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Rationale and Design of the Dinner Time 2 Trial: A Randomized, Crossover Trial to Compare the Effects of Delayed Eating vs Delayed Sleeping on Overnight Metabolism in Healthy Volunteers

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Background: Obesity and its associated metabolic complications are leading causes of morbidity and mortality worldwide. Recent studies suggest that the timing of meals

may be critically important for weight control and metabolic health. Consuming calories later in the day is associated with greater risks of obesity and metabolic syndrome. Interventional diet studies show more weight loss with early, rather than later, eating. Our team conducted a randomized, crossover study ("Dinner Time Study") that compared the metabolic effects of routine dinner (6pm) vs late dinner (10pm) with a fixed sleep period (11pm-7am) in young, healthy adults. We found that late dinner caused an 18% increase in post-prandial glucose and a 10% decrease in dietary fat oxidation. These metabolic consequences in the long term may lead to the development of obesity and type 2 diabetes. However, it remains unclear whether the adverse metabolic effects of late dinner are mediated by circadian misalignment (eating at the "wrong" time relative to the body's central circadian clock) or mediated by sleep (eating too close to bedtime, coinciding with the fall in metabolic rate induced by sleep). To address this question, we aim to examine the metabolic effects of early dinner, late dinner, and late dinner followed by delayed sleep, in healthy adults. **Methods:** Dinner Time 2 Study is a randomized crossover trial with 3 treatment arms with a 3-4-week washout period: (1) early dinner + routine sleep; (2) late dinner + routine sleep; (3) late dinner + late sleep. Dinner times and bedtimes will be customized to each participant's central circadian rhythm (assessed by dim light melatonin onset, DLMO). The primary objectives of this study are to (1) examine the metabolic effects of early dinner (DLMO-3h) vs late dinner (DLMO+1h) with a fixed routine bedtime (DLMO+2h); (2) examine the metabolic effects of routine bedtime (DLMO +2h) vs delayed bedtime (DLMO+6h) with a fixed late dinner time (DLMO+1h). We will examine 24-h profiles of glucose, insulin, free fatty acids, triglycerides, and dietary fat oxidation using serial blood sampling and an ingested stable isotope ([^{2}H31] palmitate) tracer. We aim to recruit 20 healthy adults, age 18-30 years old, with a BMI 18-29.9 kg/m^2. Participants who perform night shift work or have any sleep disorders or metabolic diseases including diabetes are ineligible. Each participant will have 4 overnight admissions to our Clinical Research Unit (1 DLMO visit and 3 metabolic visits). A total of 3 participants have successfully completed the protocol since recruitment started in 2021. **Conclusion:** Dinner Time 2 will greatly advance our understanding of the interactions between meal timing, sleep timing, and metabolism, which could inform the design and implementation of future studies that leverage chronobiology to combat diabetes and obesity.

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