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Getting Feasibility Right: Practical Recommendations for Designing and Evaluating Feasibility Studies in Complementary and Integrative Health Research

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Abstract

Feasibility studies represent an important stage in the research pipeline, ensuring that essential building blocks are in place before conducting subsequent definitive clinical trials. While the principles of rigorous feasibility trial design apply across scientific fields, their application to mind and body interventions merits discussion. Mind and body interventions such as meditation, yoga, and tai chi, are complex, behaviorally driven, and require high delivery fidelity. Aligned with the NCCIH Research Framework, feasibility research functions as an iterative process of intervention refinement and optimization to guide translation across the research pipeline. The goal of feasibility work is not to test hypotheses about the effects of an intervention, but rather to inform the planning of a future large-scale trial by assessing key a priori benchmarks of feasibility/acceptability. This article focuses on the utility of feasibility studies in complementary and integrative health research and offers practical recommendations on design and evaluation practices. Our aim is to provide investigators with a detailed roadmap on the "dos and don'ts" of conducting feasibility studies that improves the rigor, reproducibility, and impact of complementary and integrative health research.

Keywords

feasibility, acceptability, mind and body interventions, complementary and integrative health, pilot trial, methods

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Introduction

Feasibility studies are a critical step in the research pipeline. They ensure that the essential building blocks are in place for future large-scale clinical trials that are viable, acceptable, and logistically possible. By identifying and addressing potential barriers, such as recruitment challenges, protocol adherence issues, or implementation fidelity, feasibility trials help avoid conducting larger studies that are unlikely to yield meaningful results. In this way, feasibility trials are an investment in getting larger efficacy or effectiveness trials right,[1] increasing the likelihood that subsequent clinical trials produce rigorous and reproducible results.

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The terms *pilot study* and *feasibility study* are often used interchangeably, although some have argued that a feasibility study is a more overarching term and that a pilot study refers to a subset of feasibility work focused on rehearsing the full trial protocol.[2-4] In this present manuscript, we will use the term *feasibility study* to mean a small-scale test of the methods and procedures to inform the design and conduct of a future definitive trial.[5,6] Questions such as "Can I recruit my target population?" "Can I randomize them?" or "Is the intervention acceptable to participants?" – paired with clearly defined and measurable benchmarks – are central to feasibility work. Put simply, feasibility studies should be used to determine if the clinical trial can be done, not whether the intervention works.[5]

Feasibility studies can be particularly important for complementary and integrative health research. The National Center for Complementary and Integrative Health (NCCIH) characterizes complementary and integrative health approaches by their primary therapeutic inputs (i.e., nutritional, psychological, and physical), which are often used concurrently with one another and with conventional therapies such as pharmaceuticals.[7] These include mind and body interventions such as meditation, yoga, and tai chi, as well as natural products like medicinal plants, probiotics, and dietary supplements. This article focuses primarily on feasibility studies conducted in the context of mind and body interventions. Like other behavioral interventions, mind and body interventions are inherently complex.[8] They require high delivery fidelity, can create burden for staff and participants, and may present unique challenges to adherence. Rigorously designed feasibility studies are essential for addressing these challenges, yet limited guidance exists on how best to design and evaluate such trials in complementary and integrative health research.

Drawing on the literature and our own extensive experience, this manuscript updates and expands our earlier recommendations on the "Common Uses and Misuses" of feasibility studies published on the NCCIH website.[5] We begin by describing the relevance of feasibility across the research pipeline, aligning with the NCCIH Research Framework[9] and the NIH Stage Model.[10,11] Later sections provide practical recommendations on justifying when feasibility studies are needed, their design, and analysis. These recommendations are summarized throughout the manuscript as a series of "Feasibility Checkpoints." The overarching goal of this paper is to offer a resource that helps to advance the quality and impact of complementary and integrative health research involving mind and body interventions.

Relevance of Feasibility Studies Across the Research Pipeline

The NCCIH champions rigorous investigation on the utility and safety of complementary and integrative health approaches to improve health and healthcare.[7] A key tool to achieving this mission is the NCCIH Research Framework.[9] The conceptual framework delineates six stages of research, spanning from basic and mechanistic research to dissemination and implementation science (Figure 1). Although the NCCIH framework focuses on complementary and integrative health interventions, it overlaps partially with the National Institute of Health (NIH) Stage Model for Behavioral Intervention Development.[10,11]

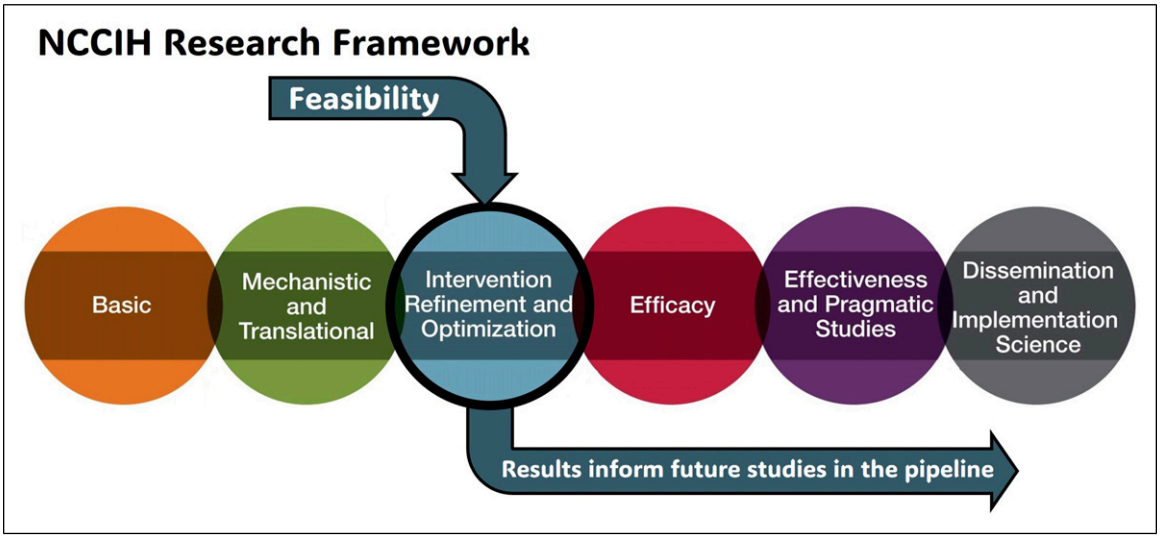


Figure 1. NCCIH Research Framework. Conceptual framework for NCCIH-funded research on complementary and integrative health interventions, emphasizing the importance of feasibility work in supporting later-stage translation of clinical trials

Both the NCCIH framework and NIH Stage Model emphasize protocol refinement and optimization via an iterative process of feasibility testing. When appropriately used, feasibility can be key to research translation by providing information to refine protocols and optimize clinical impact before advancing to a future definitive trial. For example, feasibility work can be conducted to determine whether a novel population finds a mind and body intervention acceptable, are willing to be randomized to treatment conditions, and can receive a sufficient intervention dose.[12-14] A feasibility trial may also evaluate – when justified – the feasibility and acceptability of combining evidence-based intervention components into a multicomponent intervention.[15] Moreover, feasibility is useful in preparing for late-stage translation by identifying contextual factors (e.g., culture, workflow, staffing, reimbursement) and patient preferences that might hinder or facilitate implementation of mind and body approaches in real-world settings.[16-19] Learning that a trial design or approach is not feasible and should not procced to further testing is also informative.[3]

Feasibility studies can also provide an opportunity to adapt or tailor interventions to enhance their fit within specific contexts. For example, several large-scale efficacy and effectiveness studies have shown that mindfulness-based interventions (MBIs) are effective for managing pain and psychological symptoms.[20-22] The increased demand for these interventions, in part, has led to efforts to adapt evidence-based MBIs to improve outcomes in different populations and contexts.[23] Feasibility studies can be useful for assessing whether adaptations to mind and body interventions improve fit and acceptability with the target population or delivery context.[24] Adapting evidence-based interventions also carries risks and thus requires strong scientific justification. Understanding intervention core functions and forms is critical as adaptation of foundational functions may decrease efficacy instead of improving fit.[25] Adaptations are also time and resource intensive, and their implementation may pose unique complexities.[23] Referring to systematic reviews and engaging stakeholders to assess whether adaptations are needed and how to proceed can be useful.

Importantly, strong scientific justification overall is essential before embarking on feasibility work (Figure 2). Investigators should describe and justify the need for feasibility data and ensure that no other published or completed pilot studies have already demonstrated feasibility with a similar population and similar intervention. Justification should also demonstrate why the intended future efficacy, effectiveness, pragmatic, or implementation science trial is needed and how the current proposed feasibility study will provide novel information that is scientifically necessary for the planning and conduct of said future trial. Feasibility studies should not be treated as a routine preliminary step, but as an opportunity to ensure the various elements of the planned future trial are strong enough to move forward in the research pipeline.

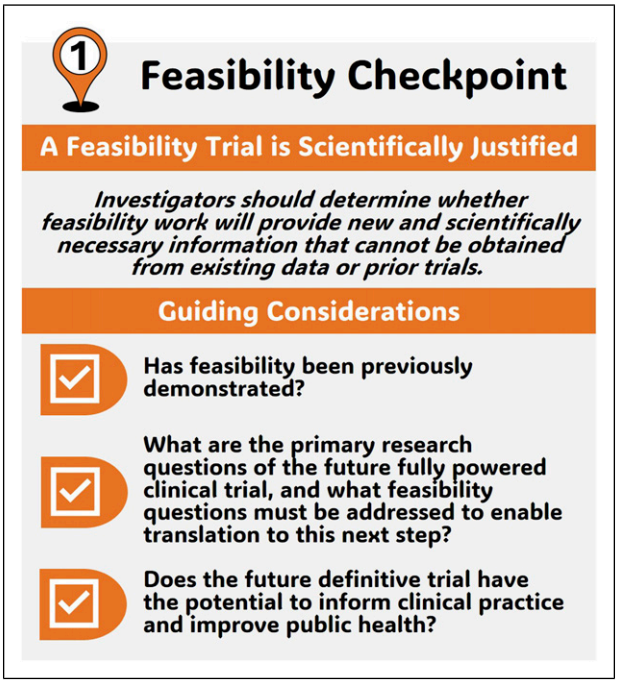


Figure 2. Check Point 1: A Feasibility Trial is Scientifically Justified. Guiding questions investigators may consider to justify the need for a feasibility study

Designing Feasibility Trials

It is recommended that feasibility studies be designed to reflect, to the extent possible, the structure and procedures of the future intended trial.[2,6,26] This approach allows investigators to evaluate key practical issues that could influence the success of the subsequent adequately powered trial.[27] Importantly, the goal of feasibility work is not to test hypotheses about efficacy or effectiveness (for reasons that will be discussed later), but to ensure that the future trial is both scientifically rigorous and operationally achievable.

What Feasibility Should be Designed to Do

By aligning closely with the future trial design, feasibility studies should be designed to evaluate issues related to the practicality and viability of moving forward with a future definitive trial. In this sense, feasibility studies function to establish the building blocks upon which a full-scale definitive trial is conducted. Before efficacy or effectiveness can be tested, the foundation must be laid by demonstrating that recruitment, retention, fidelity, acceptability, randomization, data collection, and other operational procedures are achievable in the intended population and context. Without these building blocks established, any attempt to evaluate efficacy or effectiveness is premature and risks generating misleading or invalid conclusions. Moreover, proceeding to a fully powered definitive trial without evidence that the study procedures are feasible raises ethical concerns. Clinical trials require substantial time and resource investments by participants and the healthcare or community sites that serve them. Some interventions may also involve inherent risk. Conducting a large-scale trial without evidence that the core design elements are feasible unnecessarily exposes participants to potentially risky interventions and/or research burdens without a reasonable likelihood that the study can answer whether the intervention works.

Choosing Feasibility Benchmarks

A central step in feasibility study design is establishing a priori benchmarks to evaluate if the building blocks of a trial are strong enough to support continuation to the future large-scale clinical trial (Figure 3). These benchmarks entail a predefined, quantitative or qualitative threshold set before the initiation of a study that specifies the minimum level of performance required for a given feasibility outcome.[2,3,5] They provide an objective standard against which feasibility can be assessed, reduce the risk of post hoc bias in interpreting results, and guide decisions about whether and how to proceed to a larger definitive trial. Benchmarks should be realistic yet meaningful and aligned with the demands of the planned future trial. Moreover, they should be defined for all study arms to ensure that feasibility can be evaluated across conditions. Table 1 provides a list of targets, questions, and corresponding benchmarks we commonly see used in feasibility studies. Selection of

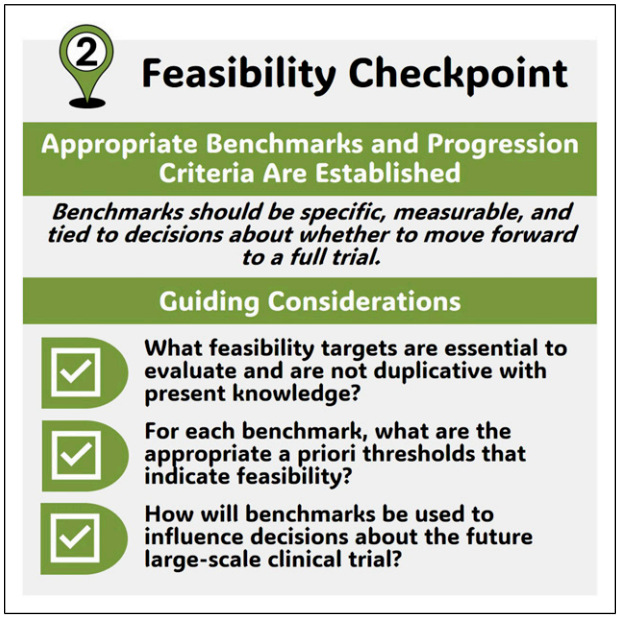


Figure 3. Check Point 2: Appropriate Benchmarks and Progression Criteria Are Established. Guiding questions to consider when selecting a priori benchmarks for evaluation

Table 1. Examples of targets, questions, and a priori benchmarks that can serve as building blocks for evaluating feasibility

Feasibility Target	Question	Benchmark
Recruitment	Can the target population be recruited and enrolled? Are the rates of recruitment and enrollment sufficient to achieve sample size requirements of the future trial? What recruitment methods are most successful?	Proportion of eligible participants screened and enrolled within a specific timeframe; average time to enroll enough participants to form groups, classes, or cohorts; established procedures for tracking success of recruitment methods
Retention	Can participants stay in the study?	Percentage of participants completing all study measurements through follow-up
Adherence	Will participants do what they are asked to do based on their study arm?	Proportion of intervention sessions completed; proportion of home practice completed; adherence rates to other protocol-specific activities, as applicable
Intervention fidelity	Can the intervention and control arms be delivered as intended?	Fidelity assessment of providers to study arm delivery protocols; treatment-specific fidelity rates
Acceptability	Are the intervention and control arms acceptable to participants, providers, and study staff?	Participant/provider/staff satisfaction and willingness to continue in study; acceptability ratings; reasons for dropouts
Randomization	Is the target population willing and able to be randomized?	Proportion of enrolled participants who are randomized and attend at least one intervention/control session; established procedure for maintaining blinding of study staff
Data collection methods	Are the proposed data collection procedures feasible, acceptable, and not overly burdensome?	Adherence rates to study data collection protocol; percent of study measures collected within the measurement window; reasons for missing data; time taken to complete assessments
Multicomponent intervention complexity	Can multiple intervention components be delivered together with fidelity? Is the multicomponent intervention acceptable to participants?	Proportion of sessions in which all components are delivered as intended; participant adherence across all components; provider ratings of feasibility of delivering combined components
Implementation logistics	Are there logistical barriers (e.g., scheduling, staff training, technology integration; recruitment procedures) that need to be resolved?	Average time from screening to randomization; staff turnover during study period; percentage of interventionists who complete training prior to enrollment; proportion of participants who complete assessments without technical assistance; proportion recruited through planned strategies (e.g., clinic referrals)

benchmarks depends on the needs of the feasibility study. If it is possible to reference successful demonstration of these benchmarks in completed trials or trials currently underway using the proposed or similar intervention and study population, further feasibility work is not justified.

If the future definitive trial will require multiple sites, evaluating multi-site feasibility is recommended to increase generalizability.[9] Sites should be selected intentionally to reflect the setting and population anticipated in the future multi-site clinical trial. Geographic and cultural differences may meaningfully influence access to, and acceptability of, complementary and integrative health interventions. The general logic of selecting benchmarks is similar across single and multi-site feasibility trials, but the focus and level of complexity may differ. Multi-site feasibility benchmarks evaluate whether study processes are reproducible, scalable, and a more representative sample can be recruited and retained. Recruitment methods (e.g., clinician referral, electronic health record screening, community outreach, self-referral) may differ in feasibility across sites. Assessing variability in feasibility metrics across sites provides important information about which strategies are most effective, the expected enrollment rate per site, and how many and what types of sites will be required to achieve adequate sample size in a future fully powered trial.

Fidelity becomes a central feasibility question in multi-site feasibility trials, particularly in the case of delivering mind and body interventions. Multi-site feasibility trials can determine methods for delivering the intervention consistently across sites and establish data collection and collation procedures to minimize data loss. Without this information, it is difficult to know if variability in outcomes is due to the intervention itself or to differences in how the trial was implemented across different settings.

Qualitative Methods

Feasibility studies often include both quantitative and qualitative methods. Quantitative measures are useful for assessing benchmarks described above, while qualitative methods (e.g., interviews, focus groups) can illuminate the "why" behind the numbers, acceptability, and/or the overall readiness of conducting a future large-scale clinical trial. For example, a feasibility study may demonstrate lower than expected adherence rates. Qualitative methods ask participants what parts of the study they found hard to do and how the study procedures could improve.[27] Combining quantitative and qualitative (i.e., mixed-methods) approaches are especially valuable when adapting interventions, assessing acceptability, or refining study protocols. Qualitative or mixed methods approaches are commonly used in early-stage feasibility work to assess barriers and facilitators to future implementation.[28]

Use of Control Conditions

In most feasibility studies, a control condition can provide valuable information about the acceptability of randomization, participant willingness to remain in their assigned treatment arm, and the overall feasibility of delivering different study arms. The choice of control group should be guided by the overarching research question of the future definitive trial.[29] For some mind and body interventions, a sham or placebo control group could serve as a strong comparator condition.[30-32] For other studies, sham treatment may not be possible, and time and attention matched or active control conditions may be preferred.[33,34] If the future large-scale trial will include a pragmatic clinical trial, the current standard of care or usual care is often the comparator condition.[35] The use of waitlist controls is discouraged because they rarely reflect real-world practice, may artificially inflate effect sizes due to participants knowing they will eventually receive the intervention, and do not provide information on long-term engagement.[36] Furthermore, it may be unethical to withhold or unintentionally discourage routine clinical care that could offer benefit.[37] Feasibility trial design characteristics are summarized in Checkpoint 3 (Figure 4).

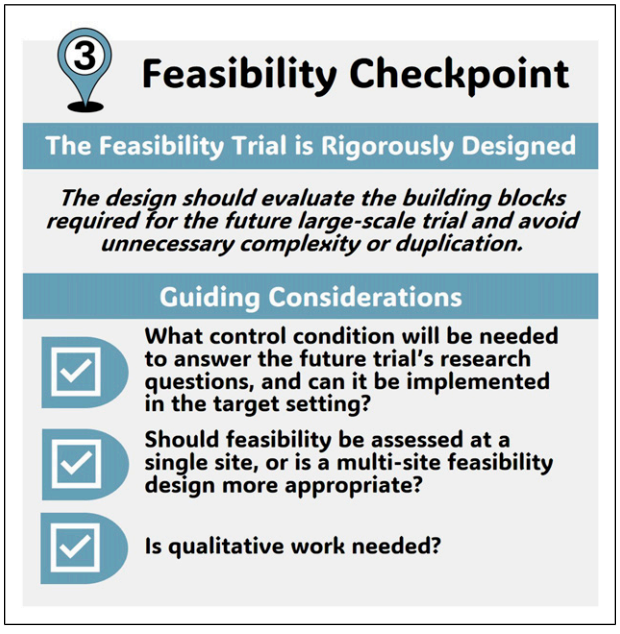


Figure 4. Check Point 3: The Feasibility Trial is Rigorously Designed. Guiding questions investigators may consider when designing a feasibility study

What Feasibility Studies Should Not Be Designed to Do

Underpowered Evaluation of Efficacy or Effectiveness

We commonly see investigators propose to use a feasibility study to evaluate the efficacy, effectiveness, or so-called "preliminary efficacy" of a mind and body intervention on a health outcome. However, feasibility studies are not designed or powered to evaluate such hypotheses.[2,5,27,38] Attempting to do so can produce misleading false positive or false-negative results, which may undermine the credibility of the feasibility work and diminish the perceived necessity of a future full-scale trial. Premature claims of efficacy or effectiveness may risk convincing funders, reviewers, or even investigators themselves that the intervention has already been validated or disconfirmed. In addition, feasibility studies occur at a stage when the optimal methods of implementing the intervention in the target population remain uncertain. Conclusions about efficacy or effectiveness under these circumstances are spurious, as poor implementation fidelity may explain null findings.[5]

Estimating Effect Size

There are significant problems with using feasibility studies to estimate effect sizes between groups.[5,27,38-40] In an underpowered feasibility trial, a large observed effect size may indicate that the true effect is not zero, but the estimate itself is unstable and likely inflated. The effect size often mispresents the true effect and increases the risks of both false positives (Type I error) and, in the case of no effect, false negatives (Type II error). The consequences of which are substantial. If the effect is underestimated, a potentially valuable intervention may be prematurely abandoned or judged unfavorably because the feasibility study failed to demonstrate clinically meaningful differences. Conversely, if the effect size is overestimated and then used to inform sample size calculations, the subsequent full-scale trial may be underpowered, increasing the likelihood of a false negative even if the intervention is effective. For a visual illustration of these problems and their repercussions, see *Pilot Studies: Common Uses and Misuses*.[5]

Importantly, the determination of a clinically meaningful effect size is part of planning a future fully powered efficacy or effectiveness trial and not an objective of the feasibility study itself. Because feasibility studies are not designed to estimate intervention effects, investigators should rely on alternative approaches when planning sample size calculations for subsequent definitive trials. The published literature, expert consensus, and stakeholder input can help define what constitutes a clinically meaningful effect.[5,41] The guiding question to ask is what effect size would be necessary to change clinical practice, guideline recommendations, or health policy. To answer this, convening stakeholder groups of patients, clinicians, or policymakers can be invaluable for identifying outcomes that matter in real-world contexts. In determining what qualifies as a clinically meaningful effect, investigators should also weigh the intensity of the intervention and the balance of potential risks versus expected benefits. Observational data, as well as the effect sizes achieved by established standard of care treatments, can serve as useful starting points. Researchers may need to integrate several of these approaches and define a range of plausible effect sizes.

Evaluating Safety and Tolerability

Another misconception of feasibility studies is that they can be designed to evaluate the safety and tolerability of an intervention. In general, these are not appropriate objectives for feasibility studies due to the small sample sizes used.[5,27] If any safety concerns are detected, group-specific rates with 95% confidence intervals (CIs) should be reported for adverse events.[5] However, there are extreme exceptions to this rule in the event of unfortunate cases where a death or repeated serious events occur.[40] A feasibility trial could be used to examine the feasibility of adverse events reporting. For example, benchmarks could be designed to evaluate the usefulness, level of understanding, and the degree to which a safety survey lacked important safety-related issues.[42]

Statistical Considerations in Feasibility Trials

Sample Size Determination

Although feasibility trials are not powered to detect meaningful differences in outcomes between groups, the sample size still needs justification. Appropriate justifications may be based on the precision needed to estimate feasibility benchmarks, or by practical considerations such as participant availability and budgetary constraints. Teresi et al (2022) notes that feasibility indicators such as recruitment, retention, and adherence should drive sample size decisions, with emphasis on CIs rather than point estimates given the wide CIs expected with small samples.[38] For example, in the case of participant adherence – defined as the proportion of participants who meet the prespecified adherence threshold (e.g. attending 8 out of the total 10 study

sessions) – assuming an overall adherence rate of 70% and aiming for 95% confidence intervals of ±13%, a sample size of 48 participants would provide a reasonably precise estimate. Several rules of thumb have also been proposed. For example, Whitehead, et al (2016) suggests that a sample of 30 per arm (60 total with 2 arms: intervention and control) may be adequate to establish feasibility for quantitative studies.[4] Sim and Lewis (2012) recommend at least 50 participants overall based on considerations of recruitment efficiency and precision of estimates.[43] Lewis, Bromley, and Joseph (2025) offer a multi-objective framework that sizes the study to each feasibility parameter using progression criteria (e.g., go, amend, stop), which is particularly useful when studies involve multiple benchmarks with different thresholds.[44] Qualitative studies often reach saturation with approximately 30 participants in total,[4] though this may vary depending on sample heterogeneity and the depth of data collected.

Overall, the sample size for a feasibility study should strike a balance between the level of precision required to assess feasibility benchmarks to inform future trial planning and the practical constraints of resources, recruitment, and time. It is worth noting that different justification approaches may yield somewhat different sample sizes that could be proposed provided the rationale is transparent.

Descriptive Statistics for Feasibility Outcome Measures

Feasibility outcomes are typically summarized using descriptive statistics. Categorical measures, such as recruitment, retention, and adherence, should be reported as counts and proportions with two-sided 95% CIs to convey the precision of the estimates. Continuous measures, such as time to complete study procedures or number of sessions attended, should be summarized using means with standard deviations or medians with interquartile ranges, as appropriate. These statistics are often provided both overall and for each of the intervention groups, examining estimates within groups can highlight operational differences that may inform the design of a future definitive trial. Such information also provides inputs for planning parameters such as expected attrition and adherence rates.

Analysis of Clinical Outcomes

As a feasibility study is not intended to serve as a preliminary test of intervention efficacy or effectiveness, analysis of clinical outcomes should also remain descriptive. Confidence intervals may be presented for outcomes at a fixed time point, or within-group differences (e.g. pre-to post-intervention within group assessment). Formal hypothesis testing of intervention effect is not recommended, and all findings should be interpreted with caution. Statistical significance should not be inferred from non-overlapping CIs of clinical outcomes from each group, as feasibility trials are not powered to detect meaningful intervention effects.

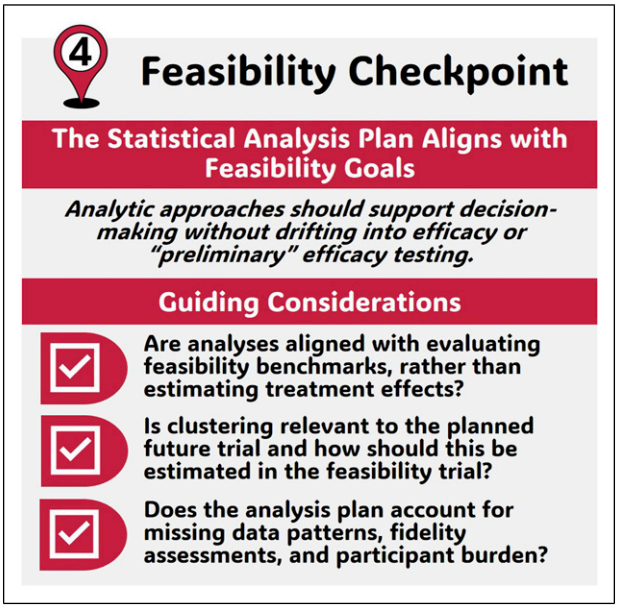


Figure 5. Check Point 4: The Statistical Analysis Plan Aligns with Feasibility Goals. Guiding questions investigators may consider when selecting appropriate statistical analyses

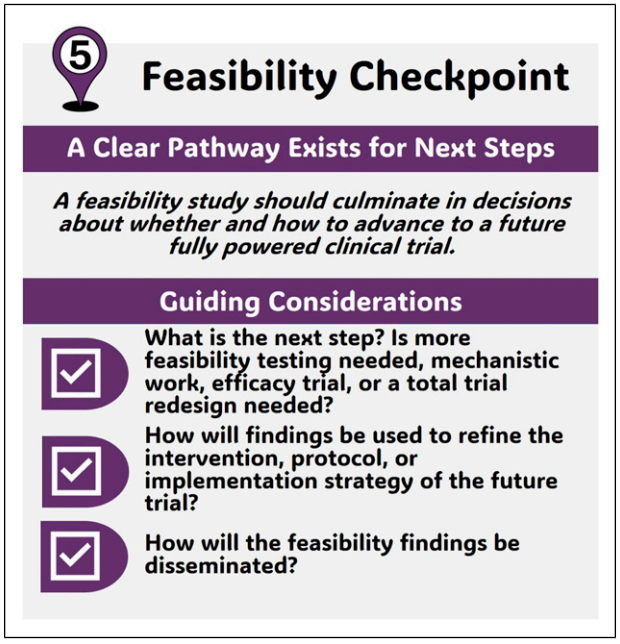


Figure 6. Check Point 5: A Clear Pathway Exists for Next Steps. Guiding questions investigators may consider when planning the next steps after a feasibility study has been completed

Clustering

In mind and body trials, participants commonly receive the intervention in group sessions or by shared interventionists.[45] Such clustering may induce correlation in outcomes within groups, reducing the effective sample size and increasing the type I error rate.[46] Because a fully-powered trial will need to account for this clustering in its design, feasibility studies should mirror the intended interventionist–participant structure of the future trial. Doing so allows the feasibility study to provide preliminary estimates of the degree of clustering, such as the intraclass correlation coefficient (ICC), which can inform sample size calculations and design considerations for the subsequent trial.

Missing Data

Missing data should be carefully monitored in feasibility studies, as the extent and patterns of missingness provide important information about the feasibility/acceptability of trial procedures and participant burden. Understanding where and why data are missing can guide intervention and protocol refinements and improve data collection strategies for a future large-scale efficacy or effectiveness trial. Because feasibility studies are not designed to evaluate intervention effects, statistical techniques such as imputation are not recommended. Instead, the focus should be on transparently reporting the amount and nature of missing data. Including the proportion of missing data as a feasibility outcome with a prespecified benchmark can inform the implementation and acceptability of study procedures. Checkpoint 4 illustrates some of the essential elements of the statistical analysis plan used in feasibility studies (Figure 5).

Conclusion

Feasibility studies play a critical role in advancing complementary and integrative health research by increasing the probability that future large-scale clinical trials are methodologically sound, operationally achievable, and well positioned to generate meaningful evidence. They are best used to answer unresolved questions related to process ("Can I do this?"), rather than to draw premature conclusions about intervention effects ("Does it work?").[5] Key questions of process in mind and body research often include: "Can I recruit my target population?" "Can I randomize them?" "Will participants do what they are asked to do?" Or in the case of a multi-site feasibility study, "Can I deliver the intervention with fidelity across sites?" Ideally, when designed with the future large-scale clinical trial in mind and appropriately selected analytic procedures, feasibility studies should generate results that provide the foundation for informed decision-making on next steps in the research pipeline (Figure 6). These next steps may include additional feasibility or mechanistic work, a trial redesign, or translation to a

fully powered clinical trial. Every attempt should be made to publish feasibility findings (including null or negative results) to inform the mind and body research community and reduce duplication. Adoption of these practical guidelines should facilitate progress toward rigorous, reproducible, and impactful clinical research in complementary and integrative health.

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