

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a randomized controlled trial on the feasibility and effects of ten-hour time-restricted eating on cardiometabolic disease risk among career firefighters doing 24-hour shiftwork: The Healthy Heroes Study
AUTHORS	Manoogian, Emily; Zadourian, Adena; Lo, Hannah; Gutierrez, Nikko; Shoghi, Azarin; Rosander, Ashley; Pazargadi, Aryana; Wang, Xinran; Fleischer, Jason; Golshan, Shahrokh; Taub, Pam; Panda, Satchidananda

VERSION 1 – REVIEW

REVIEWER	Waldman, Hunter University of North Alabama, Kinesiology
REVIEW RETURNED	25-Dec-2020

GENERAL COMMENTS	<p>The current study seeks to examine the impact of a chronic time-restricted feeding protocol on markers of cardiometabolic health in professional firefighters. The investigative team has justified their problem and purpose statement with a methodology that will adequately answer their primary and secondary outcomes. Overall, this is a well-thought out study and each confounder or limitation has been thoroughly considered, discussed, and if possible, accounted for in the study design. The following comments below are minor grammatical/structure revisions to assist with future correspondence.</p> <p>Minor Revisions: Page 6, Line 48 - Please remove "unhealthy" from this sentence as the term energy-dense diet is sufficient. Page 7, 1st sentence - Should be re-worded as it reads quite confusing at the moment and is a presumption of potential ongoing research studies that might not be accurate. Rather than stating, "has never been tried...", the authors would consider simply stating that TRE studies are lacking.. Page 7, line 53 - improved should read improve Page 10, line 25 - The authors have included HbA1c twice in this sentence as a secondary outcome measure Page 11, line 54 - It would be beneficial to the methodology here to include how many of these firefighters (%) read the materials provided Page 12, line 23 - similar to the above comment, it would be beneficial in the methodology to include how many firefighters (%) changed their TRE window during the duration of this study Page 12, line 49 - Lowercase the T in the word The Page 15, line 13 - switch should read switched Page 15, line 56 - HbAa1c should read HbA1c Page 18, line 22 - please correct your alpha spacing</p>
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	Page 29, line 30 - The first sentence reads, "No TRE studies have been done on firefighters." Again, this sentence does not seem appropriate as the authors are assuming that there are no ongoing TRE investigations with firefighters at the moment. It would be more appropriate to remove this sentence and allow future readers to make this conclusion on their own, if this is in fact true when this study is published.
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REVIEWER	McAllister, Matthew Texas State University, Health & Human Performance
REVIEW RETURNED	04-Jan-2021

GENERAL COMMENTS	<p>The protocol proposed by Manoogian et al, is a comprehensive RCT aimed at utilizing time</p> <p>restricted eating to potentially improve aspects of cardiometabolic health in professional</p> <p>firefighters. This is an important study and I am thankful that the authors have developed an</p> <p>extensive study to test this intervention in firefighters since this population is at elevated risk</p> <p>for mortality due to cardiovascular disease. As this is merely a study protocol, results and</p> <p>implications are not available for evaluation. However, some minor comments regarding a</p> <p>request for clarification are provided below. The authors present a wide variety of blood</p> <p>markers of cardiometabolic health but the authors may want to consider the possibility of</p> <p>including AGE and AOPP as outcome measurements since we have previously tested this</p> <p>dietary intervention (14:10) in firefighters (non RCT) and found reductions in both, despite</p> <p>finding no changes in cytokines and several other cardiometabolic markers:</p> <p>https://journals.lww.com/nsca-jscr/Abstract/9000/Impact_of_Time_Restricted_Feeding_on_Markers_of_94173.aspx</p> <p>Also, firefighters tend to have high levels of AOPP compared to other populations despite many other markers being within normal ranges. This is just a suggestion to consider.</p> <p>Abstract</p>
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“TRE” should be defined upon first use, which would be line 13, as opposed to 16-17.

Methods:

General questions: What were their dietary habits prior to enrollment? Were these data gathered? Were the subjects excluded if they practiced TRE in the past? Many FF experience some form of fasting due to their occupational demands/schedules.

What is meant by “the research team also works with participants to help adjust for challenging schedules”?

Were the self-chosen 10 hr eating windows variable?
Were they told to follow the same window?

Exclusion criteria- any dietary exclusions? Many firefighters take a variety of dietary supplements that potentially could impact these results as well. Was this screening done for dietary supplement use?

Inclusion criteria- any accommodation if they did not own, or did not prefer using a smartphone to track dietary habits?

Intervention

Under “time-restricted eating” did the authors mean to state participants may consume **coffee**, not “caffeine” without cream or sugar? Further, many firefighters consume energy drinks that sometimes contain a range of kcals. Were these also allowed if they were calorie free, or very low in caloric density?

Considering the occupational demands and many factors that can impact outcome measurements, were there any standardized conditions related to strenuous physical activity, smoke exposure, etc. prior to testing?

	<p>Statistical analysis</p> <p>In my opinion, the analysis appears sound and appropriate but I would request the review of a statistician for an expert opinion on the analysis.</p> <p>I think a bit more clarity on which specific measures to be examined would be helpful. Authors state: "Daily averages will be computed for the baseline and end of the intervention" --for what?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Hunter Waldman, University of North Alabama

Comments to the Author:

The current study seeks to examine the impact of a chronic time-restricted feeding protocol on markers of cardiometabolic health in professional firefighters. The investigative team has justified their problem and purpose statement with a methodology that will adequately answer their primary and secondary outcomes. Overall, this is a well-thought out study and each confounder or limitation has been thoroughly considered, discussed, and if possible, accounted for in the study design. The following comments below are minor grammatical/structure revisions to assist with future correspondence.

Thank you for the helpful review. We have made all possible suggested changes. Please see notes below for details on changes that couldn't be made.

Minor Revisions:

Page 6, Line 48 - Please remove "unhealthy" from this sentence as the term energy-dense diet is sufficient.

- Done

Page 7, 1st sentence - Should be re-worded as it reads quite confusing at the moment and is a presumption of potential ongoing research studies that might not be accurate. Rather than stating, "has never been tried...", the authors would consider simply stating that TRE studies are lacking...

- Done

Page 7, line 53 - improved should read improve

- Done

Page 10, line 25 - The authors have included HbA1c twice in this sentence as a secondary outcome measure

- Removed

Page 11, line 54 - It would be beneficial to the methodology here to include how many of these firefighters (%) read the materials provided

- We agree this is interesting information to include. Unfortunately, we do not have available resources to accurately determine if they read the material.

Page 12, line 23 - similar to the above comment, it would be beneficial in the methodology to include how many firefighters (%) changed their TRE window during the duration of this study

- We have added a sentence to clarify that we will include this information when we report the results.

Page 12, line 49 - Lowercase the T in the word The

- Done

Page 15, line 13 - switch should read switched

- Done

Page 15, line 56 - HbAa1c should read HbA1c

- Done

Page 18, line 22 - please correct your alpha spacing

- Done

Page 29, line 30 - The first sentence reads, "No TRE studies have been done on firefighters." Again, this sentence does not seem appropriate as the authors are assuming that there are no ongoing TRE investigations with firefighters at the moment. It would be more appropriate to remove this sentence and allow future readers to make this conclusion on their own, if this is in fact true when this study is published.

- This was revised to as "To date, there are no published studies assessing TRE as an intervention in firefighters."

Reviewer: 2

Dr. Matthew McAllister, Texas State University

Comments to the Author:

I appreciate the amount of detail and sophistication of the proposal. This is an important and meaningful research project and I have only found minor issues in terms of suggested clarifications. I have attached a document outlining those.

Comments attached document:

The protocol proposed by Manoogian et al, is a comprehensive RCT aimed at utilizing time restricted eating to potentially improve aspects of cardiometabolic health in professional firefighters. This is an important study and I am thankful that the authors have developed an extensive study to test this intervention in firefighters since this population is at elevated risk for mortality due to cardiovascular disease. As this is merely a study protocol, results and implications are not available for evaluation. However, some minor comments regarding a request for clarification are provided below. The authors present a wide variety of blood markers of cardiometabolic health but the authors may want to consider the possibility of including AGE and AOPP as outcome measurements since we have previously tested this dietary intervention (14:10) in firefighters (non RCT) and found reductions in both, despite finding no changes in cytokines and several other cardiometabolic markers:

https://journals.lww.com/nscajscr/Abstract/9000/Impact_of_Time_Restricted_Feeding_on_Markers_of_94173.aspx

Also, firefighters tend to have high levels of AOPP compared to other populations despite many other markers being within normal ranges. This is just a suggestion to consider.

- Thank you for the suggestion. We will consider incorporating AGE and AOPP for follow-up analysis.

Abstract

"TRE" should be defined upon first use, which would be line 13, as opposed to 16-17.

- We have defined TRE upon first use in line 6 of the abstract.

Methods:

General questions: What were their dietary habits prior to enrollment? Were these data gathered? Were the subjects excluded if they practiced TRE in the past? Many FF experiences some form of fasting due to their occupational demands/schedules.

- The first two weeks of the study for all participants is a baseline assessment to assess current dietary habits (and health). To do this we used the myCircadianClock app to capture all dietary

intake during this period. Participants were not excluded based on their current or previous eating behaviors.

What is meant by “the research team also works with participants to help adjust for challenging schedules”?

- For participants that had schedules that made a 10-h TRE window challenging, the research team would meet with them to go through their schedule and find solutions to help them incorporate the 10-h TRE intervention into their work and off days. E.g. adjusting their exercise timing with TRE window.

Were the self-chosen 10 hr eating windows variable? Were they told to follow the same window?

- Nearly all firefighters eat together one or two meals at the fire station during 7am-7pm. Therefore, most firefighter participants chose a 10-h window that lies between 7am-7pm. Once a participant chooses an eating window it should be consistent throughout the study. On page 12, we mention that the eating window could be changed as necessary, but they needed to inform us of a change, and it should be done very rarely.

Exclusion criteria- any dietary exclusions? Many firefighters take a variety of dietary supplements that potentially could impact these results as well. Was this screening done for dietary supplement use?

- There are no exclusions based on dietary intake including supplements. At the first visit, participants are asked what medication and supplements they take. Supplements are also logged on the myCircadianClock app.

Inclusion criteria- any accommodation if they did not own, or did not prefer using a smartphone to track dietary habits?

- Accommodations were not planned for individuals without smartphones. We are not aware of this being a limiting factor for any participants. All firefighters use smartphone for their work-related communications and to stay in touch with their family while on shift. So, all of them owned smartphones and were proficient in their use.

Intervention

Under “time-restricted eating” did the authors mean to state participants may consume coffee, not “caffeine” without cream or sugar?

- Although coffee is the most common item included, we did intend to say caffeine as it could be consumed as coffee, tea, or other caffeine supplement. As long as there were no added calories or artificial sweeteners, caffeine was permitted as needed. We have edited the text to say:
 - o “Participants may consume caffeine (without additional nutritional content such as cream, sugar, or artificial sweeteners) outside the eating window as needed, and log it in the mCC app.”

Further, many firefighters consume energy drinks that sometimes contain a range of kcals. Were these also allowed if they were calorie free, or very low in caloric density?

- Anything with greater than 5kcal content or artificial sweeteners were not allowed outside their eating window. But they were asked to diligently log everything they consumed, even outside their eating window. As one of the goals of the study is feasibility of TRE among firefighters, we wanted them to log every ingestion event.

Considering the occupational demands and many factors that can impact outcome measurements, were there any standardized conditions related to strenuous physical activity, smoke exposure, etc. prior to testing?

- There were no standardized conditions prior to testing. At each visit, we obtained information on the number of days (and types of shifts) they had worked for the week leading up to the visit.

Statistical analysis

In my opinion, the analysis appears sound and appropriate but I would request the review of a

statistician for an expert opinion on the analysis.

I think a bit more clarity on which specific measures to be examined would be helpful. Authors state: "Daily averages will be computed for the baseline and end of the intervention" --for what?

- Thank you for catching that, the wording was vague. We have changed it to read "The 95% eating window will be computed for the baseline and end of intervention."

VERSION 2 – REVIEW

REVIEWER	Waldman, Hunter University of North Alabama, Kinesiology
REVIEW RETURNED	Waldman, Hunter University of North Alabama, Kinesiology

GENERAL COMMENTS	The authors have addressed all minor concerns and have presented a well-written manuscript. This will be an impactful study once completed and published.
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REVIEWER	McAllister, Matthew Texas State University, Health & Human Performance
REVIEW RETURNED	24-Mar-2021

GENERAL COMMENTS	Authors have addressed all of my comments. Good luck with the execution of the study!
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