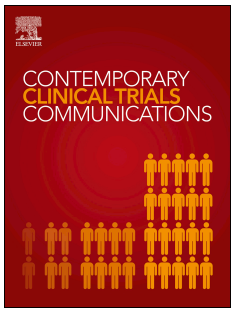

Time-Restricted Eating in Alzheimer's Disease: TREAD Pilot Trial Design

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Abstract

Background and objective: Time-restricted eating (TRE) may slow neurodegeneration and cognitive decline by stimulating metabolic processes that are neuroprotective. The primary aim of the TRE in Alzheimer's Disease (TREAD) pilot trial is to evaluate the feasibility of implementing a TRE intervention among individuals with mild cognitive impairment (MCI) and to obtain preliminary data on cognitive domains and blood biomarkers that are responsive to TRE.

Methods: TREAD is an intervention trial for 30 adults aged 55-89 years with MCI. A pre/post design is used, with neuropsychological assessments, surveys, and blood biomarkers of cardiometabolic health and AD obtained before and after the intervention. The TRE intervention involves 16h of continuous fasting and an 8h eating window on 5 or more days per week for 12 weeks. Feasibility measures include participant enrollment, retention, adherence, acceptability of the intervention, and safety. Cognitive measures include executive function, working memory, processing speed, auditory attention, auditory verbal learning, visuospatial memory, category fluency, and phonemic fluency.

Summary: TREAD is exploring an innovative approach to address cognitive decline and will provide critical preliminary data to inform and power a larger, longer-term, randomized controlled trial of TRE on cognitive trajectory among adults with cognitive impairment.

1. Introduction

Alzheimer's disease (AD) is the most prevalent neurodegenerative disorder and is characterized by cognitive impairment and adverse effects on social function, physical function, quality of life, and mortality. AD and AD-related dementias affect an estimated 6.9 million Americans [1] and more than 55 million people worldwide [2]. Mild cognitive impairment (MCI) represents the earliest clinical diagnosis of cognitive decline [3] and a potential window of opportunity for preventive therapies that may slow the progression to dementia.

Time-restricted eating (TRE) is a promising non-pharmacological, dietary approach for which there is compelling mechanistic rationale for its benefits on metabolic pathways that influence AD pathology and cognitive decline [4]. TRE is a form of intermittent fasting characterized by an extended fasting period (~12-16h) and a restricted eating window (~8-12h). TRE promotes ketone production and a cascade of metabolic effects (**Fig. 1**) that may stimulate autophagy and reduce neuroinflammation, tauopathy, and amyloid-beta plaque deposition [5, 6]. Additionally, TRE may improve neuronal stress resistance by enhancing antioxidant defenses and DNA repair [7-9]. Observational studies of TRE in people with MCI [10-12], single-arm pilot trials of TRE in people with subjective cognitive decline [13] and AD [14], and TRE intervention trials in people without MCI [15-19] provide strong scientific rationale for pursuing this line of investigation. This pilot trial is an innovative approach that builds on a strong scientific foundation to address a critical clinical need and advance AD research.

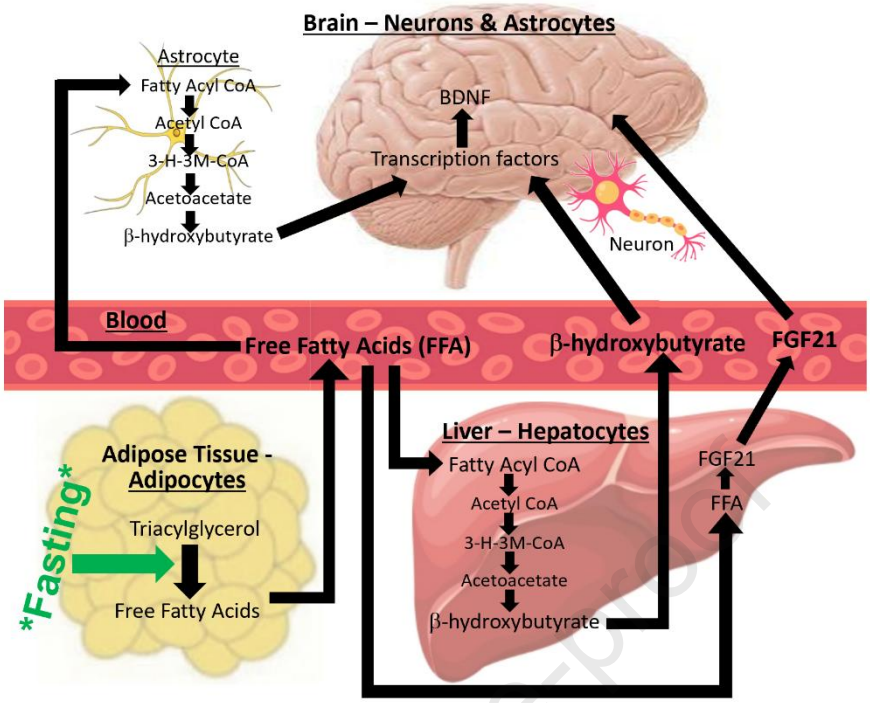

Fig. 1. Time-restricted eating (TRE) is characterized by extended fasting periods, which cause lipolysis in adipose tissue. Triacylglycerols are broken down into free fatty acids (FFA) and glycerol. FFA travel to the blood, liver, and astrocytes in the brain; FFA are metabolized to the ketone beta-hydroxybutyrate (β-OHB). β-OHB produced in the liver travels to the blood and to neurons in the brain, stimulating production of brain-derived neurotrophic factor (BDNF) and other metabolites that may contribute to neurogenesis in the hippocampus. Ketogenesis in astrocytes also produces β-OHB for neurons. FFA in the liver may lead to the production of fibroblast growth factor 21 (FGF21).

2. Design and Methods

2.1. Design

TREAD uses a pre/post design (**Fig. 2**) in which all participants receive the TRE intervention. TREAD is registered in ClinicalTrials.gov (NCT06429124) and is approved by the Institutional Review Board of Barrow Neurological Institute / St. Joseph's Hospital and Medical Center in Phoenix, AZ.

Fig. 2. TREAD pilot trial design

2.2. Specific Aims

Aim 1 of TREAD is to determine the feasibility of implementing a TRE intervention among individuals with MCI. Aim 2 is to obtain preliminary data on cognitive domains and biomarkers of metabolic health and AD that may be responsive to TRE in this population.

2.3. Participants

Eligible participants are men and women aged 55-89 years who have MCI based on the Mayo Clinic criteria [20], a body mass index (BMI) of 18.5 to <40.0 kg/m^2, are not current smokers or shift workers, do not have a medical condition for which TRE is contraindicated, and have a family member or friend who will serve as their study partner. Capacity to consent is

assessed prior to enrollment to ensure that participants understand the study aims and procedures. Medical history information is obtained from participants and the electronic medical record. Recruitment is performed by physicians in the Alzheimer's & Memory Disorders Program at Barrow Neurological Institute in Phoenix, AZ. The enrollment goal is 30 participants.

2.4 TREAD intervention

The intervention is a 16/8 TRE regimen characterized by 16h of continuous fasting and an 8h eating window on 5 or more days per week for 12 weeks (**Fig. 2**). Participants can follow an 8h eating window that fits their lifestyle, whether early TRE (8 am-4 pm), late TRE (12-8 pm), or a window in between. The intervention is delivered by a registered dietitian (RD) with expertise in neurological conditions. The RD meets with participants and their study partners weekly by phone to provide support, encouragement, and guidance, while obtaining updates and addressing any challenges. Calorie restriction is not a component of the intervention, although some participants may consume fewer calories as a result of the TRE regimen.

Promoting adherence and tracking participants' eating windows are facilitated by the ASU Meal Monitoring smartphone app that was custom designed for TREAD (Ingenious Agency, Denver, CO). The app was designed to be very simple for older adults, with only a couple of clicks to log the time that they eat their first and last calorie each day. Once the time of the first calorie is entered, the app displays the time by which to consume the last calorie to meet the 8h goal. The app displays congratulatory messages with confetti when the TRE goal is met or thank-you messages with encouraging phrases when time is logged but the goal is not met. The data are available to study personnel immediately on a password-protected website.

2.5 Outcome Measures

Aim 1 outcome measures include participant enrollment, retention, adherence, acceptability of the TRE intervention, and safety. Enrollment success is defined by enrollment of 30 eligible participants. Retention is computed as the % of enrolled participants who complete the 12-week intervention and pre- and post-assessments. Daily TRE adherence is defined as an eating window ≤8h and overall adherence as achieving the 8h TRE goal on 5 or more days weekly throughout the 12-week intervention (i.e., ≥60 days out of 84 potential days). Adherence is based on data obtained from the Meal Monitoring app. Frequencies are determined for the proportion of days on which the eating window is within 8h, 9h, and 10h, as it is not well-established whether a 16h fasting period has significantly greater benefits than 15h or 14h. Additionally, more flexible eating windows of 9h and 10h may be more feasible and acceptable in a longer-term intervention.

The clock times of the eating windows are analyzed as well, as there is evidence that early vs. late TRE may influence its metabolic effects [21]. Objective estimates of the eating windows and fasting periods each day are obtained in a subsample of participants using a wrist-worn smart band (HEALBE GoBe3) that monitors changes in glucose levels and reveals glucose excursions that occur when calories are consumed [22, 23]. Acceptability of the intervention is based on weekly check-ins throughout the 12 weeks, a semi-structured exit interview of participants, and an exit survey of study partners. Safety is based on adverse event reporting.

Aim 2 measures are obtained before and after the 12-week intervention and include cognitive measures, questionnaires regarding quality of life and lifestyle patterns, cardiometabolic health indices, and blood-based AD biomarkers. Pilot results from this trial will be used to streamline the assessment battery and select the most meaningful measures for future randomized controlled

trials.

Neuropsychological tests are administered by an experienced psychometrist in the clinic to assess executive function, working memory, processing speed, auditory attention, auditory verbal memory, visuospatial memory, category fluency, and phonemic fluency. Tests include: Mini Mental State Examination (MMSE) [24], Comprehensive Trail Making Test (CTMT) [25], Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV) Digit Span Forward and Backward tests [26], Auditory Verbal Learning Test (AVLT) [27], Brief Visuospatial Memory Test-Revised (BVMT-R) [28, 29], and category and phonemic fluency tests [30]. Scoring of each test is based on manualized scoring criteria (i.e., age-matched and, in some cases, education-matched norms). Practice effects are mitigated by using alternate forms for memory tests (AVLT and BVMT-R). Composite scores that average performance across cognitive domains will be used to improve statistical power in a subsample.

Questionnaires that are used to obtain information on quality of life, psychological well-being, stress, resilience, sleep, dietary patterns, and physical activity include: World Health Organization Quality of Life instrument (WHOQOL-BREF) [31], Valued Living Questionnaire (VLQ) [32], Bull's Eye Values Survey (BEVS) [33], Cognitive Fusion Questionnaire (CFQ) [34], Depression, Anxiety and Stress Scales (DASS-42) [35], Perceived Stress Scale (PSS) [36], Brief Resilience Scale (BRS) [37], Believability of Anxious Feelings and Thoughts Questionnaire (BAFT) [38], Comprehensive Assessment of Acceptance and Commitment Therapy Process (CompACT) [39], Pittsburgh Sleep Quality Index (PSQI) [40], Mediterranean Diet Score [41], Modified Leisure Time Physical Activity Questionnaire [42], and Physical Activity and Sedentary Behaviour Questionnaire (PASB-Q) [43]. Physical activity is estimated objectively in a subsample using the HEALBE GoBe3 smart band [22].

Cardiometabolic health indices include resting heart rate, blood pressure, BMI, waist circumference, waist-to-hip ratio, hemoglobin A1c, insulin resistance estimated by the homeostasis model assessment of insulin resistance (HOMA-IR) [44, 45], and inflammatory cytokines. Blood-based AD biomarkers include Aβ42, Aβ40, Aβ42/Aβ40 ratio, phosphorylated tau proteins p-tau217 and p-tau181, and total tau (T-tau).

Study data are collected and managed using Research Electronic Data Capture (REDCap) [46, 47] tools hosted at Barrow Neurological Institute. Data will be summarized using counts and percentage for categorical variables and mean and standard deviation or median with interquartile range for continuous distributions. Statistical analysis will include Chi-Square tests, student t-tests, or non-parametric tests, as appropriate. The outcomes will be modeled using generalized linear mixed models for repeated measures, controlling for baseline values and covariates (e.g., sex, age) when appropriate.

3. Summary

The TREAD pilot trial will provide critical preliminary data to inform and power a larger, longer-term, randomized controlled trial of TRE on cognitive trajectory among adults with cognitive impairment. We will use the strategies that we identify as effective for intervention adherence to optimize a future trial that will explore mechanisms and specific pathways through which TRE may impact cognitive domains. The long-term goal is to provide evidenced-based nutritional strategies to prevent or delay cognitive decline and the progression of normal cognition to MCI and to dementia.

Disclosures

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CRediT authorship contribution statement

Susan Racette: Conceptualization, Methodology, Writing – original draft, review & editing. **Jordan Gunning:** Methodology, Writing – review & editing. **Danielle Eagan:** Methodology, Writing – review & editing. **Isabella Zaniletti:** Methodology, Writing – review & editing. **Tracy Smith:** Methodology, Writing – review & editing. **Candice DeCuna:** Methodology, Writing – review & editing. **Yehansa Hettiwatte:** Writing – review & editing. **Migbare Demeke:** Writing – review & editing, **Nevine Khan:** Writing – review & editing, **Emily Aliskevich:** Writing – review. **Janina Krell-Roesch:** Writing – review & editing. **Yonas Geda:** Conceptualization, Methodology, Writing- review & editing.

Declaration of competing interest

The authors declare that they do not have competing interests.

Data availability

Data are not reported in this article.

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Declaration of Interest Statement

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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