JARS–**Quant** | Table 2

Reporting Standards for Studies With an Experimental Manipulation (In Addition to Material Presented in Table 1), continued

Module C: Reporting Standards for Studies Involving Clinical Trials

Title and Title Page

- State whether the trial was registered prior to implementation.

Abstract

- State whether the trial was registered. If the trial was registered, state where and include the registration number.
- Describe public health implications of trial results.

Introduction

- State the rationale for evaluating specific intervention(s) for a given clinical problem, disorder, or variable.
- Describe the approach, if any, to assess mediators and moderators of treatment effects.
- Describe potential public health implications of the study.
- State how results from current study can advance knowledge in this area.

Method

Participant Characteristics

- State the method(s) of ascertaining how participants met all inclusion and exclusion criteria, especially if assessing clinical diagnosis(es).

Sampling Procedures

- Provide details regarding similarities and differences of data collection locations if a multisite study.

Measures

- State whether clinical assessors were
  - involved in providing treatment for studies involving clinical assessments
  - aware or unaware of assignment to condition at post-treatment and follow-up assessment(s); if unaware, how was this accomplished?

Experimental Interventions

- Report whether the study protocol was publicly available (e.g., published) prior to enrolling participants; if so, where and when.
- Describe how intervention in this study differed from the "standard" approach in order to tailor it to a new population (e.g., differing age, ethnicity, comorbidity).

Experimental Interventions (*continued*)

- Describe any materials (e.g., clinical handouts, data recorders) provided to participants and how information about them can obtained (e.g., URL).
- Describe any changes to the protocol during the course of the study, including all changes to the intervention, outcomes, and methods of analysis.
- Describe the Data and Safety Monitoring Board.
- Describe any stopping rules.

Treatment Fidelity

- Describe method and results regarding treatment deliverers' (e.g., therapists) adherence to the planned intervention protocol (e.g., therapy manual).
- Describe method and results of treatment deliverers' (e.g., therapists) competence in implementing the planned intervention protocol (e.g., therapy manual).
- Describe (if relevant) method and results regarding whether participants (i.e., treatment recipients) understood and/or followed treatment recommendations (e.g., did they comprehend what the treatment was intended to do, complete homework assignments if given, and/or perform practice activities assigned outside of the treatment setting?).
- Describe any additional methods used to enhance treatment fidelity.

Research Design

- Provide a rationale for the length of follow-up assessment.

Results

- Describe how treatment fidelity (i.e., therapist adherence and competence ratings) and participant adherence was related to intervention outcome.
- Describe the method of assessing clinical significance, including if the threshold for clinical significance was prespecified (e.g., as part of a publicly available protocol).
- Identify possible differences in treatment effects due to intervention deliverer.
- Describe possible differences in treatment effects due to data collection site if a multisite study.
- Describe results of analyses of moderation–mediation effects, if tested.
- Explain why the study was discontinued, if appropriate.
- Describe the frequency and type of adverse effects that occurred (or state that none occurred).

Discussion

- Describe how this study advances knowledge about the intervention, clinical problem, and/or population.

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