stopped early, with reason(s). For each intervention, number of periods analysed. For each primary and secondary outcome, results for each period; an accompanying figure displaying the trial data is

recommended. For each primary and secondary outcome, the estimated effect size and its precision (such as 95% confidence interval). Results of any other analyses performed, including assessment of carryover effects, period effects, intra-subject correlation.

l. **Harms:** all harms or unintended effects for each intervention. (for specific guidance see CONSORT for harms).

m. **Discussion:** trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses. Generalisability (external validity, applicability) of the trial findings. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.

n. **Other Information:** registration number and name of trial registry, where the full trial protocol can be accessed, if available, and sources of funding and other support (such as supply of drugs), role of funders.

o. **Author Acknowledgments:** All authors must disclose any funding and educational sources that are relevant to the trial. This includes clinical employers, educational institutions and companies involved in the manufacture of any treatment modalities such as supplement, pharmaceutical or medical device companies.

p. **References**: Any resources referenced in any of the above sections must be listed in this section in AMA Format.

q. **Policy for figures and tables:** Any figures or tables included in each submission must be an original figure from the authors or otherwise referenced appropriately in AMA Format. Figures and Tables must include axis labels that are clear. Captions must be included below the figure or table that outline the meaning and pertinent takeaways. Confidence Intervals must be included, if applicable. Any figure or table must be clear to the reader without having read the entirety of the article.

Publication

1. Peer Review Policy

a. Manuscripts will be acknowledged via email within one week of submission. Upon receipt, manuscripts may take up to 30 days to be reviewed by the editor, who will determine whether or not the manuscript will be accepted for peer review. Once accepted for peer review, submissions will be double-blinded for peer editing. Peer editing will take an additional 30 days. Upon completion of peer review, authors will be sent a copy of their manuscript with peer edits and suggestions to be incorporated into the final published article. Authors should respond to edits within 30 days of receipt.

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2. Publication Criteria

a. Submission must meet *N-of-1* Aims and Scope as outlined above.
b. Submissions of case reports, case studies, or case series must fulfill CARE Guidelines as outlined above.
c. Submissions of *n*-of-1 clinical trials must follow CONSORT Guidelines and have IRB approval, as outlined above.
d. Submission must meet formatting guidelines as outlined above.
e. Submissions must comply with NIH Guiding Principles for Ethical Research, which can be accessed at https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research.

Authors may appeal a manuscript rejection decision by drafting a letter to submissions@nof1journal.org with a point by point response to any concerns raised by reviews and/or journal editors.

3. Publication Ethics

a. *N-of-1* follows best practices in the ethics of scholarly publishing in alignment with the Committee on Publication Ethics: https://publicationethics.org/.

4. Publication Schedule

a. *N-of-1* will publish biannually in April and October. If a submission is accepted for peer-review within three months before the next publishing date, the article will be published in the next publication.

5. Indexing

a. *N-of-1* has incorporated formatting and submission guidelines in accordance with requirements for PubMed and Google Scholar indexing. PubMed requires two years of publications before consideration for indexing. Once this requirement has been met by May 1, 2022, *N-of-1* aims to apply for PubMed indexing. At that time, retroactively index all prior published submissions.

6. Copyright Agreement

a. *N-of-1* retains the rights to all published material. Authors may distribute preprints and postprints, provided these distributions contain copyright acknowledgement for *N-of-1* and the appropriate Digital Object Identifier (DOI).

b. Authors whose manuscripts are published by *N-of-1* agree to allow *N-of-1* to use published data for future research, including inclusion in case series pertaining to the subject or treatment modality.

7. Disclaimer
   a. Articles published in *N-of-1* reflect the editorial standards of *N-of-1,* and do not necessarily reflect the opinions or positions of our staff or individuals associated with, Whole Systems Research Institute or Whole Systems Healthcare.

Fees and Funding

In order to provide peer-review services, editing and formatting of journal articles, and database administration services, *N-of-1* requires a submission fee of $27.50 to be paid at the time of manuscript submission. Should manuscripts be accepted for peer review, authors will receive notification of acceptance. After peer review, upon acceptance for publication, corresponding author will be prompted to submit an additional $105 editorial fee through the nof1journal.com website. Fees are subject to change after journal indexing. Please contact info@nof1journal.org for updated submission and editing fees.

Questions

Questions regarding these submission guidelines or regarding any individual submission can be directed to our Editor-in-Chief, Constance Ohlinger, ND, at submissions@nof1journal.org or in writing to:

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