

## FRISBEE: Does the study fly in the face of evidence-based medicine?

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Carefully examine the validity of clinical trials before translating the results into your practice

**W**ith the rapid emergence of novel therapies, psychiatrists face the challenge of deciphering the clinical application of published clinical trials. Although double-blind, randomized, placebo-controlled trials are the gold standard, their validity should be carefully examined.<sup>1</sup> The FRISBEE mnemonic from Duke University's psychiatry residency program can help you incorporate evidence-based medicine into your patient care.

**Follow-up.** Carefully interpret studies with inadequate follow-up or high drop-out rates. The reason for patient discontinuation might not be related to the studied intervention.

**Randomization.** To control for unknown confounding variables, patient assignment must be randomized.

**Intent-to-treat analysis.** ITT assumes that complete data are available during final analysis on every subject, but subjects often drop out. To compensate for drop-outs, researchers could:

- carry forward the last available measurement as the final result, known as last observation carried forward (LOCF).
- use data only from patients who complete entire study protocol (completer analysis method).

Both methods have statistical limitations, but LOCF generally is preferred because it accounts for every subject who enrolled in the study.<sup>2</sup>

**Similar baseline.** Compare known characteristics of the treatment and placebo

groups at baseline. Confounding variables, such as illness severity or medical or psychiatric comorbidities, should appear equally among randomized patient groups. Not all variables will be similar because of random effects, however.

**Blinding.** With ineffective blinding, patients or researchers can tell which treatment was administered. If this occurs, the study's outcome likely is biased by treatment expectations. To detect faulty blinding, some studies ask patients and/or providers if they can guess the intervention that was delivered.

**Equal treatment.** Even with proper randomization and blinding, other intervention-related treatments—such as blood work to monitor side effects or the duration or frequency of provider contact—might not be administered equally among patient groups. This can clue patients and researchers into which intervention was administered and create bias.

**Equivalence to your patient.** A typical study patient often has few medical and psychiatric comorbidities or psychosocial risk factors. Your patient might be substantially different. Carefully compare the patients in the study with the patient in your office before choosing a treatment.

### References

1. Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA* 2000;284(3):357-62.
2. Lachin JM. Statistical considerations in the intent to treat principle. *Control Clin Trials* 2000;21:167-89.

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