**Informed Consent Cover page**

**Title:** Adaptation of an Evidence-based Interactive Obesity Treatment Approach (iOTA) for Obesity Prevention in Early Serious Mental Illness: iOTA-eSMI.

**NCT Number:** NCT03980743

**Date:** October 19, 2020

**Analytic plan**
RFA-MH-18-706 specifies goals of the R34 mechanism include assessment of feasibility, acceptability, tolerability, and target engagement. Thus, statistical testing of short- or long-term effects, estimation of effect size, or definitive subgroup analyses are not within the scope of the RFA. We have chosen a 2:1 randomization ratio with a total sample of 60 subjects so as to increase precision in understanding the dynamics of the active intervention. Differences between the active intervention and the control groups will be explored to inform the design of the resulting future clinical trial, which is planned as an R01 application following the completion of the proposed pilot study. The primary outcome for the present study will be weight change. Within the active iOTA treatment group, we will use analysis of the process variables to refine the intervention and plan what outcome measures are appropriate for understanding the intervention's effectiveness. In addition, potentially relevant biological variables, such as gender, age, race and ethnicity will be explored in the analysis of the pilot study through our recruitment of a diverse sample, and though our planned exploration of the effect of these variable on outcomes in the analysis.

*Planned primary and secondary analysis:* In addition to the use of change in body weight from baseline as the primary outcome for this pilot study, secondary outcomes will include change in BMI, psychophysical skills and related self-efficacy. Weight/BMI will be measured at each visit (up to 10 visits over 9 months); we will use a repeated-measures mixed model to look at trajectory over study course with a time x treatment interaction estimating the treatment effect. Increase in self-efficacy for diet and exercise is the proposed mechanism of action for the active iOTA intervention. Measures of Psychophysical Awareness will be measured at every visit (total of 5 time points). Trajectory of self-efficacy scores will be compared between treatment groups. Finally, we will use structural equation growth models to estimate the correlation between the trajectory of psychophysical skills and related self-efficacy and that of weight/BMI.

*Exploratory analyses:* will focus on characterizing feasibility, engagement and implementation challenges as measured by i) enrollment, retention and visit adherence, ii) obesity intervention acceptability,[26,27] iii) text response rates, iv) client expectations,[28] v) fidelity and vi) client and staff-rated feasibility, appropriateness, acceptability, and vii) staff burden, including evaluation of how these variables impact effectiveness with respect to BMI and self-efficacy. Exploratory analyses will also evaluate how mental health self-efficacy and psychotropic medication compliance impact iOTA treatment compliance/engagement.

***Data Management*** All data will be entered into the electronic database REDCap via a secure WUSM web portal and stored on secure WUSM servers, which can be accessed securely through the WU or FAU networks. The database management is built with multiple layers of security and follows best practices and WUSM requirements for securing sensitive data. The iOTA program will be monitored through a secure web-portal via the WU network. All automatic system generated messages in the iOTA program will be sent directly to subjects' mobile phones through an online application developed and supported by technology vendor, Integrity, who has existing WU IRB and Information Security office approval for involvement with the parent iOTA program. The research team will use the iOTA online web portal from WU computers on the WU network. Integrity captures/stores all text messaging data (data sent to participants and received back from participants) and transmits the data to the WU research team using the REDCap API via a secure WUSM web portal stored on secure WUSM servers.