

Effects of Brain Stimulation on Food Intake and Behavioral Weight Loss Treatment

NCT00739362

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Enrollment	148 participants

Key Eligibility Criteria

Inclusion (4)

- BMI ≥ 25 kg/m²
- Age 18-60 years. Women who are post-menopausal will be excluded from the study due to changes in their metabolism that could affect weight loss. We will set the cutoff at age 60 so that the age difference between the men and women is not too great for analysis purposes. Minors under the age of 18 will be excluded because the time requirements of the study are such that they would interfere with school schedules.
- Right-handedness (because the treatment will be given to the left dorsolateral prefrontal cortex and the evidence accumulated in this region was only in right-handed individuals).
- Weight stable (+/- 5 percent) for last 3 months as determined by volunteer report.

Exclusion (12)

- Weight > 300 lbs (136 kg), as this is the general size limit of the fMRI machine. Participants >300 pounds may be included if their body habitus will allow them to fit within the diameter of the MRI machine. This will be determined on a case-by-case basis after consultation with staff at Banner Health Neuroimaging Center.
- Use of medication affecting metabolism and appetite in the last three months
- Current pregnancy, pregnancy within the past 6 months or currently lactating
- History or clinical manifestations of acute or chronic disorders or conditions that may affect appetite or energy expenditure (such as, but not limited to type 1 or type 2 diabetes, Cushing's disease, thyroid disorders, coccidiomycoses)
- Gastrointestinal disease, including inflammatory bowel diseases (e.g. Chron's disease and ulcerative colitis), malabsorption syndromes (e.g. celiac disease), gastric ulcer (active) which may alter metabolism
- ... and 7 more (see full listing online)

Locations (1 total)

NIDDK, Phoenix, Phoenix, Arizona, United States

<https://clinicaltrials.gov/study/NCT00739362>

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