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Summary

Designing non-pharmacological trials: Business as usual?

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Behavioural intervention trials for disorders of gut-brain interaction face unique methodological challenges that require alternative quality indicators beyond traditional pharmacological trial standards, according to a 2025 consensus statement on trial design.

KEY POINTS

- The speaker stated that clinical practice guidelines consistently rate brain-gut behaviour therapies (gut-directed hypnosis, cognitive behaviour therapy, mindfulness interventions) as strong recommendations but low or very low quality evidence for disorders of gut-brain interaction, primarily because traditional trial rigour metrics like blinding and large sample sizes shortchange behavioural trial strengths.
- Attention control comparators are highly recommended because they control for the therapeutic relationship and non-specific elements, though they require larger sample sizes and add complexity compared to waitlist or standard care controls.
- The speaker reported that blinding to hypothesis rather than blinding participants is critical—telling patients they are receiving one of two active interventions without revealing which is hypothesised to be superior, then measuring expectancy and credibility after the first session.
- Starting with a clearly defined mechanistic hypothesis and target (such as visceral hypersensitivity driven by fear of symptoms) determines participant selection, outcome measures, and comparator choice, and allows iterative design adjustments.
- The speaker stated that most behavioural trials use one-year follow-up because placebo effects drop off after six months, with intervention arms typically diverging at three to six months rather than immediately post-treatment.

– Future directions include conducting plausibility trials with 5–10 patients before full trials, creating shared repositories of high-expectancy comparator protocols, and integrating behavioural interventions into combination trials with pharmaceutical therapies.

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