

Overall Analytic Approach: One of the main analytic goals of the single group pilot study is to obtain necessary information to plan a fully powered, efficacy or effectiveness study of the proposed intervention approach. It is necessary to determine intervention feasibility/acceptability to participants and providers, as well as identify barriers to participation and satisfaction with the treatment program. The main analysis approach will be descriptive statistics, including means, proportions, and estimation of correlation coefficients. The pilot allows for the characterization of pre-post correlations and variance of major outcome variables, which are key statistics necessary to develop a sample size determination for a fully powered efficacy study.

Aim #: Evaluate key feasibility outcomes and preliminary symptom outcomes. The primary outcome for Aim # will be a test of the feasibility and acceptability of the intervention approach. To quantitatively assess intervention feasibility outcomes (enrollment & retention), the project enrollment rate will be calculated and within person retention at each follow-up will be compared against a priori benchmarks. Means for measures of acceptability and satisfaction will be calculated and compared to norms from similar intervention approaches.

Secondary outcomes for Aim # include preliminary examination of (1) pre-post changes correlation of in outcomes of interest assessed at follow-up time points, and (2) correlations with potential target mechanisms. Key parameter estimates (variance and correlation coefficients) for mechanisms and outcomes will be calculated to power future trials. Changes in measures from baseline to each follow-up will be calculated to estimate effects of the intervention on outcomes/mechanisms.

Sample size considerations: No formal hypothesis testing will be conducted for aim #. The study sample size was chosen to allow for feasibility and acceptability analyses, as well as to obtain reasonably precise estimates of key design parameters necessary to power a future, full-scale RCT. A sample size of 32 provides a reasonably large sample size to estimate means, proportions, and the variance of key outcome variables in the target sample. For example, to examine retention, if the population value is 50%, we can be 80% confident that the sample size of 32 will provide an estimate between .40 and .60. We feel this is a sufficient level of precision for our full study planning purposes.

The following tools will be used to evaluate the acceptability, appropriateness, feasibility, implementation climate, and implementation readiness:

- **Acceptability:** Training Acceptability Rating Scale (TARS; Davis, Rawana, & Capponi, 1989; Milne, Keegan, Westerman, & Dudley, 2000) and a 4-item Acceptability of Intervention measure
- **Appropriateness:** 4-item Intervention Appropriateness Measure (IAM; Weiner et al., 2017)
- **Feasibility:** 4-item Feasibility of Intervention Measure (FIM; Weiner et al., 2017) and Therapist Training Participation (therapist drop-out, reasons for drop-out, and consultation attendance)
- **Implementation Climate:** Implementation Climate Scale (ICS; Weiner, Belden, Bergmire, & Johnston, 2011)
- **Implementation Readiness:** Organizational Readiness for Implementing Change (ORIC; Shea, Jacobs, Esserman, Bruce, & Weiner, 2014)

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Milne DL, Keegan D, Westerman C, Dudley M. (200). Systematic process and outcome evaluation of brief staff training in psychosocial interventions for severe mental illness. *J Behav Ther Exp Psychiatry.* 31(2):87-101.

Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. (2014). Organizational readiness for implementing change: a psychometric assessment of a new measure. *Implement Sci.* 9:7.

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