

AWARD NUMBER: W81XWH-19-1-0558

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

PRINCIPAL INVESTIGATOR: Courtney M. Peterson, Ph.D.

CONTRACTING ORGANIZATION: University of Alabama at Birmingham

REPORT DATE: October 2020

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
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<b>REPORT DOCUMENTATION PAGE</b>			<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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<b>1. REPORT DATE</b> October 2020		<b>2. REPORT TYPE</b> Annual Report		<b>3. DATES COVERED</b> 1 Sep 2019 – 31 Aug 2020
<b>4. TITLE AND SUBTITLE</b> Using Early Time-Restricted Feeding and Timed Light Therapy to Improve Glycemic Control in Adults with Type 2 Diabetes			<b>5a. CONTRACT NUMBER</b> W81XWH-19-1-0558	
			<b>5b. GRANT NUMBER</b> GRANT12715627	
			<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Courtney Peterson, Ph.D.; Rachel Benz, M.S.N., R.N.; Kimberly Armstead, B.S.  E-Mail: cpeterso@uab.edu			<b>5d. PROJECT NUMBER</b>	
			<b>5e. TASK NUMBER</b>	
			<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> University of Alabama at Birmingham UAB 701 S 20TH ST BIRMINGHAM, AL 35294-0001			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012			<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
			<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for Public Release; Distribution Unlimited				
<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> In this clinical trial, we will test whether two circadian-based therapies--a form of meal timing called early time-restricted feeding (eTRF) 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 will also determine which patients benefit the most from these therapies. During the first year of this award, we set-up the clinical trial. We hired and trained the core research staff; refined the protocol; secured initial IRB and HRPO approval; built the study database; designed the counseling sessions and handouts; completed all contracts and data agreements; created all SOPs; and acquired and (mostly) set-up the inpatient testing facilities. Study recruitment and in-person activities were put on hold in mid-March 2020 due to the COVID-19 pandemic and will re-open in the first quarter of Year 2.				
<b>15. SUBJECT TERMS</b> Early Time-Restricted Feeding, Bright Light Therapy, Circadian Rhythms, Intermittent Fasting				
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  13
<b>a. REPORT</b>  Unclassified	<b>b. ABSTRACT</b>  Unclassified	<b>c. THIS PAGE</b>  Unclassified		
				<b>19b. TELEPHONE NUMBER (include area code)</b>

## TABLE OF CONTENTS

	<u>Page</u>
<b>Introduction</b>	<b>4</b>
<b>Keywords</b>	<b>4</b>
<b>Accomplishments</b>	<b>4</b>
<b>Impact</b>	<b>8</b>
<b>Changes/Problems</b>	<b>8</b>
<b>Products</b>	<b>9</b>
<b>Participants &amp; Other Collaborating Organizations</b>	<b>10</b>
<b>Special Reporting Requirements</b>	<b>12</b>
<b>Appendices</b>	<b>12</b>

## 1. 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.

## 2. KEYWORDS

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

## 3. ACCOMPLISHMENTS:

- What were the major goals of the project?

TASKS	MONTHS	PROGRESS
<b>TASK 1: SET-UP CLINICAL TRIAL</b>		
<i>Advertise, interview, and hire a research coordinator with prior experience in managing clinical trials at UAB</i>	<i>2 months prior to start date</i>	<i>Complete. Hired 3 new staff in Month 2</i>
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	Supplies have been identified. Testing of supplies has been halted due to COVID-19.
Review the recent literature on bright light exposure protocols, finalize the bright light exposure protocol, and write a review article	1-4	In process. De-prioritized due to disruptions from COVID-19.
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, pending final study rehearsals
Develop procedure manuals for all study procedures	2-4	Complete
Train nursing staff in the operation of PSG equipment	2-4	Not started due to disruptions from COVID-19. See revised timeline

		for nurses to start.
Set-up the rooms for inpatient testing	2-5	Mostly complete. Will be completed in Month 14 due to new acquisition of additional testing rooms.
Develop data collection forms for nurses to use during the 38-hour inpatient testing	3-5	Complete
Train behavioral counselor	4-5	Completed training of main counselor. Need to train a back-up counselor.
Train nurses to perform 38-hour inpatient tests and study procedures	4-5	Not started. Waiting for new nurses to be hired following COVID-19 delays.
Rehearse screening process and procedures	5	Half-way complete. Delayed due to COVID-19 disruptions.
<i>Milestone achieved: IRB &amp; HRPO approval</i>	5	Complete
<i>Milestone achieved: All project-related staff trained</i>	5	In process
<i>Milestone achieved: Study is set-up and ready to recruit participants</i>	5	In process. Awaiting return to operations post-COVID-19.
<i>Milestone achieved: Submit review article on recent bright light therapy protocols and their effects on the circadian system and cardiometabolic health</i>	5	In process. De-prioritized due to COVID-19 disruptions
<b>TASK 2: CONDUCT CLINICAL TRIAL</b>		
Recruit, consent, screen, and enroll potential participants	6-38	Not started
<i>Milestone achieved: First participant enrolled</i>	6	Not started
Participants follow their assigned intervention for 16 weeks	6-42	Not started
Perform behavioral counseling every 2 weeks	6-42	Not started
Aim 1: Perform procedures related to glycemic control	6-42	Not started
• 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	Not started
• 24-hour measurement of melatonin and cortisol		
• Constant glucose infusion procedure		
Aim 3 (Sleep): Perform polysomnography (PSG) and administer sleep questionnaires	6-42	Not started
Aim 3 (Body Weight): Measure weight and body fat (DXA)	6-42	Not started
Aim 3 (Cardiovascular): Measure blood pressure and heart rate and draw blood to measure lipids and inflammatory markers	6-42	Not started
Aim 3 (Quality of Life and Psychological Health): Administer questionnaires and perform semi-structured interview	6-42	Not started
Aims 1, 2, and 3: Perform assays of glucose, insulin, C-peptide, HbA1c, cortisol, melatonin, lipids, and inflammatory markers	6-42	Not started

Collect other outcome data: daily survey, Actiwatch data, food records, accelerometry, physical activity questionnaire, appetite questionnaire, and resting metabolic rate	6-42	Not started
Monitor intervention adherence and daily surveys	6-42	Not started
Monitor participant safety	6-end	Not started
Follow-up with participants to recollect any missing data	6-end	Not started
Monitor data validity and integrity	6-end	Not started
• 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	Not started
Write and submit a manuscript on the study protocol	20-24	Not started
Accrual and adherence meetings	Twice a month	Not started
Monthly progress meetings	Monthly	Not started
Data and safety monitoring meetings	Quarterly	Not started
Submit quarterly reports to the DoD	Quarterly	Ongoing
Submit protocol amendments, adverse events, and protocol deviations to IRB and HRPO	As needed	Not started
Submit annual reports for continuing review to IRB and HRPO	Annually	Not started
<i>Milestone achieved: Last participant enrolled</i>	38	Not started
<i>Milestone achieved: Last participant completes the intervention</i>	42	Not started
<b>TASK 3. ANALYZE DATA AND REPORT STUDY OUTCOMES</b>		
Aim 3: Analyze sleep (PSG) data	6-42	Not started
Analyze food intake and Actiwatch data	6-42	Not started
Analyze physical activity data from accelerometers	6-42	Not started
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
<i>Milestone achieved: All manuscripts submitted</i>	48	Not started

- **What was accomplished under these goals?**
  - We submitted the protocol and consent form to the UAB IRB for initial approval about two months prior to the start of the award. IRB approval was obtained in Month 3 (November 2019). HRPO approval for the UAB portion of the protocol was received in Month 7 (March 2020).
  - The protocol was submitted to the Birmingham Area VA Medical Center (BVAMC) IRB in Month 2 and was approved in Month 9 (May 2020). This portion was subsequently submitted and received approval from HRPO in Month 10 (June 2020).
  - We hired and trained three new project staff—a research nurse coordinator, a postdoctoral researcher (who is also a dietitian and will serve as the dietitian for this trial), and a research associate.
  - Study staff were trained in all relevant BVAMC privacy and security measures, and WOC appointments were sought and received in spring 2020.
  - The trial was registered on Clinicaltrials.gov.
  - Several meetings were held with co-investigators to refine the protocol. This included several meetings each with the following people:
    - The study statistician Dr. Joshua Richman
    - Co-investigator and circadian expert Dr. Karen Gamble
    - Co-study physicians Drs. Tim Garvey and Dr. T. Brooks Vaughan. (We recruited the Director of Endocrinology at the BVAMC, Dr. Vaughan, to serve as a co-study physician with Dr. Timothy Garvey.)
    - Co-investigator Dr. Sarah-Jeanne Salvy, including via an in-person meeting to refine the behavioral aspects of the study
    - Paid independent consultant Dr. Frank Scheer (BWH)
    - Unpaid independent consultant and light therapy expert Dr. Richard Lang (Cincinnati Children's Hospital)
  - We set-up the DSMB and independent safety monitors.
  - We reviewed most of the literature on bright light therapy for the treatment of cardiometabolic disease. This allowed us to refine the delivery of the light therapy intervention. In particular, we will allow participants to either use a light box or light therapy glasses (there are now light therapy glasses on the market).
  - In the process of refining the protocol, we made minor changes in the questionnaires used, the light therapy intervention, and the testing procedures. Minor protocol revisions were completed in the second quarter of this award prior to submission to HRPO.
  - All contracts and subawards were initiated in Month 1, and the last subcontract was completed in Month 10 (June 2020).
  - We finalized recruitment materials, including postcards, flyers, and online screening forms. We also completed the phone script to screen potential participants and created the phone screening database.
  - We set up the recruiting processes involving electronic medical records at UAB and the BVAMC.
  - We created all data collection forms. These will be finalized once we complete the rehearsals of the study protocol (in progress). These rehearsals were put on hold during the COVID-19 pandemic.
  - We created and completed all participant handouts.
  - The extensive REDCap database has been built. This includes most case report forms (except for the paper forms) and questionnaires. Mock testing of the forms is nearly complete, pending the final study run-throughs.
  - We created data validity reports and automated forms to track participants.
  - We created forms that are automatically sent to the study physicians to sign off on.
  - The statistician is still in the process of finalizing software code in R to check for missing data. The system for checking data validity has been completed.
  - Dr. Salvy and the postdoctoral researcher/RD designed the behavioral counseling sessions and manual and developed checklists to implement the behavioral visits. They also created a "Frequently Asked Questions" guide for use for the behavioral interventions.
  - The postdoctoral researcher/RD was trained to deliver the behavioral counseling. We will train an additional staff member to serve as a back-up counselor in the next couple of months.
  - The exit interview has been finalized.
  - We drafted nearly all SOPs, except for the frequent blood sampling SOP and the PSG SOP. These are on hold until we can complete the testing rehearsals.

- We assembled the policy and procedure (P&P) manual for the study. This process will not be finalized until participants are seen and any unforeseen issues have been addressed.
- We have set-up all budget processing and routing forms and clinical billing procedures through the OnCore system.
- We sourced and obtained quotes and/or placed orders for most of the equipment and supplies. We had to identify the new vendors for our materials and replacement items from these vendors, after UAB switched one of its main medical vendors. We also placed a handful of new orders (e.g., low-blue-light bulbs for the rooms, timers, keyboards for iPads to collect data, etc.) We also figured out UAB's ordering process for the saline and 20% dextrose that is part of the frequent blood sampling protocol. We note that we have delayed ordering in some cases due to the pandemic and the slow down of business operations at UAB. We expect to complete the ordering of all supplies in Months 2-3 of Year 2 (i.e., the next handful of weeks).
- We ordered additional PPE supplies—including masks, gloves, and UV sanitizing wands—to protect staff and research participants.
- We have drafted a detailed safety plan and SOP to resume research operations in the fall. The plan outlines research procedures to dramatically reduce the risk of COVID-19 transmission and to increase staff and participant safety. This plan was approved by our Department Chair and Dean, and we are permitted to resume research operations as of September 2020 (Month 1 of Year 2)
- We finished designing and taste-tested the smoothie recipes for the meal tolerance tests.
- We have tested the blackout curtains and determined how to configure them in participants' bedrooms at their homes.
- Through negotiations with the UAB hospital, we have procured the use of four rooms within the hospital (for weekends only) to conduct the inpatient testing protocol. This required over two dozen meetings over a several-month period and was ultimately approved by the Chief Compliance Officer and the Associate Vice President of Regulatory Services for the UAB Hospital.
- In the last quarter, we also procured an additional room in the Webb building to conduct inpatient testing on weekdays. We now have all the necessary inpatient testing rooms to start this study. The rooms will become available by early November.
- We are nearly done outfitting the inpatient testing rooms. This includes procuring all equipment; developing a system of blackout curtains and doors; testing the light levels in the room; configuring the room; etc. We have completed 6 out of 8 tasks and expect to complete the final steps in the next 2-3 weeks.
- Dr. Peterson worked on and set up a staffing plan for nurses, phlebotomists, and biospecimen-processing technicians through frequent meetings with the UAB Center for Clinical and Translational Science.
- We began rehearsing the frequent blood sampling protocol for our inpatient testing protocol in early March 2020. Following the first rehearsals of the blood sampling protocol in March, we extensively revised, re-revised, and then finished the 38-hour inpatient nursing flowsheets as well as the blood processing flowsheets for this protocol. Following approval to resume research operations, we resumed the testing rehearsals in September (Month 1 of Year 2). We expect to complete the testing rehearsals in the next month or so.
- We are currently in the process of interviewing and hiring the 3 nurses who will work in the Center for Clinical and Translational Science and perform the inpatient testing for this protocol. The nurses will start in November 2020.
- We are nearly finished with our review of the literature on light therapy. Due to the COVID-19 pandemic, this is being de-prioritized in the interim, until the study is up and running at full capacity.

• **What opportunities for training and professional development has the project provided?**

Nothing to Report

• **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?**

We plan to initiate recruitment as soon as we can. Currently, we are waiting for the research kitchen to re-open (scheduled for mid-October) and the inpatient testing facilities to be fully operational (scheduled for early November). Currently, we are planning to:

- Begin recruiting and phone screening participants in the second half of October 2020 (Month 2 of Year 2)
- Finish setting up the remaining newly acquired inpatient rooms, and finish interviewing and hire three nurses to support the inpatient testing in October (Month 2 of Year 2)
- Finish rehearsing the study procedures in November 2020 (Month 3 of Year 2)
- Order remaining supplies in October and November (Months 2-3 of Year 2)
- Begin the study intervention at a reduced capacity by late November 2020 (Month 3 of Year 2)
- Resume research operations at 100% capacity in early January 2021 (Month 5 of Year 2). *This is when our institution is planning to restore business operations to normal capacity.*
- Once research operations are restored to 100% capacity, we will target enrolling participants at an average rate of 2.4 participants per week, as originally planned.

#### 4. 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

#### 5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**  
Nothing to Report
- **Actual or anticipated problems or delays and actions or plans to resolve them**

**Initiation.** Because this grant was funded as an alternate, we experienced a delay in recruiting, hiring, and training three new project staff, who all started in early to mid-October (Month 2 of Year 1).

**BVAMC.** We were informed in October 2019 that the Birmingham VA Medical Center was re-establishing its own autonomous IRB and that we could no longer rely on the UAB IRB to approve research studies that recruit patients through the local VA medical center. It took 7 months to receive IRB approval from the newly convened BVAMC IRB, partially due to disruptions from COVID-19. We do not anticipate any future IRB-related delays.

**COVID-19.** In March 2020, the UAB and BVAMC systems ceased all research activity due to the global COVID-19 pandemic. We were ordered to work from home during this time period, and the research facilities that we rely on were shutdown. Since then, our research facilities have gradually been re-opening. To safely resume in-person research activities, we were required to develop a detailed plan to reduce the risk of COVID-19. This plan was approved by our Department Chair and Dean, and we were permitted to resume our research operations as of September 2020 (Month 1 of Year 2). We will begin enrollment once the research kitchen re-opens (scheduled for mid-October) and the inpatient testing facilities are fully operational (scheduled for early November). It is possible that we may experience further delays since we must comply with all federal, state, and local guidelines, as well as contend with delays from suppliers. We will do our best to anticipate and mitigate any future delays due to COVID-19. We will also attempt to recruit at a higher rate in future years to make up for lost time.

**Inpatient Testing Facilities.** We experienced delays in setting up the inpatient testing facilities at UAB Hospital due to the allocation of research space within the hospital and state licensing rules on inpatient

rooms. We have worked closely with the UAB Center for Clinical and Translational Science and hospital administrators to identify a set of permanent inpatient rooms dedicated to our study and similar research protocols. This year, we successfully obtained four rooms for inpatient testing on weekends, which are housed within the Clinical Research Unit of the UAB Center for Clinical and Translational Science. Since the last report, we have obtained a fifth room in the Webb Building, which will be used for weekday testing. We now have the full capacity we need to start enrollment. This process was dramatically slowed down by COVID-19. The inpatient testing facilities and staff are currently scheduled to be operational in early November (the exact date is soon forthcoming).

**Maternity Leave.** Dr. Peterson was on maternity leave in early 2020.

- **Changes that had a significant impact on expenditures**  
Due to the COVID-19 pandemic, our institution shut down all in-person clinical research (except for life-saving research) in March 2020. Therefore, we were not able to begin enrollment in Year 1. We have a large balance that we will need to carry forward, which we will spend in future years to conduct the trial as originally planned.
- **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

## 6. 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**
  - **Data or Databases.** We have developed an extensive REDCap database, which will collect participant data and information, including responses to questionnaires.

- **Clinical interventions.** We fine-tuned the details of the clinical intervention for light therapy and its mode of delivery by reviewing the most recent literature, speaking to other leading researchers, and reviewing new light therapy products that recently have become available. Medical research on light therapy is a rapidly evolving field. For instance, there are now wearable glasses that deliver light therapy and are more convenient to use than lightboxes. We will allow participants to use either the originally proposed light therapy box or light therapy glasses. We expected that this change will increase participant adherence.
- **Educational aids or curricula.** We finalized participant handouts and instructions for the lifestyle interventions. We have also finalized our SOP for infection control and for resuming research operations during the COVID-19 pandemic. Our department chair and our dean recently approved our plan, and we are now allowed to resume research.

## 7. 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	6
Contribution to the Project	Dr. Peterson is serving as the study PI and is heavily involved in all aspects of setting up this clinical trial.
Funding Support	
Name	Sarah-Jeanne Salvy, Ph.D.
Project Role	Co-Investigator
Researcher Identification (ORCID #)	0000-0002-8202182X
Nearest Person Month Worked	1
Contribution to the Project	Dr. Salvy designed the delivery of the behavioral aspects of the intervention and crafted behavioral SOPs. She was also heavily involved in refining the psychosocial questionnaires, including the exit interview.
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 the design of the study database in REDCap and is creating the statistical and data validity protocols for the trial, using software programming. He also created the randomization code.
Funding Support	
Name	Karen Gamble, Ph.D.
Project Role	Co-Investigator
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.

Funding Support	
Name	Felicia Steger, Ph.D., R.D.
Project Role	Postdoctoral Scholar
Researcher Identification (ORCID #)	0000-0002-8117-4082
Nearest Person Month Worked	12
Contribution to the Project	Dr. Steger has assisted Dr. Peterson in her role as PI by helping to refine the protocol; develop and select data collection instruments; build the study database in REDCap; refine the clinical intervention; and co-design the behavioral counseling. Dr. Steger is also leading the literature search and writing of the review article on timed light therapy.
Funding Support	
Name	Rachel Benz, M.S.N., R.N.
Project Role	Research Nurse Coordinator
Researcher Identification (ORCID #)	0000-0001-6211-7771
Nearest Person Month Worked	12
Contribution to the Project	Mrs. Benz is the lead research coordinator on this trial. She has helped create the REDCap database, participant handouts, the case report, and data collection forms, and assisted in myriad other ways. She also has submitted and managed IRB documents and regulatory aspects of this trial.
Funding Support	
Name	Kimberly Armstead, B.S.
Project Role	Research Assistant
Researcher Identification (ORCID #)	N/A
Nearest Person Month Worked	12
Contribution to the Project	Ms. Armstead assisted in developing recruitment materials, the screening process, participant handouts, ordering supplies, and the REDCap database.
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?**

The study physician, Dr. Timothy Garvey, had to reduce his effort on this clinical trial because of a re-allocation of his effort across active federal grants, NIH and other center grants, and industry funding. Therefore, Dr. T. Brooks Vaughan, the Director of Endocrinology at the Birmingham VA Medical Center, will now serve as the primary study physician for the trial. Adding a second study physician benefits the trial as Dr. Vaughan sees more patients with type 2 diabetes at the Birmingham VA Medical Center than Dr. Garvey. Dr. Garvey will remain as a secondary study physician and co-investigator on the grant. The combined effort contributed by the two study physicians will be similar to what we originally proposed for a single study physician. In addition, Dr. Peterson received a no-effort grant from the University of Alabama at Birmingham to support infrastructure development (in the form of additional inpatient testing rooms) and equipment that will directly benefit this clinical trial.

- **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.

**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.
  - **Other**

The Sleep & EEG Core at Brigham and Women's Hospital will analyze the PSG (sleep) data for this trial. We have set up the data transfer methods and the fee-for-service contract to analyze this data.

## 8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

Not Applicable
- **Quad Charts**

See Next Page

## 9. APPENDICES

See attached for questionnaires and handouts.