SYRACUSE UNIVERSITY

Protocol Title: Differential effects of HIIT vs. TRE on type 2 diabetes risk in youth and younger adults

Department of Exercise Science

Principal Investigator/Key Research Personnel: Joon Young Kim is an Assistant Professor in the Department of Exercise Science, Syracuse University (email: jkim291@syr.edu / phone: 315-443-1411 / 430 White Hall, 430-H). Dr. Kim will be responsible for overall management and direct supervision of the study procedures in this project.

Student Researchers: Wonhee Cho (wcho02@syr.edu), Alaina Glasgow (acglasgo@syr.edu), Andrew Heckel (arheckel@syr.edu), Eleanor Kwacz (ekkwacz@syr.edu), Julianna Verni (jmverni@syr.edu).

Introduction:

We are inviting you to be part of our research study. We are working with SUNY Upstate to recruit participants for our current research study. You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete. Your participation is voluntary. We are looking to recruit fifty participants for our study to examine the independent and combined effects of time restricted eating and high intensity interval training protocols.

What is the purpose for the research study?

The main goal of this study is to see how two different ways of eating and exercising affect the bodies of young people who are overweight and obese. Overweight and obesity mean having a lot of extra body fat, which can lead to serious health problems like diabetes or heart disease over time. As kids become teenagers and then adults, it's a time when these problems can start. That's why it's important to find ways to help young people who are overweight and obese stay healthy and avoid getting diabetes and/or heart disease.

What are some things about the study I should know?

- If you decide you want to be part of this study you will be asked to do one of three intervention over 12 weeks. You will be randomly assigned to one of the following groups: 1) time restricted eating alone, 2) high intensity interval training alone, or 3) control group. The time restricted eating group will eat their food within a self-selected 10-hour window. The high intensity interval training will perform three exercise sessions per week. The control group will perform neither protocol.
- You will be asked to visit Syracuse University for following reasons:
    - Have your body composition measured using the InBody system.
    - Have your waist circumference measured.

- Have your cardiovascular function measured.
- Collect your blood via an intravenous blood draw during an oral glucose tolerance test.

- You might not feel comfortable for several reasons. The InBody machine has no risk associated with it with individuals without a pacemaker. Some individuals may have their arm "fall asleep" while blood pressure cuff is around their arm. Blood draws have a minor risk of infection, which occurs in less than 1 in 1,000 people. Some people may faint or become sick to the stomach at the sight of a needle or when they see blood. This occurs in about 1 in 20 people. There can be some discomfort or bruising at the site after the blood is drawn, occurring in about 1 in 4 people. There might be a risk of the loss of confidentiality as you may be seen entering or leaving the labs. We cannot guarantee that others will not assume you are a research participant. But you do not have to do anything you do not want to do.
- There will be potential risks associated with HIIT (e.g., muscle soreness, cramping) which can be minimized with enough warm-up stretching and monitoring workout within your limit. In addition, in order to minimize potential risk associated with TRE (e.g., light-headedness, hunger), you will be instructed to drink water as needed.
- I also have to let you know if you were to tell me about anyone or anything that has hurt you or made you feel very upset, whether it's related to this study or not, I would have to tell someone who is not in the study.
- By participating this research, you will be examined how you are healthy and will be given your health information such as metabolic function, body composition, blood pressure, lipid profile, cardiovascular function with no cost.
- Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. Time restricted eating and high intensity interval training have both been shown to be an effective strategy in reducing BMI, and body fat percentage in individuals with overweight and obesity. By partaking in this study, you could potentially reduce your weight, which has been shown to improve cardiometabolic health. Additionally, you will be given access to information about your health such as body fat percentage and blood pressure.

What will happen when the study is completed?

- When we are finished with the study, we will write a report about what we learned (Include the following when appropriate: or we might also share what we learned at special meetings, etc.). The report will not include your name or that you were in the study.

Will I receive any kind of payment for participation?

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Compensation will be given out after each visit via Amazon gift cards. In total, 200 dollars will be given out for participants who complete the study protocol. Participants in the Control will obtain 100 dollars upon their completion of the visits.

- For the intervention group, there will be four time points for participants receiving compensation. The first and last compensation will be for the time and effort of one-time visit (i.e., one-day measurement visit). Upon completion of each visit, participants will receive $50 of gift card for each visit. If participants come to the lab but are not able to complete all tasks or measurements during a visit, they will receive $10 for their time and effort for the visit. The second and third compensation will require 2 weeks of intervention. Upon completion of each 2 weeks of intervention, participants will receive a total of $50 of gift card for each 2 weeks of intervention (a total of $100 of gift card after completion of the entire 4 weeks of intervention). Each compensation will be provided based on their time and effort with the pro-rating schedule below.
- [HIIT intervention: lab visit] 1st week of intervention: $8/day; 2nd week of intervention: $9/day; 3rd week of intervention: $8/day; 4th week of intervention: $9/day
- [TRE intervention: home-based food track survey] 1st week of intervention: $3/day; 2nd week of intervention: $4/day; 3rd week of intervention: $3/day; 4th week of intervention: $4/day
- For the control group, the compensation will be given based on their one time visit so pro-rating schedule will not be applicable.

What else should I know before I decide to join the study?

- I have already asked your parents and they said it okay for you to be in the study. But, you can choose if you want to be in the study or not. It's up to you to decide on your own. No one will be mad at you if you decide you do not want to be in the study. Once you start, if you change your mind, you can stop at any time. No one will be angry if you decide to stop. You just have to let us know. You can ask us questions at any time before you decide to be in the study or during the study if you decide to join. You can ask your parents, grandparents, teachers, etc. about being in the study.
- Data will be shared with Dr. Kim, Wonhee Cho, Alaina Glasgow, Andrew Heckel, Eleanor Kwacz, and Julianna Verni via Syracuse University One Drive. The data will include identifiable information while it is protected with password and will not be shared any other person outside of the research team.
- Your contact information along with study ID will be maintained in a separate spreadsheet such that no one, except for only selected members of the research team (Dr. Kim, Wonhee Cho) will have access.
- Your identifiers will be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional consent from the participant or the legally authorized representative.

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- We will be sharing the following information about you/your child with the research staff at SUNY Upstate in order for the OGTT to be scheduled at the Clinical Research Unit:
    - Your name
    - Your date of birth
    - Your address
    - Your phone number
    - Your gender
    - Other required PHI (protected health information) that is needed to create and schedule participants for OGTT at SUNY CRU

All of my questions have been answered; I agree to participate in this research study. I have received a copy of this form to keep.

---------- **Date: _____**

Printed Name of the Participant

_____

Signature of the Participant

---------- **Date: _____**

Printed Name of the Researcher

_____

Signature of the Researcher

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Protocol Title: Differential effects of HIIT vs. TRE on type 2 diabetes risk in youth and younger adults

Department of Exercise Science

Primary Investigator: Joon Young Kim is an Assistant Professor in the Department of Exercise Science, Syracuse University (email: jkim291@syr.edu / phone: 315-443-1411 / 430 White Hall, 430-H)
Student Researchers: Wonhee Cho (wcho02@syr.edu), Alaina Glasgow (acglasgo@syr.edu), Andrew Heckel (arheckel@syr.edu), Eleanor Kwacz (ekkwacz@syr.edu), Julianna Verni (jmverni@syr.edu).

Introduction:

- The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate.
- We are working with SUNY Upstate to recruit participants for our current research study.
- You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete.
- Your participation is voluntary.
- We are looking to recruit fifty participants for our study to examine the independent and combined effects of time restricted eating and high intensity interval training protocols.

What is the purpose for this research study?

- Overweight or obesity (defined as a body mass index [BMI] ≥25 kg/m^2) serves as a precursor to serious cardiometabolic health disorders.
- The transition from adolescence to young adulthood has recently been recognized as a critical time period for the development of diseases such as type 2 diabetes and cardiovascular disease.
- It is during this life stage that young adults begin to establish health behavior patterns that last into late adulthood.
- Thus, it may be beneficial to develop strategic ways specifically targeting emerging young adults with overweight and obesity to delay the onset of or prevent type 2 diabetes and cardiovascular disease.
- Time restricted eating, a type of short-term fasting, is defined as periods of no energy intake followed by periods of ad libitum (as much as desired) energy intake and has been shown to be an effective strategy in reducing BMI and body fat percentage in adults with overweight and obesity.
- High intensity interval training, is a type of workout that focuses on short intense burst of exertion, followed by longer periods of rest and has also been shown to be an effective strategy in reducing BMI and body fat percentage in adults with overweight and obesity.
- Therefore, the primary aim of our research at Syracuse University is to compare the independent effects of a time restricted eating and high intensity interval training protocols on body composition and cardiovascular risk factors in young adults with overweight and obesity.

What will I be asked to do?

- You will be randomly assigned to one of the following groups: 1) time restricted eating alone, 2) high intensity interval training alone, or 3) control group.
- The time restricted eating group will eat their food within a self-selected 10-hour window.
- The high intensity interval training will perform three exercise sessions per week.

- The control group will perform neither protocol.
- Have your body composition measured using the InBody system.
- Have your waist circumference measured.
- Have your cardiovascular function measured.
- Collect your blood via an intravenous blood draw during an oral glucose tolerance test.

What are the possible risks of participation in this research study?

- There will be potential risks associated with HIIT (e.g., muscle soreness, cramping) or TRE (e.g., light-headedness, hunger).
- The InBody machine has no risk associated with it with individuals without a pacemaker.
- Some individuals may have their arm "fall asleep" while blood pressure cuff is around their arm.
- Blood draws have a minor risk of infection, which occurs in less than 1 in 1,000 people.
- Some people may faint or become sick to the stomach at the sight of a needle or when they see blood. This occurs in about 1 in 20 people.
- There can be some discomfort or bruising at the site after the blood is drawn, occurring in about 1 in 4 people.
- There might be a risk of the loss of confidentiality as you may be seen entering or leaving the labs.
- We cannot guarantee that others will not assume you are a research participant.

What are the possible benefits of participation in this research study?

There are no direct benefits as a result of participation of this study. However, by participating this research, you will be examined how you are healthy and will be given your health information such as metabolic function, body composition, blood pressure, lipid profile, cardiovascular function with no cost.

Time restricted eating and high intensity interval training have both been shown to be an effective strategy in reducing BMI, and body fat percentage in overweight or obese adults. By partaking in this study, you could potentially reduce your weight, which has been shown to improve cardiometabolic health.

How will my privacy be protected?

For data collection occurring in Clinical Research lab (CRL) & the Human Performance lab (HPL) located at the Women's Building (Dept. of Exercise Science) at Syracuse University , and SUNY Upstate, only the research staff and you will be in attendance. Also, our lab is in a publicly accessible building. Thus, privacy when entering/exiting the facility cannot be guaranteed.

We will keep data collected during the study as confidential as possible with the exception of certain information we must report for legal or ethical reasons such as child abuse, elder abuse, sexual misconduct, or intent to harm self or others.

We will be sharing the following information about you with the research staff at SUNY Upstate in order for the OGTT to be scheduled at the Clinical Research Unit:

- Your name
- Your date of birth
- Your address
- Your phone number
- Your gender
- Other required PHI (protected health information) that is needed to create and schedule participants for OGTT at SUNY CRU

How will my data be maintained to ensure confidentiality?

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All research staff have completed CITI training and are aware of general ethical guidelines regarding research participant privacy and confidentiality. We will have weekly laboratory meetings to discuss study progress and during these meetings, we will continue to review aforementioned policies to ensure all staff are maintaining participant privacy and confidentiality standards. Data will be shared with Dr. Kim, Wonhee Cho, Alaina Glasgow, Andrew Heckel, Eleanor Kwacz, and Julianna Verni via Syracuse University One Drive. The data will include identifiable information while it is protected with password and will not be shared any other person outside of the research team.

All other forms, data spreadsheets, and identifiers used as part of software data acquisition will use participant study ID numbers only. Contact information along with study ID will be maintained in a separate spreadsheet such that no one, except for only selected members of the research team (Dr. Kim, Wonhee Cho) will have access.

Your identifiers will be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional consent from the participant or the legally authorized representative.

How will I be compensated?
Compensation will be given out after each visit via Amazon gift cards. In total, 200 dollars will be given out for participants who complete the study protocol. Participants in the Control will obtain 100 dollars upon their completion of the visits.

- For the intervention group, there will be four time points for participants receiving compensation. The first and last compensation will be for the time and effort of one-time visit (i.e., one-day measurement visit). Upon completion of each visit, participants will receive $50 of gift card for each visit. If participants come to the lab but are not able to complete all tasks or measurements during a visit, they will receive $10 for their time and effort for the visit. The second and third compensation will require 2 weeks of intervention. Upon completion of each 2 weeks of intervention, participants will receive a total of $50 of gift card for each 2 weeks of intervention (a total of $100 of gift card after completion of the entire 4 weeks of intervention). Each compensation will be provided based on their time and effort with the pro-rating schedule below.
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- For the control group, the compensation will be given based on their one time visit so pro-rating schedule will not be applicable.

Will clinically relevant research results will be returned to the participant?
Yes, you will receive information on your percent body fat; however, please note, this is not for diagnostic purposes. We are not able to diagnose diseases or health conditions. You may share information provided with your primary healthcare provider to learn more about your health.

What are my rights as a research participant?
- Your participation is voluntary.
- You may stop any measurement at any time.

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- You are free to withdraw from this research study at any time without penalty.

Whom may I contact with questions now, during, or after the research is complete?

- Everything we will ask you to do for this study will be used for research purposes only. If you have questions now, during, or after the research is completed, please send an email to Dr. Kim (Principal Investigator) at jkim291@ syr.edu, and Wonhee Cho (Student staff) at wcho02@syr.edu, and they will get back to you very soon.
- If you have questions or concerns about your rights as a research participant, you may contact the Syracuse University Institutional Review Board at (315) 443-3013.

All of my questions have been answered, I am between the age of 18 and 30, and by signing this consent form, I agree to participate in this research study. I have received a copy of this form for my personal records.

---------- **Date:** _____

Printed Name of the Participant

_____

Signature of the Participant

---------- **Date:** _____

Printed Name of the Researcher

_____

Signature of the Researcher

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Protocol Title: Differential effects of HIIT vs. TRE on type 2 diabetes risk in youth and younger adults

Department of Exercise Science

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Introduction:

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- You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete.
- Your child's participation is voluntary.
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What is the purpose for this research study?

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- The transition from adolescence to young adulthood has recently been recognized as a critical time period for the development of diseases such as type 2 diabetes and cardiovascular disease.
- It is during this life stage that adolescents begin to establish health behavior patterns that last into late adulthood.
- Thus, it may be beneficial to develop strategic ways specifically targeting emerging adolescents with overweight and obesity to delay the onset of or prevent type 2 diabetes and cardiovascular disease.
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- High intensity interval training, is a type of workout that focuses on short intense burst of exertion, followed by longer periods of rest and has also been shown to be an effective strategy in reducing BMI and body fat percentage in youth with overweight and obesity.
- Therefore, the primary aim of our research at Syracuse University is to compare the independent effects of a time restricted eating and high intensity interval training protocols on body composition and cardiovascular risk factors in youth with overweight and obesity.

What will my child be asked to do?

- Your child will be randomly assigned to one of the following groups: 1) time restricted eating alone, 2) high intensity interval training alone, or 3) control group.
- The time restricted eating group will eat their food within a self-selected 10-hour window.
- The high intensity interval training will perform three exercise sessions per week.

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- The control group will perform neither protocol.
- Have your child's body composition measured using the InBody system.
- Have your child's waist circumference measured.
- Have your child's cardiovascular function measured.
- Collect your child's blood via an intravenous blood draw during an oral glucose tolerance test.

What are the possible risks of participation in this research study?

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- There might be a risk of the loss of confidentiality as you may be seen entering or leaving the labs.
- We cannot guarantee that others will not assume you are a research participant.

What are the possible benefits of participation in this research study?

There are no direct benefits as a result of participation of this study. However by participating this research, your child will be examined how they are healthy and will be given their health information such as metabolic function, body composition, blood pressure, lipid profile, cardiovascular function with no cost. Time restricted eating and high intensity interval training have both been shown to be an effective strategy in reducing BMI, and body fat percentage in individuals with obesity. By partaking in this study, your child could potentially reduce their weight, which has been shown to improve cardiometabolic health.

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Yes, you and your child will receive information on your child's percent body fat; however, please note, this is not for diagnostic purposes. We are not able to diagnose diseases or health conditions. You may share this information provided with your primary healthcare provider to learn more about your child's health.

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- Your child is free to withdraw from this research study at any time without penalty.

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All of my questions have been answered, and by signing this consent form, I agree to allow my child to participate in this research study. I have received a copy of this form for my personal records.

---------- **Date:** _____
Printed Name of the Parent

_____
Signature of the Parent

---------- **Date:** _____
Printed Name of the Participant

---------- **Date:** _____
Printed Name of the Researcher

_____
Signature of the Researcher