APPENDIX

World Health Organization Trial Registration Data Set information

1. Primary Registry and Trial Identifying Number: NCT02189187 (http://clinicaltrials.gov).
2. Date of Registration in Primary Registry: June 24, 2014
3. Secondary Identifying Numbers: n/a
4. Source(s) of Monetary or Material Support: see page 12
5. Primary Sponsor: Carl Fulwiler (see page 1)
6. Secondary Sponsor(s): n/a
7. Contact for Public Queries: Carl Fulwiler (see page 1)
8. Contact for Scientific Queries: Carl Fulwiler (see page 1)
9. Public Title: "Keeping Weight Off: Brain Changes Associated With Healthy Behaviors"
10. Scientific Title: "Mind and health: developing a neural marker for mindfulness, a pathway to health"
11. Countries of Recruitment: United States
12. Health Condition(s) or Problem(s) Studied: see Introduction section
13. Intervention(s): see Interventions section of Methods
14. Key Inclusion and Exclusion Criteria: see Table 1
15. Study Type: Randomized controlled trial with evenly distributed arms
16. Date of First Enrollment: January 8, 2015
17. Target Sample Size: 80 (see page 10)
18. Recruitment Status: Recruiting
19. Primary Outcome(s): see Assessments and Data Analysis sections
20. Key Secondary Outcomes: see Assessments and Data Analysis sections

Other items from SPIRIT Checklist

3. Protocol version: 8; last modified July 1, 2015

21a, 22. The funding agency has determined that a full Data Safety Monitoring Board is not necessary for this study. Instead, any unexpected, serious, or intervention-related i.e. Serious Adverse Event (SAEs) will be reported to an Independent Monitoring Committee composed 3 scientists not involved in the study. This includes a senior biostatistician, an obesity research expert and clinician, and a senior neuroimaging researcher. Adverse events include possible health related risks such as MRI discomfort, psychological distress during the Interventions, imminent subject's risk during SCID interview or detecting structural brain image at baseline. Anticipated or unrelated AEs will be reported to the Independent Monitoring Committee, the IRB, and the NIH in accordance with their requirements. In the semi-annual SAE summary, the Independent Monitoring Committee will provide a review of each SAE, including relevant information forwarded by the study team, and verify that he has reviewed all serious adverse event reports.

23. The funding agency conducts annual on-site reviews of study procedures and progress.

31c. We will provide supplemental access to the requisite data, workflows and results, as well as provide maximum data availability to reuse in future meta-analyses and data pooling efforts. In addition, we will make all data available at the end of the award period via a NIH-funded NITRC (Neuroimaging Informatics Tools and Resources Clearinghouse - nitrc.org) project. We will release the data under the Creative Commons, Attribution-NonCommercial-Share Alike License.