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TITLE: Using Early Time-Restricted Feeding and Timed Light Therapy to Improve Glycemic Control in Adults with Type 2 Diabetes

PRINCIPAL INVESTIGATOR: Dr. Courtney Peterson, PhD

CONTRACTING ORGANIZATION: University of Alabama at Birmingham

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14. ABSTRACT

In this clinical trial, we will test whether two circadian-based therapies--a form of meal timing called early time-restricted eating (eTRE) and timed light therapy--can improve blood sugar control in adults with type 2 diabetes. Approximately 344 adults with type 2 diabetes will be randomized to the following 2 x 2 study design: (1) control group, (2) eTRF, (3) timed light therapy, and (4) eTRF and timed light therapy. Participants will follow their assigned lifestyle intervention for 16 weeks and be followed for a total of one year. In addition, we will determine whether the two circadian therapies can improve circadian rhythms, sleep quality, weight loss, cardiovascular health, quality of life, and psychological health. We are currently enrolling participants and collecting data. The delivery of the intervention and adherence have been excellent. Retention is better than we originally projected and has further increased this past year. Data collection and ongoing analyses have continued to go very well. The only challenge has been that our university's clinical research unit has been short-staffed due to the national shortage of nurses, which limited enrollment this year.

15. SUBJECT TERMS
Early Time-Restricted Feeding, Bright Light Therapy, Circadian Rhythms, Intermittent Fasting

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- **INTRODUCTION**

  This clinical trial will investigate whether two circadian-based therapies can improve blood sugar control, reduce diabetes complications, explain some of the heterogeneity of type 2 diabetes, and improve several other aspects of health. In this clinical trial, we will test for the first time whether a form of meal timing called early time-restricted feeding (eTRF) and/or timed light therapy can improve blood sugar control in adults with type 2 diabetes. Approximately 344 adults with type 2 diabetes will be randomized to the following 2 x 2 study design: (1) control group, (2) eTRF, (3) timed light therapy, and (4) eTRF and timed light therapy. Participants will follow their assigned lifestyle intervention for 16 weeks and be followed for a total of one year. In addition, we will determine whether the two circadian therapies can improve circadian rhythms, sleep quality, weight loss, cardiovascular health, quality of life, and psychological health. We will also determine which patients benefit the most from these therapies.

- **KEYWORDS**

  Type 2 Diabetes, Early Time-Restricted Eating, Bright Light Therapy, Circadian Rhythms, Chronobiology, Intermittent Fasting, Veterans

- **ACCOMPLISHMENTS:**

  - **What were the major goals of the project?**

TASKS	MONTHS	PROGRESS
TASK 1: SET-UP CLINICAL TRIAL		
Advertise, interview, and hire a research coordinator with prior experience in managing clinical trials at UAB	*2 months prior to start date*	*Complete*
Refine the protocol and informed consent	1-2	Complete
Develop recruiting materials and screening forms, and refine the screening process	1-3	Complete
Set-up recruiting processes at the Birmingham VA Medical Center and UAB Hospital	1-4	Complete
Order supplies and equipment	1-4	Complete
Review the recent literature on bright light exposure protocols, finalize the bright light exposure protocol, and write a review article	1-4	Manuscript is now 92% drafted. Will submit next quarter.
Develop procedure manuals for the lifestyle interventions and for behavioral counseling	2-3	Complete
Set-up a material transfer agreement with Brigham and Women's Hospital (BWH) to analyze sleep data (Aim 3)	2-3	Complete
Finalize the study protocol and informed consent	2-3	Complete
Set-up the study database and questionnaires in REDCap	2-4	Complete
Develop procedure manuals for all study procedures	2-4	Complete
Train nursing staff in the operation of PSG equipment	2-4	Complete
Set-up the rooms for inpatient testing	2-5	Complete
Develop data collection forms for nurses to use during the 38-hour inpatient testing	3-5	Complete
Train behavioral counselor	4-5	Complete
Train nurses to perform 38-hour inpatient tests and study procedures	4-5	Complete
Rehearse screening process and procedures	5	Complete

Milestone achieved: IRB & HRPO approval	5	Complete
Milestone achieved: All project-related staff trained	5	Complete
Milestone achieved: Study is set-up and ready to recruit participants	5	Complete
Milestone achieved: Submit review article on recent bright light therapy protocols and their effects on the circadian system and cardiometabolic health	5	In process. Revised target is next quarter.
TASK 2: CONDUCT CLINICAL TRIAL		
Recruit, consent, screen, and enroll potential participants	6-38	Ongoing
Milestone achieved: First participant enrolled	6	Complete
Participants follow their assigned intervention for 16 weeks	6-42	Ongoing
Perform behavioral counseling every 2 weeks	6-42	Ongoing
Aim 1: Perform procedures related to glycemic control	6-42	Ongoing
・Three 3-hour meal tolerance tests		
・24-hour measurement of glucose, insulin, and C-peptide		
・HbA1c		
Aim 2: Perform procedures related to the circadian system	6-42	Ongoing
・24-hour measurement of melatonin and cortisol		
・Constant glucose infusion procedure		
Aim 3 (Sleep): Perform polysomnography (PSG) and administer sleep questionnaires	6-42	Ongoing
Aim 3 (Body Weight): Measure weight and body fat (DXA)	6-42	Ongoing
Aim 3 (Cardiovascular): Measure blood pressure and heart rate and draw blood to measure lipids and inflammatory markers	6-42	Ongoing
Aim 3 (Quality of Life and Psychological Health): Administer questionnaires and perform semi-structured interview	6-42	Ongoing
Aims 1, 2, and 3: Perform assays of glucose, insulin, C-peptide, HbA1c, cortisol, melatonin, lipids, and inflammatory markers	6-42	Ongoing
Collect other outcome data: daily survey, Actiwatch data, food records, accelerometry, physical activity questionnaire, appetite questionnaire, and resting metabolic rate	6-42	Ongoing
Monitor intervention adherence and daily surveys	6-42	Ongoing
Monitor participant safety	6-end	Ongoing
Follow-up with participants to recollect any missing data	6-end	Ongoing
Monitor data validity and integrity	6-end	Ongoing
・Glycemic data (Aim 1 and glucose infusion data from Aim 2)		
・24-hour measurement of melatonin and cortisol (rest of Aim 2)		
・Sleep data (part of Aim 3)		
・Cardiovascular data (part of Aim 3)		
・Semi-structured interview (part of Aim 3)		
・Electronic questionnaires and study database in REDCap		
・All other outcomes		
Collect 8-month and 12-month follow-up data	14-end	Ongoing
Write and submit a manuscript on the study protocol	20-24	Started. Will submit in the second quarter of next year.
Accrual and adherence meetings	Weekly	Ongoing
Monthly progress meetings	Monthly	Ongoing
Data and safety monitoring meetings	Quarterly	Ongoing
Submit quarterly reports to the DoD	Quarterly	Ongoing

Submit protocol amendments, adverse events, and protocol deviations to IRB and HRPO	As needed	Complete and ongoing
Submit annual reports for continuing review to IRB and HRPO	Annually	Complete and ongoing
Milestone achieved: Last participant enrolled	38	Not started
Milestone achieved: Last participant completes the intervention	42	Not started
TASK 3. ANALYZE DATA AND REPORT STUDY OUTCOMES		
Aim 3: Analyze sleep (PSG) data	6-42	Ongoing
Analyze food intake and Actiwatch data	6-42	Ongoing
Analyze physical activity data from accelerometers	6-42	Ongoing
Final quality check of entire study database and study closeout	36-43	Not started
Analyze, write, and submit a manuscript on the baseline data	35-40	Not started
Aims 1-3: Perform statistical analyses on all data	38-46	Not started
Aim 1: Mathematically model data from meal tolerance tests to calculate insulin sensitivity and secretion	40-43	Not started
Aim 1: Mathematically model 24-hour glucose, insulin, and C-peptide data to extract key glycemic endpoints	40-43	Not started
Aim 2: Mathematically model the 24-hour melatonin and cortisol data to determine rhythms of the central clock	40-43	Not started
Aim 2: Mathematically model data from the constant glucose infusion procedure to determine rhythms of the peripheral clocks	40-43	Not started
Aim 3: Analyze quality of life and psychological health data	40-45	Not started
Aim 3: Mathematically model the 24-hour blood pressure data to extract blood pressure endpoints	44-45	Not started
Write and submit manuscripts on the study results and disseminate findings	42-48	Not started
Milestone achieved: All manuscripts submitted	48	Not started

- **What was accomplished under these goals?**

Recruitment

In the **first quarter** of Year 4 (September 2022 - November 2022), all recruiting was temporarily on hold for a couple months due to the university's Clinical Research Unit being short-staffed (see more details on page 8). The Clinical Research Unit was at 42% of total needed nursing capacity due to the national shortage of nurses during the COVID-19 pandemic. Due to the bottleneck of research nurses, our randomization rate was capped, and we had to halt our active recruiting campaigns, as we had a backlog of participants to randomize. In the last week of the quarter, we resumed recruiting, and we prepared ~300 postcards to send to patients with type 2 diabetes identified through medical records at the UAB Hospital. As a result, we prescreened only 73 applicants by phone or online this quarter.

In the **second quarter** of Year 4 (December 2022 - February 2023), we resumed sending postcards to patients with type 2 diabetes identified through medical records at the UAB Hospital. In the second quarter, we sent out ~350 postcards per week. We also resumed recruiting via social media ads in late January 2023. The ads are run on Facebook, Google, and other platforms through a company called Trialfacts, which is a dedicated recruiting services company for clinical trials and human research studies. On average, the digital TrialFacts ads bring in ~40 new applicants per week, of which 5-10% typically qualify for an in-person screening visit. We also continued to refresh our posters and flyers posted throughout the hospital and on campus and our digital ad on the research pages of our university's website. In the second quarter, we prescreened 409 new applicants online and/or by phone.

In the **third quarter** of Year 4 (March 2023 - May 2023), we continued to send out ~300 postcards per week. In addition, we resumed recruiting through the local VA hospital, the Birmingham VA Medical Center (BVAMC). Our statistician, Dr. Joshua Richman, performed a query of the BVAMC electronic medical records to identify potentially eligible participants. We obtained the list and began

mailing postcards in March 2023. This quarter, we sent 3,000 postcards to veterans who receive care at the Birmingham VA Medical Center (BVAMC). The digital TrialFacts ads also brought in about ~25-40 applicants per week, which was lower than the previous quarter. In total, in the third quarter, we prescreened 465 new applicants online and/or by phone and scheduled 75 Screening Visit 1 appointments. Historically, about 50% of those who attended Screening Visit 1 were eligible. However, for the first time this quarter, we noticed that only 25% of those attending the Screening Visit 1 were eligible, a lower eligibility rate than we've seen previously. This quarter, more applicants were excluded due to having better-controlled blood sugar (i.e., lower HbA1c values) than in previous quarters and due to the inability to follow study requirements. We decided to monitor this closely in the near future to see whether the eligibility rate will rebound.

In the **fourth quarter** of Year 4 (June 2023 - August 2023), we sent out postcards to ~5,800 patients at the BVAMC and ~3,500 patients at UAB Hospital. We continued running the digital TrialFacts ads. This quarter, to try to improve the recent modest declines in TrialFacts applicants and the drop in the eligibility rate, Dr. Peterson met with and worked with TrialFacts staff to do a deep dive into the advertising analytics. After a couple meetings, TrialFacts is now showing the ads to a new "look-like audience." This has been very successful in boosting the number of TrialFacts applicants back to typical levels of 40-55 applicants per week. In total, 723 new applicants applied—a quarterly record. However, the eligibility rate in terms of passing Screening Visit 1 has remained at half the expected rate (25% vs. 50%)—the second quarter in a row that this has happened. If this rate rebounds to typical levels, we will be on track to meet our recruitment goals as soon as the Clinical Research Unit is fully staffed (anticipated next quarter). In case this continues to be a trend, we are currently closely monitoring our advertising methods and the number of applicants who are excluded by each eligibility criterion, in case we need to pivot or make minor changes next quarter.

Screening and Enrollment

This year, we pre-screened 1,670 applicants by phone or online, which is about 140 per month on average (a 40% increase over last year). In total, since we began enrolling patients in May 2021, we have pre-screened 3,494 applicants. In order, the most common reasons for ineligibility are an HbA1c outside of 7-10%, spending more than 1.5 hrs/day outside, having an exclusionary medical condition, and being on insulin. In total, we have scheduled 343 in-person screening visits (includes no-shows). Of these, 91 applicants were eligible to enroll in the study, and 83 participants have been randomized. See the CONSORT diagram on the following page.

Retention

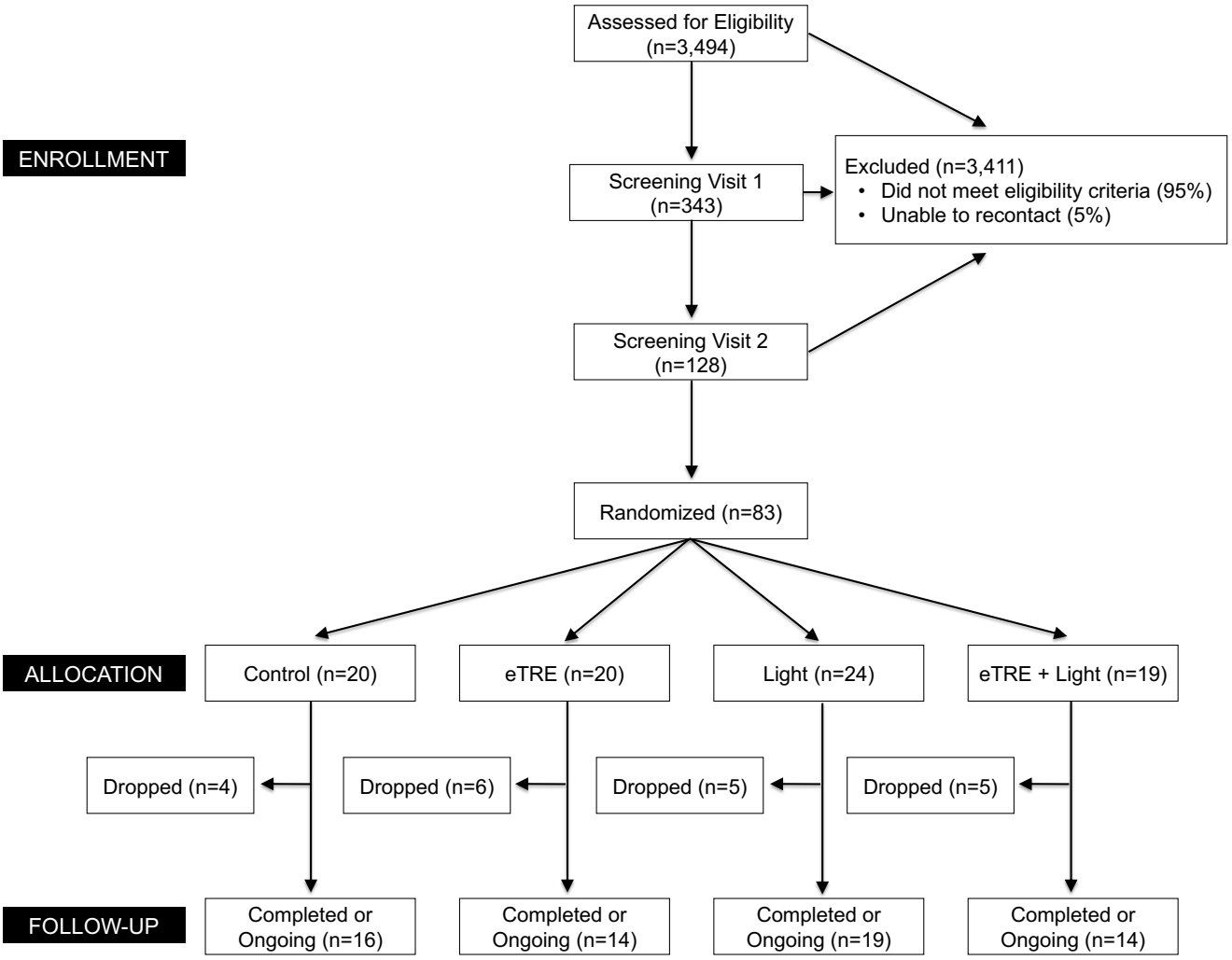
Retention has been good and slightly better than expected. Currently, retention is 76%, which is better than our projected rate of 70%. To date, 20 participants have dropped out of the study. The most common reasons for dropping out of the study include venous access issues and lost to follow-up, followed by lack of sufficient time to participate in the study.

Adherence

Most participants have been very dedicated and committed, so adherence has been excellent and on track with what we hoped. Nearly all participants have adhered >80% of the time. Mean adherence to the light therapy protocols is about 95%, with nearly all participants adhering 6 or more days per week, as they are instructed to do. For the meal timing interventions, the mean adherence is slightly lower but still excellent, at approximately 90% of the specified target.

Data Collection & Analyses

Data collection has gone well overall, with only a couple of minor issues. Venous access issues (n=5) and hyperglycemia during the constant glucose infusion (n=6) are the most frequent causes of incomplete data collection. In those cases, we attempted to regain access, discontinued the infusion and discharged the participant, and/or attempted to repeat the testing later. In addition, earlier this year, we switched to using CGMs (Dexcom G6 Pro) during the constant glucose infusion procedure, instead of the YSI machine, which was unable to be calibrated back to factory standards. Lastly, we had two instances of missing PSG (sleep) data, both occurring on the same night, due to software-related issues.



All other aspects of data collection have gone very well. We continue to analyze multiple types of data on an ongoing basis, including selected serum analytes, PSG (sleep) data, Actigraphy watch data, food records, and resting metabolic rate data. See the Milestones Table for a complete list of raw data that is analyzed on an ongoing basis. In the third quarter, Dr. Peterson, brought on new collaborators from Dr. Josiane Broussard's Sleep and Metabolism lab at the University of Colorado to help analyze the large volume of actigraphy watch data on sleep and light exposure patterns. This new (unpaid) collaboration is going very well, and Dr. Peterson and Dr. Broussard's team are currently meeting every 1-2 months.

Adverse Events & Safety

There have been no serious or unexpected adverse events possibly related to the protocol over the past year. Adverse events definitely or possibility related to the study include hyperglycemia likely related to the 10% dextrose infusion (n=6), headache (n=3), and nausea (n=1), all during the inpatient testing. Adverse events unrelated to the study include hypotension (n=1) (due to a vasovagal episode), heart palpitations (n=1), a hypertensive episode (n=1), and macular edema (n=1). None of the AE's needed to be reported immediately to the IRB and have been or will be reported at the time of the continuing review. We have continued to meet with our independent safety monitors once a quarter (Drs. Holly Wyatt and Stewart Frank) to evaluate patient safety.

Regulatory & Subcontracts

We submitted continuing reviews to all regulatory bodies and have received approval from the UAB IRB. We are currently awaiting approval from the BVAMC IRB and HRPO. Subawards were also completed for the past year.

Staffing & Training

- **Nurses**. Our biggest challenge continues to be that enrollment is bottlenecked by the university's Clinical Research Unit operating at 42% capacity, due to the national nursing shortage. As reported previously, in late June and July of 2022 (last year), our university's clinical research unit lost two of its four full-time research nurses who perform inpatient testing. As a result, for 13.5 of the last 14.5 months, our research nurse unit has been understaffed. After one successful and two failed attempts to hire two additional full-time nurses over a 9-month period, the Clinical Research Unit finally succeeded on the third attempt at hiring the last needed full-time nightshift nurse in May 2023. However, a week later, one of the dayshift nurses decided to step down to accept a different position. In the fourth quarter, a fourth nurse was hired (again), but she was terminated a couple weeks after starting (in August 2023) due to subpar job performance. Since it is paramount to the success of this study that the university's Clinical Research Unit is no longer short-staffed, Dr. Peterson was finally able to convince and negotiate a deal with the Director of the Center for Clinical and Translational Science (CCTS), the Director of Nursing for the Clinical Research Unit, the Medical Director of the CCTS, and the Director of the Infusion Unit in the hospital that allows the Clinical Research Unit to hire travel nurses as temporary staff. (The Clinical Research Unit was not previously allowed to hire travel nurses, which is why the unit was understaffed for so long.) With these new permissions from major leaders at the university and the hospital, we are now hiring a travel nurse in the interim to resolve the nurse capacity issue (until a full-time staff member can be successfully hired), and the new travel nurse will start on September 11th and will require 4-6 weeks of training. At this time in October 2023, we expect to start being able to enroll participants at 100% of our target rate.
- **Research Coordinators**. We have also experienced turnover among our own staff of coordinators. Ms. Rachel Hart (full-time) and Mr. Isaac Martinez (part-time) moved to the university's cancer center and no longer work for the department as research coordinators. In the interim, after Mr. Martinez left but before Ms. Hart left, Ms. Elizabeth (Bunny) Fogle temporarily assisted as a coordinator for a few months. To replace Ms. Hart, we hired Ms. Andrea McCullough, who started halfway through the year. A couple months later, we decided to hire one full-time research coordinator, to ensure that we can definitely meet our enrollment goals for the remainder of the grant period. (Dr. Peterson had this idea, which was also independently suggested by Dr. Ryan Sapp.) At the end of the third quarter, we hired added a full-time coordinator position to our team and hired Ms. Cara Randall. Our team spent time over the last few months training both new coordinators. They are an excellent team.
- **Student Workers.** We hired and trained a couple new student workers to assist with mailing postcards and with processing biospecimens.
- **Behavioral Counselor**. The behavioral counselor, Ms. Sara Hannum, retired during the end of the third quarter. Two new behavioral counselors started this year. Ms. Anne Hubbell started in the first quarter this past year, and Mr. Wil Owens started at the end of the third quarter. Both have been fully trained and are doing a great job fostering participant adherence.
- **All study staff** were retrained in all relevant BVAMC privacy and security measures, and WOC appointments are still active. Both new study coordinators, Ms. Andrea McCullough and Cara Randall, are working on their WOC applications.

Other Activities

- Monthly meetings continue with co-investigators, including the following people:
    - The study statistician Dr. Joshua Richman
    - Co-investigator and circadian expert Dr. Karen Gamble
    - Study physician Dr. T. Brooks Vaughan
    - Co-investigator Dr. Sarah-Jeanne Salvy
    - Paid independent consultant Dr. Frank Scheer (BWH)
- We also continue to have our quarterly safety and progress meetings with our independent safety monitors, Drs. Stuart Frank and Holly Wyatt.
- Finally, we are nearly finished with writing the review article on light therapy. We have brought on an expert in light therapy and circadian rhythms, Dr. Parisa Vidafar, to ensure the completeness of our literature search. We continue to meet every 3-6 weeks to work on the literature review article. Since the team is spread out across different university/institutions, progress is a slower, but the manuscript draft is now 92% complete. We are currently waiting on Dr. Vidafar to complete the figures and her contributions to the introduction section.

- **What opportunities for training and professional development has the project provided?**
  In the past year, the project has provided introductory research training to one undergraduate student, Ms. Destini Elston, who is a female from an underrepresented minority group (Black/African American). Ms. Elston has learned the basics of clinical research, including screening, data collection, and how to process blood specimens.

- **How were the results disseminated to communities of interest?**
  Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

  During the next reporting period, we will recruit eligible participants at our target rate of 2 per week. Our target goal is to enroll about 100 participants over the next year. We have already requested a one-year no-cost extension, and meeting this goal will put us on track to completing the study in a reasonable timeframe.

  Currently, our main bottleneck is the national shortage of nurses, which has led to our clinical research unit being temporarily short-staffed for over a year. We now have a contract in place with a travel nurse agency that allows us to hire temporary nurses. We are optimistic that our clinical research unit will soon find a permanent full-time nurse. Once the new travel nurse is fully trained in October 2023, we expect to be able to randomize patients at our target rate. We will continue all our usual recruiting campaigns:

  1. **Social Media Advertising**. We will continue our digital advertising campaign on Facebook, Google, Instagram, and Twitter. When active, these ads typically bring in about 40-45 applicants per week.

  2. **Mailing Postcards**. We will continue mailing roughly ~300-500 postcards per week to patients with type 2 diabetes identified via electronic medical records at the UAB Hospital and the BVAMC. We will continue to target patients who have recently seen their healthcare provider, as we have found this strategy to be more effective for recruiting participants.

  3. **UAB Clinical Trials Webpage.** We will continue to recruit patients through UAB's Clinical Trials Webpage (called the Clinical Trials Reporter), which brings in a steady flow of participants.

  4. **Flyers at UAB Hospital**. We will continue to refresh our laminated flyers in the UAB Hospital, including in plastic mounts in high-traffic areas such as the pharmacy and waiting rooms.

  In addition, we will closely monitor our digital advertising campaigns and the eligibility rate associated with passing Screening Visit 1. If the latter remains lower than expected—as it has for the last two quarters—we will reconsider our recruiting strategies and/or potentially adjust the eligibility criteria in the first quarter of next year.

  Also, in the next year, we will continue screening and enrolling applicants, delivering the intervention, and collecting and analyzing study data on an ongoing basis. We will also start running some of the serum analytes that need to be assayed in batch. Finally, the statistician, Joshua Richman, will begin writing the statistical analysis code to analyze the data.

- **IMPACT:**

  - **What was the impact on the development of the principal discipline(s) of the project?**
    Nothing to Report

  - **What was the impact on other disciplines?**
    Nothing to Report

  - **What was the impact on technology transfer?**
    Nothing to Report

  - **What was the impact on society beyond science and technology?**

Nothing to Report

- **CHANGES/PROBLEMS:**

  - **Changes in approach and reasons for change**

    The two interventions—time-restricted feeding and bright light therapy—have caused far fewer episodes of hyperglycemia, hypoglycemia, hypotension, and hypertension than expected (i.e., very few in the outpatient setting). As a result, to reduce participant burden, we now perform the biweekly checks of glucose and blood pressure only when participants are symptomatic.

  - **Actual or anticipated problems or delays and actions or plans to resolve them**

    Previously, we previously experienced a one-year delay due to the COVID-19 pandemic temporarily shutting down our research facilities, affecting research operations, and delaying renovations within the hospital. In addition, recruitment was bottlenecked over the last year due to our Clinical Research Unit operating at 42% of inpatient research nurse capacity.

    Moving forward, we have taken the following action steps to mitigate future issues:
    - We hired and trained an additional full-time coordinator (Ms. Cara Randall) in order to screen more patients and schedule more screening visits. This was also suggested to us by Dr. Ryan Sapp.
    - We will monitor the success of the digital ads on a weekly basis and work closely with the company TrialFacts to examine the online traffic and analytics.
    - We secured multiple approvals through the university and the hospital to hire travel nurses whenever the Clinical Research Unit is short-staffed in the future. This is a big victory for us, as the biggest challenge has been the shortage of research nurses and we were not previously allowed to hire our own nurses to do the inpatient testing. The first travel nurse will start training on September 11th and be ready to work independently sometime in October. At this time, we expect the Clinical Research Unit to begin operating at capacity.
    - We will monitor the eligibility pass-through rate at Screening Visit 1, as described earlier. If this rate rebounds to typical levels, we will be on track to meet our recruitment goals as soon as the Clinical Research Unit is fully staffed. In case the recent dip in the eligibility rate continues to be a trend, we are currently closely monitoring our advertising methods and the number of applicants who are excluded by each eligibility criterion, in case we need to pivot or make minor changes next quarter.

  - **Changes that had a significant impact on expenditures**
    Nothing to Report

  - **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
    Nothing to Report

  - **Significant changes in use or care of human subjects**
    Nothing to Report

  - **Significant changes in use or care of vertebrate animals.**
    Not Applicable

  - **Significant changes in use of biohazards and/or select agents**
    Not Applicable

- **PRODUCTS**

- **Publications, conference papers, and presentations**

  - **Journal publications**
    Nothing to Report.

  - **Books or other non-periodical, one-time publications**
    Nothing to Report

  - **Other publications, conference papers, and presentations**
    Nothing to Report

- **Website(s) or other Internet site(s)**
  Nothing to Report

- **Technologies or techniques**
  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Nothing to Report

- **Other Products**
  Nothing to Report (same products as last year)

- **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

  - **What individuals have worked on the project?**

Name	Courtney Peterson, Ph.D.
Project Role	Principal Investigator
Researcher Identification (ORCID #)	0000-0002-4845-6782
Nearest Person Month Worked	5
Contribution to the Project	Dr. Peterson is serving as the study PI. She oversees all aspects and operations of the clinical trial (except where noted below). She also is reviewing study data on an ongoing basis to ensure data validity.
Funding Support	
Name	T. Brooks Vaughan, M.D.
Project Role	Co-Investigator and Study Physician
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	1
Contribution to the Project	Dr. Vaughan oversees patient safety and medical eligibility for the clinical trial.
Funding Support	
Name	Sarah-Jeanne Salvy, Ph.D.
Project Role	Co-Investigator and Clinical Psychologist
Researcher Identification (ORCID #)	0000-0002-8202182X
Nearest Person Month Worked	1
Contribution to the Project	Dr. Salvy designed the behavioral aspects of the intervention and crafted behavioral SOPs. She currently oversees the behavioral counseling and participant adherence and is responsible for ensuring quality control.
Funding Support	
Name	Joshua Richman, M.D., Ph.D.

Project Role	Co-Investigator and Statistician
Researcher Identification (ORCID #)	0000-0002-6166-7488
Nearest Person Month Worked	1
Contribution to the Project	Dr. Richman assisted with designing the study database in REDCap and created the statistical and data validity protocols for the trial, using software programming. He also created the randomization code. He is overseeing data management and the study database on an ongoing basis.
Funding Support	
Name	Karen Gamble, Ph.D.
Project Role	Co-Investigator and Circadian Biologist
Researcher Identification (ORCID #)	0000-0003-3813-8577
Nearest Person Month Worked	1
Contribution to the Project	Dr. Gamble has provided important guidance on the light therapy intervention, protocol, and circadian rhythms measurements. She also helped negotiate for and set up the inpatient testing rooms. Dr. Gamble is currently overseeing the collection of circadian data.
Funding Support	
Name	Shelby Leverett, B.S.N.
Project Role	Research Nurse in clinical research unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	6
Contribution to the Project	Perform nursing and collect research data during the 38-hour inpatient tests.
Funding Support	
Name	Cynthia Venton, B.S.N.
Project Role	Research Nurse in clinical research unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	6
Contribution to the Project	Perform nursing and collect research data during the 38-hour inpatient tests.
Funding Support	
Name	Lynn Dill, B.S.N., R.N.
Project Role	Research Nurse Manger
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	12
Contribution to the Project	Lead research coordinator and nurse manager
Funding Support	
Name	Rachel Hart, B.S.
Project Role	Research Coordinator
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	7
Contribution to the Project	Research coordinator
Funding Support	
Name	Andrea McCullough, B.S.
Project Role	Research Coordinator
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	6
Contribution to the Project	Research coordinator. Replaced Rachel Hart.
Funding Support	
Name	Elizabeth (Bunny) Fogle

Project Role	Research Coordinator
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	4
Contribution to the Project	Research coordinator.
Name	Cara Randall, B.S.
Project Role	Research Coordinator
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	4
Contribution to the Project	Research coordinator, with a focus on recruiting, screening, and consenting participants. Replaced part-time role of Bunny Fogle with this full-time role.
Funding Support	
Name	Sarah Hannum
Project Role	Behavioral Counselor
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	3
Contribution to the Project	Provides behavioral counseling to participants during intervention phase of study
Funding Support	
Funding Support	
Project Role	Behavioral Counselor
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	2
Contribution to the Project	Provides behavioral counseling to participants during intervention phase of study
Funding Support	
Name	Wil Owens, M.S.
Project Role	Behavioral Counselor
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	1
Contribution to the Project	Provides behavioral counseling to participants during intervention phase of study. Replaced Sarah Hannum, who retired this year. Also analyzes food records.
Funding Support	
Name	Shelby Leverett, B.S.N.
Project Role	Dayshift Research Nurse in the Clinical Research Unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	6
Contribution to the Project	Insert IVs, perform nursing duties, and collect research data during the 38-hour inpatient tests
Funding Support	
Name	Cynthia Venton, B.S.N.
Project Role	Nightshift Research Nurse in the Clinical Research Unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	6
Contribution to the Project	Insert IVs, perform nursing duties, and collect research data during the 38-hour inpatient tests
Funding Support	
Name	Jordan Oldacre, R.N.

Project Role	Dayshift Research Nurse in the Clinical Research Unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	5
Contribution to the Project	Insert IVs, perform nursing duties, and collect research data during the 38-hour inpatient tests
Funding Support	
Name	Joseph Landers, R.N.
Project Role	Nightshift Research Nurse in the Clinical Research Unit
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	1
Contribution to the Project	Insert IVs, perform nursing duties, and collect research data during the 38-hour inpatient tests
Funding Support	
Name	Destini Elston
Project Role	Undergraduate student worker
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	4
Contribution to the Project	Miscellaneous tasks, such as photocopying, specimen-processing, organizational duties, participant reminders, etc.
Funding Support	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Dr. Sarah-Jeanne Salvy (co-investigator) is no longer supported by two grants:

Moved to Past Support
R01 HD092483 (Salvy and De la Haye) 7/1/17 – 6/30/23 2.4 Calendar
NIH/NICHD
Obesity Prevention for Infants Through Maternal and Social Interaction
This study tests the sustained effectiveness of delivering in-home obesity prevention on infants and mothers' obesity risks. This model of implementation provides a unique opportunity to test the meditational effects of maternal and social mechanisms on infants' obesity risk.
Role: MPI

U54MD000502 (Salvy and Dutton) 9/1/17 – 8/31/23 1.2 Calendar
NIH/NIMHD
Leveraging Ongoing Home Visitation Programs to Address Obesity Disparities Among Underserved, Low-Income Mothers and Children (Project #2)
This two-arm, parallel, randomized controlled trial tests the effectiveness of an obesity intervention based on habit formation and manipulation of the home environment to address obesity and health-related disparities among socioeconomically disadvantaged mothers and their young children enrolled in federally funded maternal-child health services.
Role: MPI

Dr. Karen Gamble (co-investigator) has two new sources of support:

New Support
R01 AA029072-01A1 (Bailey) 4/1/2023 – 3/31/2028 0.6 calendar
NIH/NIAAA (annual total costs)

Circadian and Mitochondrial Dysfunction in Alcohol-Related Liver Disease
The broad goal of this project is to provide mechanistic insight into how disruption in mitochondrial bioenergetic rhythms during alcohol ingestion plays a causal role in liver injury.
Role: Co-I

R01 AG081433 (Volpicelli-Daley) 4/1/2023 – 3/31/2028 0.6 calendar
NIH/NIA (annual total costs)
Role of GlcSph in Cognitive Deficits in Lewy Body Dementias
The goal of this project is to determine if the lipid glucosylsphingosine plays a role in toxicity caused by pathologic α-syn and mutant GBA1.
Role: Co-I

All investigators still remain under the maximum effort allowed. There have been no other changes in active support among key personnel.

- **What other organizations were involved as partners?**
  Organization Name: Cedars-Sinai Medical Center
    - **Location of Organization:** Los Angeles, CA
    - **Partner's contribution to the project**
      - **Collaboration**
        Co-investigator Dr. Sarah-Jeanne Salvy assisted in the development of the behavioral aspects of the research protocol, including the design of behavioral counseling, behavioral interviews, psychological questionnaires, and the corresponding SOPs**.** She is currently overseeing all behavioral counseling and is responsible for ensuring quality control of the behavioral aspects of the intervention. She meets with the behavioral counselors every week to review adherence and trouble any issues with counseling.

  Organization Name: Brigham and Women's Hospital
    - **Location of Organization:** Boston, MA
    - **Partner's contribution to the project**
      - **Collaboration**
        The project's consultant, Dr. Frank Scheer, provided detailed feedback on the study protocol and timed light therapy intervention. He continues to attend the monthly co-investigator meetings and provide suggestions.

- **SPECIAL REPORTING REQUIREMENTS**

  - **Collaborative Awards**
    Not Applicable

  - **Quad Charts**
    See Next Page

- **APPENDICES**

  Nothing to Report.