

Best Practice Recommendations for Conducting and Reporting Controlled Trials in Clinical Hypnosis Research

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Abstract

There is an abundance of outcomes research for clinical hypnosis showing promising results. Nonetheless, hypnosis is still underutilized in clinical care. For a behavioral intervention to enter mainstream clinical care, efficacy needs to be demonstrated with exceptionally high quality of evidence, and its reporting needs to be complete and sufficiently clear to enable replication and clinical use. The present article provides best practice guidelines formulated by the *Task Force for Establishing Efficacy Standards for Clinical Hypnosis* for conducting and reporting clinical hypnosis research. The recommendations are presented in two tiers. Tier I recommendations include essential best practices, such as a call for the use of detailed research and intervention manuals, plans for and reporting of participant-education about hypnosis, the use of hypnotizability scales with good psychometric properties, and clear reporting of the hypnotizability measurement. Tier I also includes the sharing of intervention manuals, the reporting of the induction procedure, the labeling of the intervention for participants, and the definition of hypnosis used. Tier II includes preferred recommendations, calling for measurement of adherence to home practice, measurement of hypnotizability using scales with both subjective and behavioral measures of responsiveness, and the involvement of participants from the full hypnotizability spectrum. Tier II also includes the assessment of variables related to proposed mechanisms of action, the reporting of participants prior hypnosis experiences, and the relationship of expectancies and treatment outcomes. This list of recommendations will be useful for researchers, reviewers, and journal editors alike when conducting, reporting, or evaluating studies involving clinical hypnosis.

Keywords

hypnosis, outcomes research, best practices, reporting guidelines, research methods

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Introduction

Hypnosis is used in a large variety of clinical contexts, including the treatment of medical and psychological problems such as chronic pain, acute pain, irritable bowel syndrome (IBS), anxiety, depression, sleep disturbances, oncological treatment side effects, hot flashes, and stress.¹⁻⁴ However, as in many clinical and experimental domains, there is a need for more high quality well-controlled randomized clinical trials. This paper presents a set of recommendations developed by the *Task Force for Establishing Efficacy Standards for Clinical Hypnosis*, which aim to provide guidance towards improving methodological rigor and transparency in the reporting of efficacy research on clinical hypnosis applications.

At present there are published primary studies on many applications of hypnosis (for current applications and their research

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base see eg¹). Furthermore, in the past ten years there has been an increase in systematic reviews and meta-analyses of hypnosis applications. However, recently published systematic reviews and meta-analyses have identified a considerable risk of bias in the reviewed clinical trials.^{3,5-11} In addition, there is some evidence showing that the studies with low risk of bias and high methodological quality report lower effect sizes,^{8,12} although this relationship is not uniform across all applications (see eg,¹⁰). Thus, the authors of these and other systematic reviews have generally called for studies in the field of hypnosis to use more rigorous methodologies.

Another related issue is rigor in reporting results of clinical trials. Many publications of randomized clinical trials of hypnosis interventions have been unclear or incomplete in reporting of the design elements that are necessary for the evaluation of the quality of evidence,¹³ or have not provided sufficient details for possible direct replication.^{14,15} Indeed, it has been long recognized that full and detailed reporting of clinical trial protocols is necessary for readers to judge the quality of evidence, and lack of clear reporting of interventions prevents further study and clinical use of the intervention.¹⁴ Thus, reporting guidelines of clinical research have been published such as the Consolidated Standards of Reporting Trials (CONSORT)¹⁶ or the Strengthening the Reporting of Observational studies in Epidemiology (STROBE)¹⁷ statements, which have been endorsed by most major journals and societies of clinical medicine. The need for better reporting has also been noted in reviews of the literature of clinical hypnosis trials.¹²

In recognition of the need for efficacy standards in the field of clinical hypnosis, the *Task Force for Establishing Efficacy Standards for Clinical Hypnosis* (henceforth the *Task Force*) was established in 2018¹⁸ with the support of six professional organizations in the field of hypnosis (the Society for Clinical and Experimental Hypnosis, the American Society of Clinical Hypnosis, the American Psychological Association Division 30, the Milton Erickson Foundation, the National Pediatric Hypnosis Training Institute, and the International Society of Hypnosis). The Task Force was convened by [anonymized] and [anonymized], and was composed of nine selected researchers from Hungary, Italy, the UK, and the US, who committed to participating in the Task Force deliberations. The participants are the authors of this paper. Three additional researchers agreed to serve as consultants to the Task Force: [anonymized], [anonymized], and [anonymized].

The Task Force identified that in order to establish a list of efficacious clinical hypnosis applications there was a need for more clinical trials with high methodological quality and good reporting standards. In order to address this need, the Task Force set out to develop recommendations for conducting and reporting future outcomes research on clinical hypnosis. This paper is the end-product of this work.

The primary goal of the present paper is to raise awareness of the issues that need to be considered, and to provide specific guidelines for researchers on conducting and reporting clinical hypnosis trials in order to ensure the highest quality standards. To serve this purpose, we list guidelines for high quality research

design and reporting. The guidelines listed in this paper are specific to hypnosis research. The scope of this work does not allow for a comprehensive guide for clinical research in general, but we provide a list of generic clinical research guidelines and their sources in Supplement 1.

Material and Methods

In the following section we list the Best Practice Recommendations by the Task Force. The following recommendations are intended to guide clinicians and researchers who want to conduct high quality clinical trials assessing the effectiveness of certain applications of clinical and medical hypnosis, as well as reviewers and editors who are assessing the quality and merit of these trials. The recommendations apply to research studies in which human participants are prospectively assigned to one or more interventions involving hypnosis to evaluate the effects of those interventions on health-related biomedical, subjective, or behavioral outcomes.

The guidelines are divided into two parts: (1) recommendations for designing and conducting research, and (2) recommendations for reporting the research. These guidelines were developed during a series of meetings of the Task Force between February 2019 and February 2022. Initially, a list of best practice guidelines were collected from different sources such as the CONSORT statement,¹⁶ Template for Intervention Description and Replication (TIDieR) checklist,¹⁵ and the Cochrane Handbook for Systematic Reviews of Interventions.¹⁹ These guidelines were then supplemented by the Task Force members during and between the meetings with hypnosis-research-specific recommendations. The recommendations were later sent out to the external members of the Task Force ([anonymized], [anonymized], [anonymized]) who also provided their input. In a final meeting the content of the list and the wording of the recommendations were approved by all Task Force members.

Specific Problem Areas in Methodology and Reporting

In the majority of the hypnosis studies included in recent systematic reviews, risk of bias was rated either high or uncertain for topics considered in the Cochrane Risk of Bias Tool,^{20,21} which is the most commonly used tool in systematic reviews to assess methodological quality. Risk of bias in clinical hypnosis studies was reported in all common bias domains assessed in this tool, including inadequacy of allocation concealment, random sequence generation, blinding of personnel and outcome assessors, handling of incomplete outcome data (eg, attrition bias), and selective reporting of outcome findings.^{5-9,22} Furthermore, risk of bias was reported in areas such as determination of data collection stopping rules (no or inadequate sample size calculation), lack of specification of demographic characteristics of the sample, no use of a treatment manual, and not describing the intervention as hypnosis.^{5,22} Only a handful of clinical hypnosis studies were rated as having low risk of bias across all of these bias domains in the reviews. As previously noted, these problems do not only pertain to poor study design, but also to poor reporting practices.

Results

Best Practice Recommendations for Conducting and Reporting Clinical Hypnosis Research

Clinical research is a vast domain where researchers need to consider a range of domain specific and domain general

considerations when planning and conducting their studies. The problem areas discussed above include some methodological problems that are domain general, relevant to most clinical research of psychological interventions, but also some that are more specific to hypnosis research. In this paper we focus on formulating recommendations that are specific to studies including hypnosis. For general recommendations and considerations on conducting clinical research, the reader should consult the following papers and handbooks: the Cochrane handbook for systematic reviews of interventions,¹⁹ Risk of Bias 2 tool,²¹ the CONSORT statement,¹⁶ the STROBE checklist,¹⁷ the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist,²³ and papers and handbooks on clinical psychology research.²⁴⁻²⁶

Conducting clinical trials according to the current state of the art is not enough on its own to produce research that is useful and informative for the field. The study, the intervention, and the findings also need to be reported clearly and with sufficient detail (either in the paper or by using easily accessed supplemental materials) to allow readers to evaluate the methodological quality of the work, and the implications of the findings for populations of interest, and to independently replicate the intervention. In fact, it is possible that there are many clinical hypnosis trials already published that would meet the highest quality standards if they provided greater details of their methods and findings, the lack of which leads to uncertainty and undermines the ability of researchers and clinicians to make the best use of the results. There are already several excellent checklists for reporting clinical trials and clinical interventions. In line with the current consensus in the medical research

community, we highly recommend the use of the SPIRIT checklist²³ when reporting protocols for clinical trials, the CONSORT checklist¹⁶ when reporting randomized controlled clinical trials, or the STROBE checklist¹⁷ when reporting on observational clinical studies. These should be used in conjunction with the TIDieR checklist¹⁵ for better reporting of the clinical interventions used in the trials.

Following the best practices is essential for producing high quality evidence. However, it is outside the scope of the present paper to give a complete guide on conducting and reporting clinical research in general, but we provide a non-comprehensive list of the most important recommendations from the sources listed above in Supplement 1.

However detailed the above-mentioned domain general guidelines may be, they do not cover some methodological elements that are specifically important to report in clinical hypnosis research, or they do not cover them in sufficient detail. Accordingly, the Task Force created this list of recommendations that are specific to trials involving hypnosis. Importantly, the recommendations presented below are designed to be used as a supplement to the above mentioned, field-general guidelines and checklists for clinical trials.

We present our recommendations in two tiers. In Tier I we list essential recommendations that should apply to all or most prospective controlled clinical hypnosis trials. Tier II recommendations also promote high quality research and reporting, but they are more situational, and might not apply or might not be feasible in some clinical trials. A summary of these recommendations is listed in Box 1. Below, we provide context and reasoning for these recommendations.

Box 1. List of recommendations for conducting and reporting controlled clinical trials assessing the efficacy of hypnosis interventions.

Tier I - Essential Recommendations for Research Practice

Designing and conducting studies

- Use detailed research protocols or treatment manuals, intervention scripts, and/or recorded interventions for all study groups.
- Specify the procedures used for participant-education about hypnosis.
- If hypnotizability is measured in the study, use a validated scale with sound psychometric properties.

Reporting

- Make hypnosis scripts, recordings of the intervention, or manuals of the intervention available directly in the manuscript, as a supplement, or as an external reference or link where the materials can be easily accessed by interested parties.
- Describe in detail the procedures for participant education about hypnosis. If it was manualized, provide access to the manual; if not, describe the general approach taken in the study for participant-education about hypnosis.
- Clearly describe the hypnotic induction procedure. If it was manualized, provide access to the manual; if not, provide enough detail so that the induction used could be replicated by others.
- Describe how the intervention was labeled to participants (eg, whether it was presented to them as “hypnosis”).
- Describe the criteria, rationale, or definition used to determine that the intervention was considered hypnosis (or hypnosis-based).
- If hypnotizability was measured in the study, describe in detail how it was measured (including the timing of measurement within the sequence of study procedures, the scale used, the mode of administration [online vs in-person; live vs recorded] and the role of the person(s) administering the measurement and whether they were blind to group allocation and outcome data).
- If hypnotizability was measured in the study, describe the psychometric properties of the hypnotizability scale used, including the internal consistency in the study sample.

Tier II - Preferred Recommendations for Research Practice

Designing and conducting studies

- Measure adherence to any home practice or homework that is a part of the treatment.
- Assess participant hypnotizability.
- Utilize someone other than the interventionist to assess hypnotizability.
- Use a hypnotizability measure that takes into account both subjective and behavioral measures of responsiveness.
- Do not restrict enrollment to only high and low hypnotizable individuals.
- Assess response expectancy using validated measures.
- Use valid measures to assess the level of rapport, therapeutic alliance, or therapeutic relationship between the client and the therapist (if any).
- Include measures of variables that may elucidate potential mechanisms of action of the hypnosis intervention.

Reporting

- Report information about participants' prior experiences with hypnosis (eg, whether participants were naive to hypnosis, or whether they had prior experiences with hypnosis, and if known, what were these experiences).
- Report response expectancies pertaining to relevant outcomes separately for different intervention groups and, if measured, for different levels of hypnotizability.
- Report the associations between response expectancies and the study outcomes.

Notes on Tier I. Essential Recommendations for Research Practice.

Use detailed research protocols or treatment manuals, intervention scripts, and/or recorded interventions for all study groups. The use of a detailed research protocol or treatment manual, intervention scripts, and/or recorded intervention is needed to ensure that the intervention is delivered as intended for all participants. A sufficiently standardized intervention protocol in combination with good training of interventionists can ensure that the intervention is consistently delivered. Consistency in the implementation of treatment procedures leads to less noise in the data and improves statistical power.²⁷ Moreover, use of and reporting of a detailed and standardized research protocol optimizes the possibility of accurate replication of the tested intervention in future studies. Standardization does not have to mean that every participant receives exactly the same intervention. Intervention manuals can include strategies for tailoring the intervention in a controlled manner, which might increase intervention effectiveness.²⁸ The procedure should be similarly detailed for control and treatment groups to achieve these benefits.

Specify the procedures used for participant-education about hypnosis. A client's or study participant's expectations, hopes, and misconceptions related to hypnosis are important factors in determining treatment success.²⁹⁻³¹ Thus, the research protocol or the intervention manual should specify how the patient is introduced to and/or educated about the hypnotic intervention, to ensure that these processes are standardized across participants. For example the APA Division 30 brochure "Hypnosis: What it is and how it can help you feel better" can be used as an aid for participant education, and to dispel negative expectations about hypnosis^{32(p30)} during a discussion about the intervention with the therapist.

If hypnotizability is measured in the study, use a validated scale with sound psychometric properties. There are a variety of scales available to assess hypnotizability.³³⁻³⁵ We

recommend using scales that have demonstrated reliability (internal consistency or test-retest reliability) of at least 0.70, and scales that have been validated, because these improve statistical conclusion validity and internal validity of any research claims connected to hypnotizability.³⁶ Scales that have been shown to have good reliability and validity at the time of writing this paper include the *Stanford Hypnotic Susceptibility Scale: Forms C* (45-60 min to administer),³⁷ the *Barber Suggestibility Scale* (10-15 min to administer),^{38,39} the *Elkins Hypnotizability Scale* (25-30 min to administer),⁴⁰⁻⁴² the *Waterloo-Stanford Group C (WSGC) Scale of Hypnotic Susceptibility* (45-60 min to administer),⁴³ and the *Harvard Group Scale of Hypnotic Susceptibility: Form A* (45-60 min to administer).^{44,45} It is important to note that current hypnotizability measures have several limitations, and further improvements are necessary to boost the utility of measuring hypnotizability in clinical hypnosis research, see for example.³³

Share hypnosis scripts, recordings of the intervention, or intervention manuals. The reproducibility of the interventions that are described in research papers is crucial for both clinicians and researchers. This is recognized by international reporting guidelines for clinical research study protocol and research reports such as CONSORT and SPIRIT.²³ Subsequently, these guidelines have been supplemented by a TIDieR.¹⁵ As stated above, the Task Force recommends following the TIDieR guidelines for reporting clinical interventions.

TIDieR gives clear instructions on what details should be shared about interventions. However, the Task Force provides some instructions that refer specifically to hypnosis treatments, which should be used as a supplement to TIDieR. Specifically, the Task Force recommends that in order to ensure the reproducibility of treatment protocols, the authors should provide the hypnosis scripts, recording, and treatment manual (all that are available) as a supplemental file or appendix to the publication, or via an external reference. If for some reason direct publication

of the script/recording or intervention manual is not possible, one of the following alternative options is advised: (a) use a protected repository (a non-complete list of such repositories can be found on the Open Science Framework as Approved Protected Access Repositories at <https://osf.io/tyyxz/wiki/8.%20Approved%20Protected%20Access%20Repositories/>); (b) clearly state that the script/recording/manual is available upon request by other researchers together with details on how and under which circumstances access will be granted; or (c) clearly state that the script/recording/manual will not be shared, and state the reason(s). In these shared materials, inform potential future users regarding appropriate hypnosis training and supervision of sessions. Without appropriate clinical hypnosis competence, the interventions could be less effective or even harmful.

Describe the procedures for participant education about hypnosis. TIDieR also instructs authors to share the informational materials used in the intervention provided to participants and intervention deliverers. For hypnosis interventions, this instruction should extend to clearly describing the procedure used for informing the participant about hypnosis, so this can be reproduced along with the other elements of the intervention. For example, was participant education about hypnosis manualized? If so, make the manual available. If not, describe the general approach taken in the study to educate and orient participants about hypnosis.

Describe the hypnosis induction, how the intervention was labeled for participants, and how hypnosis is conceptualized in the study. Despite several efforts, there is still no universally accepted definition of hypnosis. For example, the latest definition published by the Hypnosis Definition Committee of the American Psychological Association Division 30 was formulated by a group of prominent researchers in the field.⁴⁶ However, it was immediately followed by critical opinion pieces published in the same journal issue formulated by equally prominent researchers most of whom are members of the same professional society, see eg.⁴⁷ Given the lack of consensus regarding what constitutes hypnosis, it is not surprising that there is an inconsistency in the literature about what is considered a hypnosis intervention or a hypnosis-based intervention. Interventions such as guided imagery, autogenic training, therapeutic suggestions, and Ericksonian conversation may be considered hypnosis-based treatments by some, but not by others. Settling the issue of definition is outside the scope of this paper. Nevertheless, the Task Force recognizes the need for more clarity in the reporting of the interventions utilizing hypnosis.

One of the signature components of hypnosis interventions is a hypnosis induction procedure, which is simply defined in the latest APA Division 30 definition paper as “A procedure designed to induce hypnosis.” However, there are interventions that are considered hypnotic or hypnosis-based by some researchers that do not involve a formal hypnosis induction. The Task Force recommends that it should always be reported in clinical hypnosis research papers whether or not the intervention included a formal induction, and if so, this procedure should be described in detail.

Another important issue is the labeling of the intervention to the research participants. Sometimes clinicians and researchers do not identify the intervention as hypnosis. Some studies have shown that the use of the label “hypnosis” on an intervention can itself contribute to an increase in the treatment effect compared to an identical intervention labeled differently.⁴⁸⁻⁵⁰ Accordingly, we recommend that authors make clear whether an intervention was identified as hypnosis to participants, and if not, how it was labeled or described to them. Note that the use of the label “hypnosis” does not always result in increased response to hypnotic suggestion. For example, some studies have indicated that sizable proportions of participants are less responsive to verbal suggestions following a hypnotic induction.^{51,52} However, this effect has been only demonstrated in laboratory studies so far, and might not be generalizable to clinical contexts. One reason for this is the higher motivation of clinical patients.⁵³ More research is required to be able to properly predict the effect of labeling the intervention as hypnosis for a given individual.

Finally, it is important to clarify whether the authors themselves consider the treatment they used to be a hypnosis intervention or a hypnosis-based intervention, and if so, the rationale underlying their beliefs. This may be trivial in some cases, for example if the researchers used a formal induction. However, if there is no formal hypnosis induction, it is important to clarify why the treatment is considered a hypnosis intervention. For example, the authors might argue that even though no formal hypnosis induction was used, the intervention was labeled hypnosis for the participants, and they consider this intervention as hypnosis in the theoretical framework of Kirsch⁵⁴ wherein the only specific ingredient of a hypnosis treatment is the label “hypnosis.” Alternatively, another might argue that even though no induction was used, they worked with patients in the emergency room who suffered traumatic injury, so they had a narrow focus of attention and were in an altered state of consciousness, so they are considered to be in a naturally occurring hypnotic state based on the recent APA Division 30 definition of hypnosis⁴⁶ (although it should be noted that hypnosis of such a kind is controversial). Importantly, in this recommendation we are not identifying either of these rationales, or any others, as correct or incorrect. Rather, we are advocating for clarity about the rationale of the authors. Such clarity will help clinicians and researchers to better place the intervention in their theoretical frame of reference, and it will also help reviewers of the literature to be able to accurately group similar interventions together, in order to achieve a clearer picture of efficacy.¹⁸

Describe in detail how hypnotizability was measured. The Task Force recommends that detailed description should be given about how hypnotizability was measured in the study. The report should include the timing of the measurement of hypnotizability within the sequence of study procedures, since it is possible that knowledge of hypnotizability might influence expectancies of treatment outcome by both participants and researchers. Furthermore, although hypnotizability is generally considered as a stable trait,⁵⁵ it is important to

note that several studies indicate that hypnotizability can be increased with various approaches, such as hypnotizability training,⁵⁶ altering expectancy^{57,58} (but some failed replications also exist, eg⁵⁹) and sensory deprivation.⁶⁰ Modification effects tend to be modest but could be clinically meaningful in certain contexts. It is possible that extensive practice with hypnosis, which is not uncommon in clinical studies, could alter the measured hypnotizability values from pre- to post intervention.⁶¹⁻⁶⁴ Thus, it should be noted whether hypnotizability was measured before, after, or during the intervention period, and also, how data regarding participants' hypnotizability levels was managed and concealed. For the same reason, it is important to disclose in the report the role of the person(s) conducting the measurement and whether they were blind to group allocation and outcome data. As mentioned above, there are many hypnotizability scales. Authors should describe the scale used for hypnotizability measurement, its known psychometric properties as reported in previous validation studies, and internal consistency in the sample of their study.

Notes on Tier II. Preferred Recommendations for Research Practice. Measure adherence to any home practice or homework that is a part of treatment. Many hypnosis-based interventions include instructions for home practice exercises for the participants between sessions with the interventionist. This could include listening to recordings of the hypnosis sessions, listening to supplementary hypnosis recordings, or carrying out specific self-hypnosis practice. For example, a recent systematic review on the effects of hypnosis-based interventions on sleep outcomes indicated that more than 50% of the interventions included instructions for home practice.⁶⁵ It is possible that higher adherence to home practice instructions could lead to better clinical outcomes, and there is some evidence supporting this in the psychotherapy literature.^{66,67} However, although it is common to prescribe home practice and homework in clinical hypnosis interventions, very few studies actually measure adherence to the instructions. Accordingly, we recommend that adherence of participants to such instructions is measured in clinical hypnosis studies. Furthermore, it is recommended to use techniques that facilitate adherence to home practice (see^{68,69} for more details). Smartphone and mHealth technology can also be integrated into research protocols to prompt home practice and provide a log of practice session completion.⁷⁰⁻⁷²

Assess participant hypnotizability. Hypnotizability (sometimes called hypnotic suggestibility) refers to trait responsiveness to hypnotic suggestions,⁷³ through the use of a standardized work-sample instrument.³⁵ Even though hypnotizability assessment is not strictly necessary for establishing efficacy of a hypnosis-based treatment in a scientifically rigorous way, the assessment of hypnotizability is recommended when feasible in clinical hypnosis research, because this can help us understand the role that hypnotizability might play in the outcomes of the treatment studied. When the treatment effect is stronger in those participants higher in hypnotizability – as is found sometimes but not always eg⁷⁴ that provides greater

evidence that the effect is related to trait hypnotizability, and thus, to the hypnotic suggestions used in the intervention.³⁵ Nevertheless, it should be noted that the predictive utility of hypnotizability on clinical outcomes tends to be small to medium in most clinical studies, eg.^{10,75} Thus, in research where hypnotizability as a correlate or moderator of clinical outcomes is of central interest, the study should be powered accordingly with large sample size targets.

Utilize someone other than the interventionist to assess hypnotizability. The knowledge of the hypnotizability of a participant could potentially influence the therapeutic process in multiple ways. In some cases this could be beneficial, where the intervention can be individualized to accommodate different needs based on different hypnotizability levels of participants. However, this knowledge could also be a threat to construct validity in assessment of the clinical impact of an intervention. For example, if the interventionist or another staff member knows or suspects that a participant has low hypnotizability, they might expect the participant to be less responsive to the treatment, which might turn into a self-fulfilling prophecy. Participants might also respond differently due to demand characteristics. For example, if the participant's hypnotizability was measured by the interventionist, and it was low, the participant might act in ways that would reinforce that they are less responsive to the treatment, whereas if the interventionist is unaware of their hypnotizability level, they might act more freely. Or the interventionist might consciously or unconsciously invest less energy into the treatment, since they believe the participant to be a low responder. Thus, in research studies where hypnotizability is measured, it is important to evaluate the risks and benefits of concealing the level of hypnotizability from different research staff members. One method for doing this would be assessment of hypnotizability by a data collector trained in hypnosis who is blind to treatment conditions. Another would be to measure hypnotizability only after the outcomes have been assessed. Even the latter approach could produce biases, such as participants displaying greater hypnotizability purely because they expected to do so after displaying a positive response to the intervention. In any case, these variables should be transparently reported. Sometimes it is possible to measure hypnotizability and the other variable(s) in different contexts (eg two different courses at a university), and interrelate them only afterwards.

Use a hypnotizability measure that takes into account both subjective and behavioral measures of responsiveness. Responsiveness to suggestions is traditionally measured via observable behavioral reactions in the most commonly used hypnotizability scales such as the *Stanford Hypnotic Susceptibility Scale: Forms A, B, and C*,³⁷ and their group versions, the *Harvard Group Scale of Hypnotic Susceptibility: Form A*⁴⁵ and the *WSGC Scale of Hypnotic Susceptibility*.⁴³ However, the effects of hypnotic suggestions can also be manifested in subjective experiences, and sometimes, suggested effects might only manifest in subjective experience and not lead to changes in overt behavior. Furthermore, a purely behavioral scoring is stipulated to be prone to bias from social compliance,

and taking into account subjective experiences might correct this bias.⁷⁶⁻⁷⁸ Thus, multiple scales incorporate subjective as well as behavioral scoring of hypnotic suggestibility.^{40,79,80} This can also improve the content validity of the measurement. Thus, we recommend the use of hypnotizability scales that incorporate both behavioral and subjective scoring. See also.⁸¹

Do not restrict enrollment to only high and low hypnotizable individuals. When the sample composition is based on hypnotizability, it is recommended to include medium hypnotizables as well (instead of contrasting high vs low hypnotizables), as medium hypnotizables form the majority of the general population.^{35,82-84} This will increase the generalizability of the study findings. The inclusion of medium hypnotizables, and avoidance of extreme-groups designs,⁸⁵ can also be informative for mechanistic research.^{53,86} Including the medium hypnotizability range can also help to uncover non-linear relationships between hypnotizability and the outcome or other moderating variables. shed light on potential curvilinear relationships.

Assess response expectancies of participants using valid measures. Response expectancies for relevant outcomes are an important predictor of treatment outcome in nearly all forms of psychological treatments, including hypnotherapy,²⁹ and they are proposed as a major causal component of treatment effects in some theories of hypnosis.⁵⁴ Thus, in interventional studies where expectancy is considered as a potential mechanism, researchers should consider the measurement of response expectancies for relevant outcome variables before and/or during the intervention in clinical hypnosis trials, and they should analyze and report the relationships of response expectancies relative to the main outcomes. If expectancies are considered a relevant mechanism, researchers should also report descriptive data about expectancies of treatment outcomes in study groups separately, and note whether there were differences in expectancies between the groups at baseline. This can help to evaluate the importance of distinct treatment elements versus common factors as mechanisms for change. Valid measures of response expectancies include the Stanford Expectations of Treatment Scale (SETS),⁸⁷ and the credibility/expectancy questionnaire (CEQ).⁸⁸ At the same time, studies employing such measures should similarly consider whether and to what extent the *measurement* of expectancies shapes behavior through demand characteristics (eg, consistency motivation).

Use valid measures to assess the level of rapport, therapeutic alliance, or therapeutic relationship between the client and the therapist (if any). It has been demonstrated in many studies that therapeutic relationship and related concepts such as therapeutic alliance and rapport, are important factors in determining treatment success.⁸⁹⁻⁹¹ Relatedly, in a recent large-scale international survey among hypnosis practitioners, we found that rapport with the client was rated as the most important factor in producing desirable clinical hypnosis therapeutic outcomes.⁹² Thus, the Task Force strongly recommends the assessment and reporting of the therapeutic relationship, alliance, or rapport between the therapist and the client. These variables can be assessed with various measures with established validity and reliability.^{89,90,93-95}

Attitude toward hypnosis is a construct that is related to several of the recommendations mentioned above. Due to popular media, many people have misconceptions about hypnosis and hypnotherapy that affect willingness to use these interventions as well as outcome expectancy. Rapport and patient education are very important for dispelling misconceptions and fostering a reasonable attitude toward hypnosis-based treatments. Thus, the assessment of attitudes and beliefs about hypnosis might also be beneficial to understand individual differences in treatment responses. The following works provide good summaries about the potential impacts of attitudes and beliefs related to hypnosis.^{96,97}

Include valid and reliable measures of variables that may elucidate potential mechanisms of action of the hypnosis intervention. Response expectancies and the therapeutic relationship are just some of many potential factors that may contribute to the outcome of hypnotherapy, so for certain applications other factors might be additionally, or even more, relevant. Understanding the mechanisms underlying a treatment effect is critically important in clinical research.⁹⁸ It allows for the improvement of the efficacy of the interventions by identifying and focusing on the effective components. It also makes it possible to target the interventions more effectively. Thus, researchers should consider the possible underlying mechanisms of action, and include measurements in the clinical trials that allow for testing and estimating the effect of these mechanistic components. The mechanisms studied should always be based on theory and/or prior findings (see eg⁹⁹; exploratory research can still be informative but should be correctly acknowledged as exploratory).

Report information about participants' prior experiences with hypnosis, and provide a detailed report of response expectancies by outcome and research group together with its predictive power. As noted above, expectations about what will happen during hypnosis, and what are the short and long term benefits and potential harms of the hypnotic treatment, can play an important role in determining the treatment outcomes.²⁹ To develop a better understanding of these factors, and prior influences shaping expectations, the Task Force recommends that the report should document whether participants were naive to hypnosis at measurement, and if not, the report should specify how many and what type of previous sessions they had undergone. Furthermore, response expectancies pertaining to each relevant outcome should be presented separately for different intervention groups or conditions. If the study uses hypnotizability as a predictor of treatment outcome, the relationship between hypnotizability and outcome expectancies should be reported as well. The correlation or predictive power of response expectancies relative to the main outcomes should also be presented in the paper when possible.

Discussion

In this paper, we presented the best practice recommendations for conducting and reporting clinical hypnosis research, formulated by the Task Force. When applied by researchers, the

recommendations are intended to be used right from the planning stage of a research project. This is true even for the reporting guidelines, because these guidelines require data collection as well. The list of recommendations also has other uses. For example, it can be used when assessing the methodological quality and risk of bias of clinical hypnosis research papers for systematic reviews and meta-analyses, or when making clinical recommendations based on the existing literature. The reporting guidelines can also be used during peer review of papers describing hypnosis interventions, and journal editors can endorse or require its use from authors to ensure that submissions concerning clinical hypnosis trials report all necessary information.

The list of recommendations was originally designed to apply to controlled clinical trials involving a hypnosis intervention. However, case studies, feasibility studies, and uncontrolled pilot studies are also critically important in the research ecosystem. In turn, the recommendations may be fully or partially relevant for these types of studies as well, so we encourage researchers and reviewers of non-controlled clinical trials to utilize them where applicable. Furthermore, even though the items specifically focus on hypnosis interventions, these recommendations may inform the design, implementation, and critical evaluation of relevant clinical trials (eg, the use of interventions involving non-hypnotic verbal suggestions) and serve as a model for the development of other mind-body medicine intervention-specific recommendations in the future. Although the recommendations were designed for clinical research, most of them are applicable to laboratory or non-clinical observational studies as well. Thus, we encourage researchers conducting non-controlled clinical trials and non-clinical studies to follow the guidelines from our list of recommendations that apply to their research studies.

The Task Force focused on formulating recommendations that capture the current state of the art, but changes will likely be necessary as the field progresses. Also, the recommendations listed here are designed to be applicable in general to most controlled clinical hypnosis trials. There may be research best practices and reporting guidelines in specific sub-fields and clinical applications that are not listed here, because they are too specific to that area. Accordingly, the list of recommendations should not be considered complete and will be updated in the future. Furthermore, as noted above, there are a host of important recommendations and reporting guidelines that are not specific to hypnosis research. We present these in Supplement 1.

One such area where field-general recommendations already exist is the area of the use of blinding (also known as masking) of people involved in the study with regards to group allocation. This topic has been discussed extensively at the Task Force meetings, so even though this issue is not included in the list of recommendations, we still wanted to mention it in the paper. Blinding study participants, research personnel, and data assessors has a long tradition in medical research, and for good reasons, the main one being that it prevents or reduces threats to construct validity related to participant and researcher expectations.¹⁰⁰ The main benefit of blinding

participants in terms of their group allocation is to be able to distinguish the effects of the intervention-specific components from the effects of common factors such as expectancies. However, the use of blinding is much more controversial when it comes to psychotherapy research.¹⁰¹ Particularly, as discussed above, both research evidence and theory indicate that response expectancy is a crucial effective component of psychotherapy, and hypnosis-based interventions especially.^{29,102} Thus, making participants unaware or uncertain whether they are receiving an intervention could interfere with the treatment, and in some cases could possibly be ethically questionable.¹⁰³ Furthermore, the distinction between the effects of intervention-specific effective components and common factors is not crucial to establishing efficacy of clinical hypnosis trials. Hypnosis can be highly efficacious even if the sole causal factor is response expectancy. Taken together, the Task Force does not consider participant-blinding in terms of receiving a hypnosis treatment strictly necessary in efficacy trials of clinical hypnosis interventions.

However, this is not to say that blinding of participants would be useless in clinical hypnosis trials. If the effect of expectancy on the outcome is of central interest, blinding through the utilization of a placebo control or a minimally effective control condition may be useful.¹⁰⁴⁻¹⁰⁷ For example, blinding of participants as to whether they are in the active treatment arm can be achieved with supportive listening, a placebo intervention specific to their condition, or a minimally effective hypnosis treatment condition such as a hypnotic induction without specific treatment-oriented suggestions. Blinding of participants can hold additional benefits as well, such as decreased likelihood for dropout or seeking additional adjunctive interventions.¹⁰⁰

Furthermore, the use of blinding for research personnel, such as data collectors, data analysts, or the principal investigator, and members of the medical care team, such as physicians, psychologists, or nurses, with regards to group allocation is essential to mitigate threats to construct validity. The benefits include (but are not limited to) lower likelihood to transfer expectations and attitudes about intervention effectiveness to participants and to bias results through differentially adjusting dose, withdrawing participants, or encouraging or discouraging participants to continue in the trial, and so on.¹⁰⁰

The Task Force discussed recommendations related to hypnotizability scales extensively. While in some clinical studies, application of the above highlighted scales are appropriate, in some clinical settings it is not feasible to include some or any of them. One of the common reasons for not including hypnotizability measurement in therapy is time constraints. Some of the above mentioned tests take a considerable amount of time to administer, often as long or more than the clinical intervention itself. Another reason might be the inappropriateness of the items used in the scale for the clinical context or the sample. There are multiple hypnotizability scales that are designed to overcome these challenges, which are often referred to as “clinical scales”, such as the Stanford Hypnotic Clinical Scale,¹⁰⁸ Elkins Hypnotizability Scale—Clinical Form,⁴⁰ and

the Hypnotic Induction Profile.¹⁰⁹ The clinical scales generally have poorer psychometric properties than the laboratory scales, so when possible, the Task Force recommends the use of the laboratory scales.^{108,110,111} Nevertheless, if the use of the laboratory scales are not feasible, the researchers might consider using a clinical scale, taking into consideration the tradeoff on the reliability or validity of the measurement.

Advances in digital technology can make the adoption of best practice guidelines easier. As mentioned above, such tools can enable objective monitoring of home practice, and even facilitating adherence via gamification. Mobile apps can make intervention delivery standardized while enabling self-administration, drastically increasing the reach of clinical interventions. Short, informative online materials can aid in participant education about hypnosis in a standardized fashion. Computerized hypnotic suggestibility scales such as the HIP/App¹¹² or the SWASH¹¹³ can help in scaling up hypnotizability measurement or screening, or with further development may even enable automation of these research steps, which could also help in maintaining blinding of the interventionist with regards to the hypnotizability of the participant. Digital tools can also make it very easy to transparently report methods used enabling close reproducibility. Similarly, using electronic data capture in research workflows can increase the reliability of data management while at the same time making data sharing easier. Future developments in digital technology will no doubt unlock more potential for conducting high quality research.

In implementing the recommended guidelines for conducting clinical trials on hypnosis interventions, researchers may encounter several practical challenges. For example, writing up research protocols and treatment manuals can be time consuming. A manual with too little detail might be misinterpreted by research or clinical staff, while a manual with too much detail is not handy in day-to-day operations, and important details might be missed just due to information-overload. Thus, piloting the manual is important as well as supplementing it with summaries and checklists for day-to-day use. Another practical challenge can be changing previous habits. Researchers, clinicians, and study participants may have established habits or preconceived notions about hypnosis that could influence their adherence to the recommended protocols. For instance, clinicians accustomed to more traditional therapeutic approaches may find it challenging to adopt standardized hypnosis induction procedures or to accurately implement scripted interventions. Overcoming these challenges requires targeted efforts to educate and familiarize stakeholders with the rationale and procedures underlying the recommended guidelines, as well as ongoing support and training to facilitate adherence to standardized practices. Additionally, fostering a culture of openness to new methodologies and a willingness to adapt existing practices can help mitigate resistance to change and promote the adoption of best practices in hypnosis research.

Finally, it is important to note that methodological quality and reporting practices are not the only areas where the field of clinical hypnosis research can improve. In addition to the issues mentioned already, the presence of publication bias (ie,

the inordinately high proportion of positive findings in the literature, especially among studies with low sample sizes), and large heterogeneity among hypnosis research studies also limit the generalizability of the findings and result in more cautious recommendations by reviewers of the field. This indicates a need for a field-wide improvement in publication (eg, pre-registration, publication of non-significant results, registered reports) and in the standardization of research.

Conclusions

The present article summarizes two years of deliberations of the *Task Force for Establishing Efficacy Standards for Clinical Hypnosis*. The Task Force reviewed widely respected best practice principles including the CONSORT statement,¹⁶ TIDieR checklist,¹⁵ and the Cochrane Handbook for Systematic Reviews of Interventions¹⁹ and developed best practice guidelines for research and reporting for clinical research in hypnosis. The guidelines are presented in two tiers: Tier I includes essential recommendations that should apply to most prospective controlled clinical hypnosis trials, whereas Tier II includes recommendations that are more situational.

The Tier I guidelines aim to increase the standardization and clarity of research and treatment protocols, and to promote the use of valid and reliable measures. They also recommend sharing research materials such as manuals and scripts, clear description of participant education and hypnosis induction, and reporting details about the hypnotizability measurement. Tier II includes recommendations for facilitating and measuring adherence, assessment of hypnotizability with robust measures by someone other than the interventionist and including participants from the whole hypnotizability spectrum. Tier II also includes guidelines for measurement and reporting of response expectancy and the therapeutic relationship, and assessment of potential other mechanisms.

Researchers should keep these guidelines in mind while research studies are designed and implemented, to ensure that the required information will be available for the research report. The Task Force recommends that hypnosis researchers carefully follow these best practice and reporting guidelines in order to elevate the quality of research designs in the clinical hypnosis field. The field of evidence-based healthcare has increased the standards for research on clinical applications, and if hypnosis is to be considered as an evidence-based behavioral intervention, then its evidence must be of the highest quality.

Abbreviations

CONSORT	Consolidated Standards of Reporting Trials
TIDieR	Template for Intervention Description and Replication
STROBE	Strengthening the Reporting of Observational studies in Epidemiology
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
Task Force	The Task Force for Establishing Efficacy Standards for Clinical Hypnosis

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Author Contributions

ZK drafted the guidelines based on the Task Force meetings, was involved in coordinating Task Force discussions on the guidelines and led manuscript write-up.

DM initiated the Task Force, was involved in coordinating Task Force discussions on the guidelines and participated in manuscript write-up. GDB, GE, DBT, KV, OP, PDS and PJW attended the meetings of the Task Force on the guidelines, contributed to formulating and editing the guidelines, reviewed and approved the final wording of the guidelines, and participated in writing the manuscript.

Availability of Data and Materials

The dataset(s) supporting the conclusions of this article is(are) included within the article (and its additional file(s)). The online supplement (Supplement 1) is also accessible at: <https://osf.io/t832x>

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