

## Data Sharing Statement

### Data

**Data available:** Yes

**Data types:** Deidentified participant data, Data dictionary

**How to access data:** Data related to this study and article will be shared as follows. Individual-level data will be available, after deidentification, as well as a data dictionary and individual trial participant data that underlie the results reported in this article (text, tables, figures, and appendices). In addition, the study protocol, statistical analysis plan, and annotated case report forms will be available. The data will be available immediately following publication for three years. Researchers who are interested in obtaining the data should provide a methodologically sound proposal with a set of specific aims to Dr. Julie Kanter at University of Alabama, Birmingham ([jkanter@uabmc.edu](mailto:jkanter@uabmc.edu)).

**When available:** With publication

### Supporting Documents

**Document types:** The study protocol and statistical analysis plan are provided as Supplements to the manuscript. Annotated case report forms will also be available.

### Additional Information

**Who can access the data:** Qualified researchers who are interested in obtaining the data should provide a methodologically sound proposal with a set of specific aims to Dr. Julie Kanter at University of Alabama, Birmingham ([jkanter@uabmc.edu](mailto:jkanter@uabmc.edu)).

**Types of analyses:** Individual-level data will be available, after deidentification, as well as a data dictionary. Individual trial participant data that underlie the results reported in this article (text, tables, figures, and appendices will also be available).

**Mechanisms of data availability:** Data related to this study and article will be shared as follows. Researchers who are interested in obtaining the data should provide a methodologically sound proposal with a set of specific aims to Dr. Julie Kanter at University of Alabama, Birmingham ([jkanter@uabmc.edu](mailto:jkanter@uabmc.edu)).