

using trial data from the Establishing Moderators and Biosignatures of Antidepressant Response in Clinical Care† (EMBARC) study. The primary objective of the algorithm is to switch treatment in patients who will not reach clinical effectiveness by the end of the stage, and the secondary objective is to avoid accidentally switching treatment in patients who will reach clinical effectiveness by the end of the stage. †Trivedi et al. *Journal of Psychiatric Research* 78 (2016) 11-23 **METHODS/STUDY POPULATION:** First, the algorithm was derived assuming a linear or non-linear trajectory. Next, performance of the algorithm was assessed using data from the Establishing Moderators and Biosignatures of Antidepressant Response in Clinical Care† (EMBARC) study. This two-stage SMART design measured the effectiveness of sertraline in 242 patients with non-psychotic Major Depressive Disorder (MDD). The algorithm was applied to baseline and interim measurements from the EMBARC study to predict end-stage Hamilton Depression (HAM-D17) scores, the primary outcome of the study. True positive rate (TPR) and false positive rate (FPR) were used to measure respectively the primary study objective (switching treatment in patients who will not reach clinical effectiveness by the end of the stage), and the secondary study objective (avoiding accidentally switching treatment in patients who will reach clinical effectiveness by the end of the stage). TPR and FPR were calculated for the following prediction scenarios: (1) three separate two-point predictions: Baseline and Week 2, Baseline and Week 4, Baseline and Week 6, and (2) a single three-point prediction: Baseline and Weeks 2 and 6. †Trivedi et al. *Journal of Psychiatric Research* 78 (2016) 11-23 **RESULTS/ANTICIPATED RESULTS:** When using two-point prediction, we found TPR to increase and FPR to decrease as the interim measurements approached closer to the end of the stage. We also found TPR to increase when using a three-point prediction, but at the expense of FPR also increasing. Across these scenarios, TPR ranged between 70 and 90%, and FPR ranged between approximately 20 and 50%. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Although SMART designs ultimately assign patients to more effective treatments, this process can take time and leave a patient (currently on an ineffective treatment) waiting until the end of a stage to try a potentially superior treatment. This disadvantage of the SMART design is currently addressed by this algorithm. By introducing a regression and likelihood approach to predict whether a patient should switch or stay on their current treatment, we move closer to the goal of designing rigorous, patient-centered studies. This work has the potential to improve individual clinical outcomes for patients enrolled in pragmatic clinical trials.

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Increased Monounsaturated Fat Consumption is Associated with Improved Body Composition in Subjects with Obesity and Heart Failure with Preserved Ejection Fraction

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OBJECTIVES/SPECIFIC AIMS: We hypothesized that increasing percent calories from MUFA (%MUFA) would be associated with an increased FFM/FM index. **METHODS/STUDY POPULATION:** Nine consecutive HFpEF patients with obesity participated in a 12-week pilot feasibility trial of UFA supplementation (NCT03310099).

Subjects were educated at baseline by a dietitian on UFA rich foods including high MUFA choices such as extra-virgin olive oil, canola oil and avocados. Participants were given a list of items, corresponding serving sizes and asked to eat at least one serving of these UFA rich foods per day for 12 weeks. Adherence was encouraged through weekly phone calls by the dietitian. Standardized 5-pass 24-hour dietary recall was performed by a dietitian at baseline and 12 weeks. The recalls were analyzed to establish intake of MUFA in percent calories (%kcal) with Nutrition Data Systems for Research software (NDSR). Body composition including FM%, fat free mass percent of body weight (FFM%) and ratio of FFM to FM (FFM/FM Index) was measured with bioelectrical impedance analysis (RJL systems) at baseline and 12 weeks. Statistical analysis was performed with SPSS (24.0). Spearman rank test was used for correlations. Values are expressed as numbers and percentages or as median and interquartile range (IQR). **RESULTS/ANTICIPATED RESULTS:** Subjects were mostly female (56%) with a median age 56 (IQR 50-59). Baseline median body mass index (kg/m²) was 36.7 (36.2-48.0), median FM% was 44.5 (IQR 32.5-53.4), median FFM% was 55.5 (IQR 46.7-67.5) and median FFM/FM Index was 1.25 (IQR 0.88-2.1). The only significant change was an increase in %MUFA from baseline 12.4% (IQR 6.9-14.3) to 12 weeks 21.8% (17.6-36.9) ($p = 0.008$). Increased %MUFA was highly associated with increased FFM% ($r = 0.783$, $p = 0.013$) (Figure 1A), decreased FM% ($r = -0.783$, $p = 0.013$) (Figure 1B) and increased FFM/FM index ($r = 0.800$, $p = 0.010$) (Figure 1C). All correlations remained statistically significant after adjustment for changes in energy intake. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Increasing dietary %MUFA is protective against negative changes in body composition in patients with obesity and HFpEF, independent of changes in caloric intake. Future work should focus on whether the correlation found in this pilot study translates in improved body composition and finally, exercise tolerance and clinical outcomes.

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Intermittent Theta Burst Stimulation to Relieve Depression and Executive Function impairment in older adults

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OBJECTIVES/SPECIFIC AIMS: The objective of the study is to examine the ability of iTBS to improve depression and executive impairment in depressed older adults. If effective, this treatment will have the potential to improve the quality of life in LLD. **METHODS/STUDY POPULATION:** From 12- 2016 to date older adults (60 – 85 y/o) in a major depressive episode, with evidence of executive dysfunction (on the NIH Tool Box battery) were enrolled. iTBS protocol: This brief paradigm (3 min 9 seconds duration) was administered on weekdays for four weeks (20 sessions total). Stimulation intensity was set up to 120% of the observed motor threshold. Depression primary outcome: Change in the Montgomery Asberg Depression Rating Scale (MADRS) from baseline to the end of iTBS course. Executive function primary outcome: Change in executive measures from the electronic NIH Tool Box cognitive domain battery⁸. Executive secondary outcome: Change in scores from baseline to the end of iTBS on the Frontal Systems Behavior Scale (FrSBe), this self reported instrument measures dys-executive behavior. Statistical Analysis: paired t-test examined changes in depression and executive variables from baseline to post iTBS. Pearson correlation examined