



ADVANCING THE CLINICAL EVALUATION OF DAIVA-VYAPASHRAYA CHIKITSA: TOWARDS AN ADAPTED RCT FRAMEWORK

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ABSTRACT

Randomized controlled trials (RCTs) are widely regarded as the strongest design for estimating causal effects. However, the conventional RCT model was developed mainly around interventions that can be standardized, dosed, delivered uniformly and, where possible, blinded. Daiva-vyapashraya Chikitsa presents a different methodological situation. It includes mantra, prayer, homa, fasting and other ritual or spiritual measures whose effects may depend on the practitioner, participant, setting, belief, expectation and manner of delivery. This review examines major limitations of conventional RCT methodology when applied to Daiva-vyapashraya Chikitsa, using methodological literature on non-pharmacological and complex interventions and selected trials of spiritual and mantra-based interventions. Major concerns are intervention heterogeneity, poor standardization, inability to blind participants and providers, difficulty developing credible sham controls, treatment-fidelity problems, expectancy and contextual effects, practitioner effects, outcome selection and tension between internal and external validity. RCTs remain useful, but they should be preceded by intervention development, feasibility work and process evaluation and should use methods adapted to complex non-pharmacological interventions.

KEYWORDS: Daiva-vyapashraya Chikitsa, Ayurveda, randomized controlled trial, mantra, methodology, spiritual intervention.

INTRODUCTION

Evaluating Daiva-vyapashraya Chikitsa with contemporary clinical research methods requires attention to both causal inference and the characteristics of the intervention itself. Randomization can balance known and unknown prognostic factors, but non-pharmacological interventions present methodological challenges that are less prominent in drug trials. The CONSORT extension for non-pharmacological treatments identifies difficulties related to blinding, provider effects, treatment delivery, adherence and clustering by care providers or centres.^[1] Comparative evidence also indicates that patient, provider and assessor blinding is less frequently achieved in non-pharmacological trials and that provider skill can influence treatment effects.^[2]

Daiva-vyapashraya Chikitsa is particularly relevant to this problem. In Ayurvedic terminology, *daiva* may refer to the divine, fate, destiny, divine will or a religious rite, *vyapashraya* means taking recourse to or relying on something, and *chikitsa* refers to medical treatment or therapeutics. In simple Hindi, the term can be understood broadly as “दैव या धार्मिक/आध्यात्मिक उपायों का आश्रय लेकर की जाने वाली चिकित्सा.” It should not, however be reduced to a single modern category such as prayer therapy.

The Monier-Williams Sanskrit-English Dictionary defines *mantra* as an “instrument of thought,” sacred speech, prayer or hymn, *homa* as an offering made into fire, and *upavasa* as fasting or religious abstinence. These meanings show why the intervention is

heterogeneous: mantra, homa and upavasa do not have the same components, dose, mechanism or delivery process.

1. Heterogeneity and lack of standardization

A central limitation is that Daiva-vyapashraya Chikitsa is not a single standardized treatment. Even within mantra-based practice, variables may include the selected mantra, pronunciation, chanting mode, repetition frequency, duration, tempo, supervision and setting. A contemporary RCT of mantra meditation shows that a mantra intervention can be operationalized with defined sessions, frequency and a comparator, but this does not mean that all mantra practices are equivalent.^[3] Complex interventions are characterized by interacting components, variable delivery systems and sometimes uncertain mechanisms of action.^[4]

This creates a treatment-fidelity problem. If two practitioners deliver the “same” intervention differently, the outcome may reflect differences in delivery rather than the intervention itself. Treatment-fidelity guidance recommends attention to provider training, treatment delivery, treatment receipt and participant enactment.^[5] Future trials should therefore define the intervention in sufficient detail to reproduce it while documenting permitted flexibility.

2. Difficulty with blinding

Blinding is one of the clearest limitations. In drug trials, an identical placebo can often blind participants and providers. A participant who is chanting a mantra, performing a ritual or following a fasting practice usually knows what they are doing. The practitioner also knows which intervention is being delivered. A systematic study of non-pharmacological RCTs found that blinding is more difficult and often requires non-standard approaches such as sham or simulated procedures.^[6]

The 2017 CONSORT NPT update recommends that when blinding is impossible, researchers should report this explicitly and describe methods to reduce bias, such as independent outcome assessment.^[1] In Daiva-vyapashraya trials, assessor blinding may therefore be more realistic than participant or therapist blinding.

3. The problem of sham and control groups

The control group defines what the trial is actually testing. In non-pharmacological research, a sham procedure may reproduce attention, time, ritual context and expectation while omitting the proposed active component. Developing such a control is difficult.^[7]

For Daiva-vyapashraya, a sham mantra or ritual could itself become a meaningful intervention. Repetition of a neutral sound may influence breathing, attention or relaxation. A no-treatment group may exaggerate the apparent treatment effect because it does not control for attention, expectation or therapeutic contact. Recent methodological guidance therefore emphasizes that

control interventions should be designed according to the causal question rather than treated as interchangeable placebos.^[7]

A randomized trial of spiritual healing for chronic pain is instructive. It compared face-to-face healing with simulated healing and also examined distant healing against no healing.^[8] The design demonstrates both the value and difficulty of constructing controls for spiritual interventions.

4. Expectancy, belief and contextual effects

Expectation is particularly important for Daiva-vyapashraya. A participant may have strong faith in mantra, prayer or ritual, while another may be sceptical. These expectations can influence subjective outcomes, adherence and the therapeutic relationship. A methodological review of prayer and distant-healing research recommended recording participants' beliefs about prayer and healing and other sources of prayer or healing and considering them during analysis.^[9]

The methodological implication is that the causal question should be stated explicitly. A trial may ask whether Daiva-vyapashraya in usual clinical conditions improves outcomes or whether a specific ritual component adds an effect beyond attention, expectation and relaxation. These questions require different control conditions.

5. Practitioner and delivery effects

In many Daiva-vyapashraya interventions, the practitioner is part of the treatment. Knowledge, pronunciation, ritual competence, interpersonal style, confidence and perceived credibility may vary between practitioners. The JAMA comparison found that provider skill could influence treatment effect much more often in non-pharmacological interventions.^[2] CONSORT NPT guidance also highlights clustering by providers and centres, which can affect sample-size requirements and analysis.^[1]

Using one experienced practitioner may improve consistency but reduce generalizability. Using many practitioners increases external validity but introduces variability. Future studies should record practitioner training and fidelity and consider provider-related clustering.

6. Difficulty identifying the active component

Complex interventions may work through several pathways at the same time. The MRC framework recommends development and evaluation of complex interventions rather than moving directly from an idea to a definitive RCT.^[10,11] A ritual may include verbal repetition, breathing, posture, sensory stimulation, social interaction, expectation, meaning and spiritual interpretation. A two-arm RCT may show that the package works but not which component produced the effect.

This is important because the traditional rationale of Daiva-vyapashraya may not correspond to a single biomedical mechanism. Process evaluation and qualitative methods can help explain how an intervention was received and delivered. Reviews of complex-intervention trials have found that qualitative work remains uncommon and is often poorly integrated with quantitative results.^[12]

7. Intervention description and reproducibility

A trial can be randomized and statistically sound but still be difficult to reproduce if the intervention is poorly described. The TIDieR framework was developed because incomplete descriptions prevent clinicians and researchers from reliably implementing or replicating interventions.^[13] A review of complex non-pharmacological trials found persistent reporting gaps, particularly for fidelity, manuals or protocols and comparator interventions.^[14]

For Daiva-vyapashraya, reporting should include the exact procedure, materials, mantra or words, language, pronunciation standard, duration, frequency, setting, practitioner qualifications, participant instructions, adherence monitoring and permitted modifications.

8. Outcome selection and measurement

Another limitation is outcome selection. Daiva-vyapashraya may be intended to influence mental, behavioural, spiritual or subjective domains, whereas RCTs often prefer standardized biomedical outcomes. If only a biochemical endpoint is selected, a clinically meaningful effect may be missed. If only self-reported outcomes are used, expectancy and reporting bias become more important.

Prayer research has emphasized objectively measurable outcomes with adequate variability.^[9] A useful approach may combine validated patient-reported outcomes, objective physiological measures where appropriate, adherence measures and process outcomes. Outcome selection should follow the proposed mechanism and clinical purpose.

9. Internal versus external validity

Highly controlled explanatory RCTs can maximize internal validity but may make the intervention unlike ordinary Ayurvedic practice. Pragmatic trials may better represent real-world use but allow greater variability. The PRECIS framework helps investigators decide how explanatory or pragmatic a trial should be across design domains.^[15] For Daiva-vyapashraya, a pragmatic design may often be more appropriate when the question concerns effectiveness in routine Ayurvedic care.

10. What should replace the “RCT only” approach?

RCTs need not be rejected, instead, they can be positioned within a broader evidence pathway. Complex-intervention guidance links intervention development, feasibility testing, evaluation and implementation as

connected stages.^[11] For Daiva-vyapashraya, a possible pathway is: classical textual analysis → intervention definition → expert consensus → feasibility study → fidelity assessment → pilot RCT → definitive pragmatic RCT → process evaluation → implementation research.



Fig. 1: Evidence pathway for Daiva-vyapashraya clinical research.

CONCLUSION

RCTs remain important for evaluating Daiva-vyapashraya Chikitsa, but assumptions developed primarily for standardized drug trials cannot be transferred to this intervention without modification. The principal challenges concern heterogeneity, standardization, blinding, sham controls, expectancy, practitioner effects, treatment fidelity, outcome selection and generalizability. Methodological literature suggests practical responses, including detailed intervention reporting, provider training, independent outcome assessment, carefully designed controls, fidelity monitoring, process evaluation and an appropriate balance between explanatory and pragmatic designs. Daiva-vyapashraya can therefore be evaluated as a complex non-pharmacological intervention within a mixed methodological framework that aims to maintain both scientific credibility and fidelity to Ayurvedic practice.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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