Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Medicine and Health Sciences
Department of Neuromedicine and Movement Science

Jared Baker

# The effects of time-restricted eating and unsupervised interval training on fat mass, body weight and VO2peak in adults with overweight or obesity. Preliminary findings from a randomized controlled trial

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Preliminary findings from a randomized controlled trial

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# The effects of time restricted eating and high intensity interval training on fat mass, body weight and peak oxygen uptake in adults with a BMI ≥ 27 kg/m2

**Study design:**
20 men and women (aged 18-50) randomly allocated 1:1 to 7 weeks of:

## TIME RESTRICTED EATING & HIGH INTENSITY INTERVAL TRAINING (TREHIIT)



- Aerobic exercise ≥ 90% individual HRmax 3x/week (4 x 4 & 10 x 1)
- Energy intake ≤ 10 h/day
- Follow-up via telephone

## CONTROL (CON)

- No intervention

## Findings

3.3 ml/min/kg in VO2peak after TREHIIT vs. CON

No effect on weight or fat mass after TREHIIT vs. CON

## Clinical Implications

Increased VO2peak reduces risks of cardiovascular disease, type 2 diabetes and all-cause mortality

Long-term studies are needed to determine effects and feasibility beyond 7 weeks

# Abstract

**Background**
Obesity is a current epidemic and is associated with cardiovascular and metabolic diseases, as well as premature death. Even if physical activity (PA) and a healthy diet are first-line options for prevention and treatment of obesity, many adults fail to adhere to current guidelines for PA and dietary intake. Time-restricted eating (TRE) and high intensity interval training (HIIT) are two diet-exercise strategies that can improve cardiometabolic health in adults with overweight or obesity.

**Objective**
The aim of this study was to determine the combined effect of 7 weeks of TRE and unsupervised HIIT on body composition and cardiorespiratory health among adults with overweight or obesity.

**Methods**
This study was a randomized controlled trial (RCT) with two parallel groups. Men and women 18-50 years old were randomly allocated 1:1 to an intervention group (TREHIIT) or a no-intervention control group (CON). Participants in TREHIIT were asked to reduce daily time-window of energy intake to ≤ 10 h/day and to undertake three unsupervised HIIT sessions for 7 weeks. The primary outcome was change in fat mass and secondary outcomes were changes in body weight and peak oxygen uptake ($VO_2$peak), in TREHIIT compared with CON.

**Results**
There were 20 participants that were included in the analysis (TREHIIT = 11, CON = 9). There was no statistically significant difference in fat mass (-1.2 kg (95% confidence interval (CI) -3.35, 0.98, p = 0.266), or body weight (-1.6 kg (95% CI -3.79, .671, p = 0.159) between the two groups. There was a statistically significant difference in $VO_2$peak and $VO_2$peak increased after TREHIIT compared with CON (+ 3.3 ml/min/kg (95% CI 2.28, 6.35, p = 0.034)

**Conclusion**
The combination of TRE and unsupervised HIIT for 7 weeks did not reduce fat mass or body weight in adults with overweight/obesity. The intervention induced a clinically significant increase in $VO_2$peak, which helps to increase insulin sensitivity, and reduce the risks of cardiovascular disease, cardiovascular mortality and all-cause mortality.

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# Acknowledgements

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# 1. Introduction

### 1.1 Overweight or obesity

Obesity is a global epidemic and currently there are 1.9 billion adults classified as being overweight or obese worldwide (1). Individuals with a body mass index (BMI) of $\geq 25$ kg/m$^2$ are considered overweight and those with a BMI of $\geq 30$ kg/m$^2$ are considered obese. Several factors can contribute to overweight or obesity, including a sedentary lifestyle, improper diet and/or physical inactivity (1). Overweight or obesity are a current health problem because of their association with the development of type 2 diabetes, hypertension, heart disease, metabolic diseases and several types of cancer (2, 3).

### 1.2 Current recommendations for physical activity and nutrition

Research has shown that participating in regular physical activity (PA) is a key factor to losing weight, maintaining weight loss, curbing obesity, as well as preventing and managing cardiovascular diseases (CVD), type 2 diabetes and several forms of cancer (4). The current guidelines from the World Health Organization (WHO) recommends 150-300 minutes of moderate intensity PA, 75-150 minutes of vigorous intensity PA, or a combination of both per week for adults to maintain or improve health (5). Additionally, adhering to a strength training regime two times or more per week has added health benefits (5).

Adhering to the PA recommendations improves cardiovascular and metabolic health for adults with overweight or obesity (6). Additionally, individuals who engage in moderate to vigorous PA have 30-40% lower risk of mortality, and 64% lower risk of a heart attack (6). Moreover, PA can improve body composition (reduce body weight, BMI and body fat percentage) by increasing energy expenditure and creating a caloric deficit (7, 8).

Healthy nutritional habits are also vital for adults with overweight or obesity. Diets such as the Mediterranean diet, the Dietary Approaches to Stop Hypertension (DASH), the 2015 Dietary Guidelines for Americans, and the Healthy Eating Plate are all recommended by registered dietitians and nutritionists as healthy eating strategies (9). All four of these diets recommend a diet of unprocessed foods, fruits, vegetables, plant-based fats, proteins, legumes, nuts and whole grains for adults to maintain a healthy weight (9). These diet guidelines additionally recommend that each meal should consist of 50% fruits and vegetables, 25% protein, and 25% whole grains on a daily basis (9). These four dietary guidelines additionally recommend that sugar should constitute only 5-10% of daily energy intake and refined grains should be avoided (9). Omega 3 fatty acids such as fish, along with foods high in fiber are strongly recommended on a weekly basis (9). Adhering to either of these recommended diets indicate evidence for better weight management, preventing type 2 diabetes, cancer, cardiovascular disease and premature death (9).

### 1.3 Barriers to physical activity and nutrition

Fewer than one in three adults globally are currently adhering to recommendations for PA (4). There are several factors contributing to this low level of PA, including motivation, time constraint and a lack of resources to pay for access to training facilities (10, 11). Furthermore, technological advances such as cars, TV streaming services, online gaming, and delivery services have led to increased sedentary behaviour which intensify the decline in PA (12, 13).

Many people also have difficulty adhering to dietary recommendations because of the easy access to fast food and restaurants that offer high calorie, high fat and poor nutritious food (14). Furthermore, there are multinational corporations that have altered the global food system to produce and market processed packaged affordable foods that are high in fat and sugar, leading to an increase in consumption, further exacerbating obesity (15, 16). Indeed, portion sizes and energy intake from foods high in fat and caloric content and consumption of sugary drinks have increased markedly since the 1990s (17). In our current society, eating windows, which is the duration per day that an individual consumes energy are ~15 hours, with > 35% of caloric intake being at night (18, 19). Late night eating induces overnight glucose intolerance as well as reduces fat oxidation which can lead to weight gain (18,19). Due to these barriers affecting adults with overweight or obesity to adhere to recommended PA and nutritional guidelines, we need novel strategies to combat these issues.

### 1.4 Alternative exercise and diet strategies

#### *1.4.1 High intensity interval training*

High intensity interval training (HIIT) is one type of exercise that may help to bypass some of the barriers to PA. HIIT involves repeated bouts of exercise at an intense effort that elicits ≥ 80%, but often as high as 85-95% of an individual's maximal heart rate, interspersed by low-to-moderate-intensity exercise or periods of rest (20). HIIT has gained attention because individuals spend less time training, alleviating the time constraints many perceive as a barrier to exercise, while attaining effective weight loss (20). Additionally, HIIT can improve $VO_2$max by ≥ 10% after just 8 weeks, indicating efficient improvement in cardiorespiratory and metabolic health in a short time frame (20, 21). Moreover, HIIT can be performed as outdoor walking/running (22), thereby being a very low cost strategy (11).

#### *1.4.2 Time restricted eating*

Time restricted eating (TRE) is a relatively novel dietary approach and a type of eating strategy based on the circadian rhythm (23). With TRE, the energy intake typically fits in a time window of 6-10 hours during the most active part of a person's day (24). TRE reduces the number of eating occasions, body weight and visceral fat mass in individuals, and additionally decreases fat mass while preserving muscle mass (23, 25). This dietary strategy, additionally has improved glucose tolerance, cardio metabolic health, gut function, and reduced blood pressure (24). One reason for these positive effects on body

composition variables after TRE is that individuals typically reduce their energy intake. For example, one study showed that TRE decreased weekly energy intake by ~3000 kilocalories (kcal) along with a weight loss of 3% after just 8 weeks (26).

### 1.5 Combination of TRE and HIIT

Research indicates that both TRE and HIIT can be effective, however, to my knowledge, most prior studies have only investigated the individual effects of TRE and HIIT, with only one prior randomized control trial (RCT) combining the two (27). That study revealed that the combination of TRE and HIIT decreased body weight, fat mass, visceral fat area and induced a significant reduction in glycated hemoglobin (HbA1c) in women with overweight or obesity, with an additive effect compared to each isolated intervention (27). In the same study, the participants adhered to a ≤ 10-h eating window for 6.1 days/week, similar to the adherence rate reported in the study by Gabel and colleagues (26, 27). Furthermore, the participants in the study by Haganes and co-workers completed 94% of the scheduled HIIT sessions, indicating that the adherence to HIIT was good and similar to the 93.4% adherence in another study investigating HIIT (27, 28). These adherence rates were high in these two studies indicating motivation to perform HIIT among the participants in each of these respective studies.

The HIIT sessions in the study by Haganes and colleagues were performed in a laboratory setting under the supervision of researchers, which limit the translational value to clinical practice. Additionally, the study by Haganes et al, (2022) included only women. Women are currently overrepresented in weight-loss interventions (29), and more research is warranted in men. On this background, it is pertinent to investigate the combined effects of TRE and HIIT among both men and women with overweight or obesity. For clinical implementation of any lifestyle intervention to manage overweight/obesity, it is important that the intervention can be delivered without close supervision.

### 1.6 Aim and Hypothesis

The aim of this study was to determine the combined effect of TRE and unsupervised HIIT on body composition and cardiorespiratory health among adults with overweight or obesity. My primary hypothesis was that 7 weeks of TRE combined with unsupervised HIIT would induce a greater decrease in fat mass, compared with a non-intervention control group. Secondly, I hypothesized that the intervention group would have a greater decrease in body weight and a greater increase in $VO_2$peak compared with the control group.

# 2. Methods

## 2.1 Study setting and trial design

This study was a RCT with two parallel groups: Intervention (TREHIIT) and control (CON), and was conducted at the Department of Circulation and Medical Imaging at the Norwegian University of Science and Technology (NTNU), Trondheim, Norway. Each participant was enrolled in the study for a total of 8-9 weeks, which included one day of pre-assessments, one baseline week (week 0) followed by 7 weeks of intervention (TREHIIT) or non-intervention (CON), and one day of post-assessments, (Figure 1). Pre- and post-assessments followed identical protocols and were scheduled during the follicular phase in women with a regular menstrual cycle. The protocol was approved by the Regional Committee for Medical and Health Research Ethics in North Norway (REK no. 479143) and the trial is registered in Clinicaltrials.gov (NCT05505305). Testing of the participants was carried out at the NextMove Core Facility and laboratories at the Faculty of Medicine and Health Sciences, NTNU, located in St. Olavs Hospital, Trondheim, Norway. The collected data were treated in accordance with the General Data Protection Regulation and the participant's written consent.

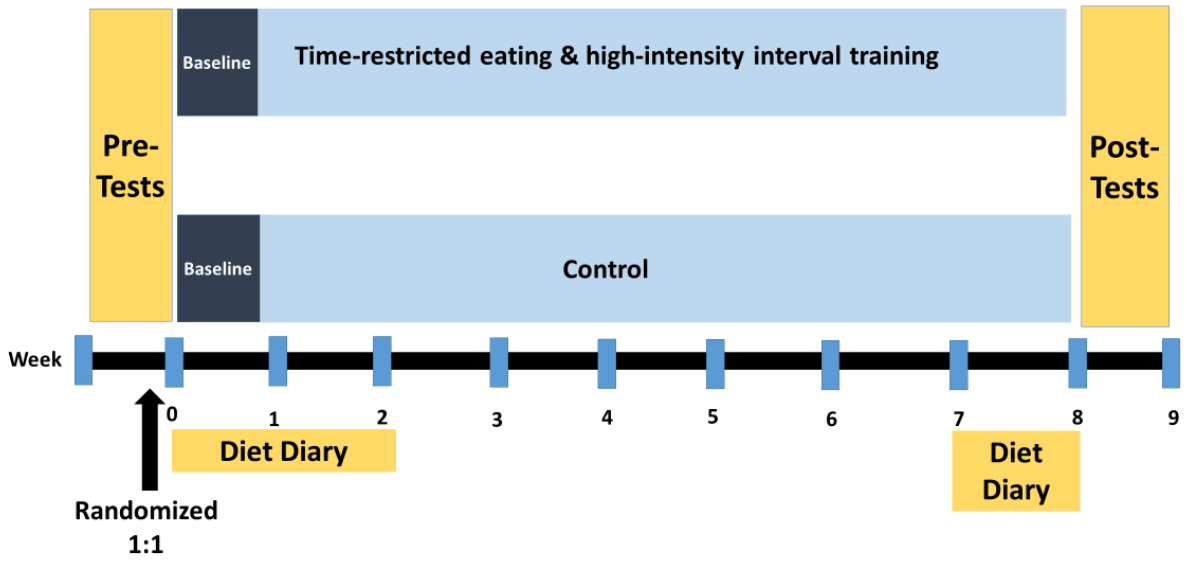


**Figure 1.** Study Design

## 2.2 Participants

To be eligible for inclusion, participants had to be between 18-50 years, have a BMI ≥ 27 kg/m², and be able to walk on a treadmill or ride a bike for ≥ 60 min. Exclusion criteria were pregnancy, breastfeeding within 24 weeks of study commencement, known CVD, diabetes type 1 or 2, taking anti-hypertension medication, taking glucose- or lipid-lowering medication, a habitual eating-window

of ≤ 12 h/day, performing HIIT more than once/week, a body mass variation > 4 kg in the last 3 months, or nightshift work.

Participants were recruited through tailored social media campaigns and flyers/posters hung throughout the Trondheim area. Participation was voluntary, with the opportunity to withdraw from the study at any time point. Before entering the study, participants signed a written informed consent (Appendix). Volunteers expressed their interest by email to PhD student Kamilla La Haganes and were contacted by investigators for a thorough pre-screening.

### 2.3 Intervention

*2.3.1 High-intensity interval training*

The participants in TREHIIT attended one supervised 4 x 4 minute HIIT session in the laboratory on the first day of the 7-week intervention. They were instructed to complete two weekly sessions of 4 x 4 minute HIIT and one weekly session of 10 x 1 minute HIIT at ≥ 90% of each individual's heart rate max (HRmax) (Figure 2). Depending on the participant's preference, they could choose to perform the HIIT sessions as outdoor or treadmill walking/running, outdoor or stationary bicycling, elliptical machine, or cross-country skiing. Each participant received a heart rate (HR) monitor (Polar H10) for the duration of the study and connected the monitor via Bluetooth to the Polar Beat app installed on their personal mobile phone. I instructed the participants to record all exercise sessions in the Polar Beat app.

*2.3.2 Time-restricted eating*

Participants were instructed to consume all energy within a window of ≤ 10 hours/day with no caloric restriction. The participants were recommended to not consume energy after 20:00 h (Figure 3). Participants were allowed to drink zero-calorie drinks outside of the energy intake window. All participants completed a baseline week (week 0) where they were instructed to continue their habitual PA and diet.

*2.3.3 Follow-up via telephone*

Participants received once weekly follow-up by phone call or video call by me without a standardized duration for the length of phone or video call. Each consultation session comprised the revision and discussion of intervention-related experiences over the past week, and addressing any challenges or questions the participants had. I provided advice and feedback based on the participant's responses. I assessed HR data from the HIIT sessions via www.polarflow.com following the introductory session, and used the data to guide conversations about training progress and/or other issues.

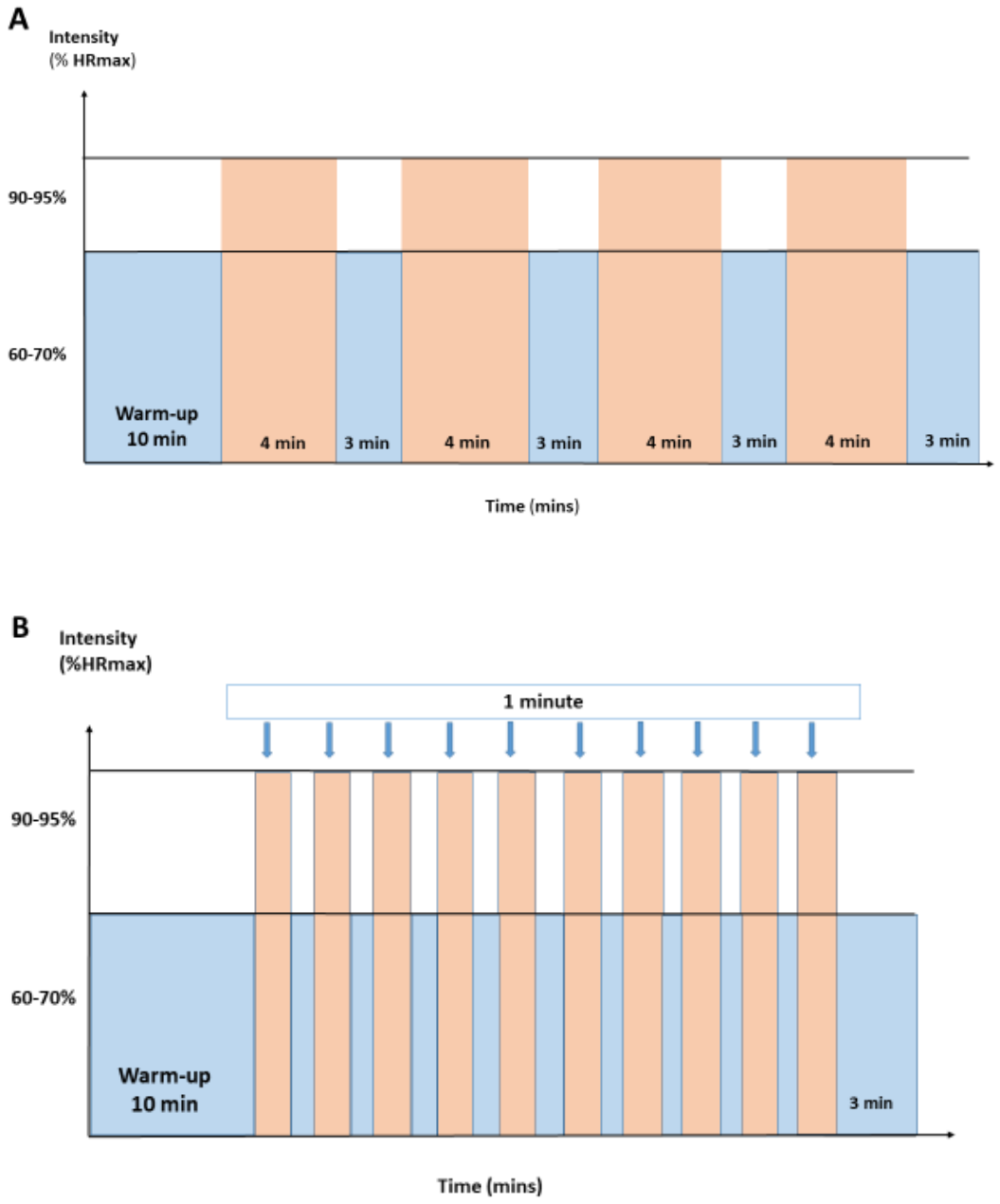


**Figure 2. High-intensity interval training (HIIT) protocol. (A)** 4 x 4 minute HIIT at ≥ 90% of individual heart rate max (pink column) with 3 minute moderate-intensity activity at 60-70% of individual heart rate max between the work bouts (blue column), and ending with ~3 minute cool-down. **(B)** 10 x 1 min HIIT at ≥ 90% of individual heart rate max (pink column), separated by 1 minute low-intensity activity at 60-70% of individual heart rate max between the work bouts (blue column), and ending with ~3 minute cool-down. Both protocols had a 10 minute warm-up.

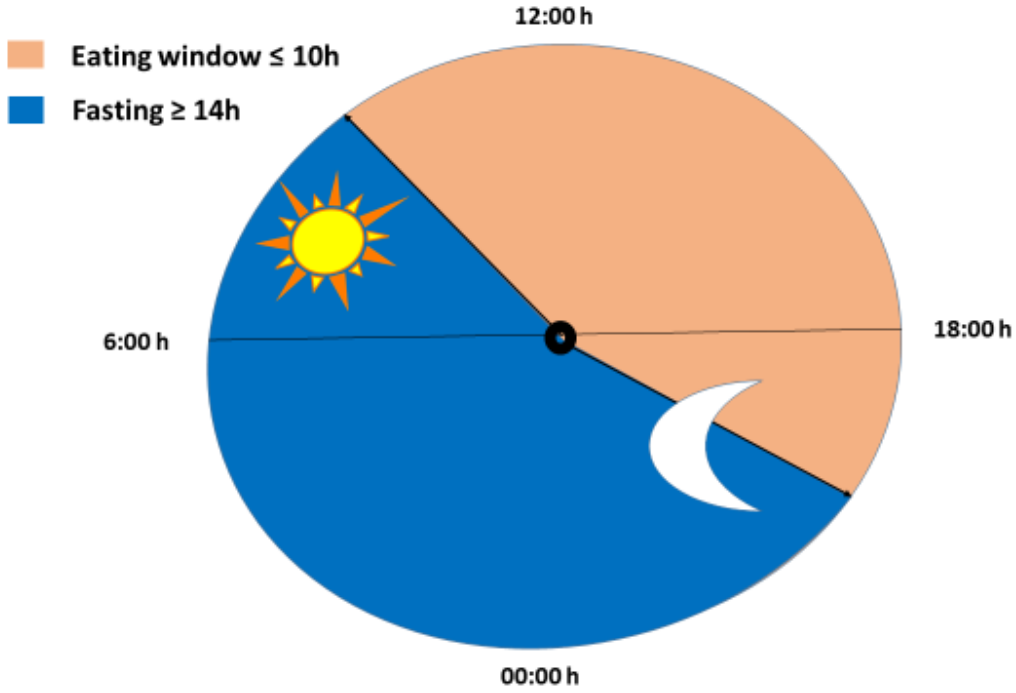


**Figure 3. Time-restricted eating (TRE).** Energy intake was restricted to ≤ 10 h/day, with ≥ 14 h/day of fasting. The last energy intake was recommended to be consumed at ≤ 20:00h.

## 2.4 Control Group

Participants in the control group were instructed to continue with their habitual dietary intake and PA during the 8-week study period, with no follow-up. Upon completion of the study, the participants in the control group were offered to attend the laboratory for an introductory session of HIIT. I also informed them about TRE and the metabolic benefits they might obtain with such an eating strategy and regular exercise.

*Study Handbook and App*

All participants were given a study handbook in which they recorded their appetite, sleep schedule and PA only for weeks 0, 1 and 8. The participants recorded their time points of their first and last daily energy intake every day in the handbook. During week 0, 1 and 8, participants recorded their diet in the FatSecret dietary app (https://www.fatsecret.com/) and sent us their recordings by email.

## 2.5 Assessments

*2.5.1 Body Composition Analysis*

Height was measured without shoes using a standard stadiometer. I estimated the participants' total body mass, fat mass, muscle mass, BMI, and visceral fat area, using bioelectrical impedance analysis (InBody720, Biospace CO, Korea). Participants wore light clothes and no shoes or socks, and had an

empty bladder. The tests were conducted between 8:00 and 9:30 h and participants were fasted from 22:00 h the previous night.

*2.5.2 Cardiorespiratory Fitness Test*

I used an individualized ramp protocol to measure $VO_2$peak. After a 10-minute warm-up, the speed or inclination of the treadmill was increased every 1–2 minute, by 0.5–1.0 km/hour or 1%–2%, until the participant reached voluntary exhaustion and/or an respiratory exchange ratio (RER) > 1.10 or a plateau in $O_2$ uptake. The participants wore an HR monitor for the entire duration of the test. $VO_2$peak was determined by the average of the three highest consecutive measurements and was reported as a relative (ml/min/kg) value. The HRmax (the highest HR during the test) was recorded and the participant reported their rate of perceived exertion according to the Borg (6-20) scale (30) immediately upon completion of the test.

*2.5.3 Other Assessments*

Blood samples and questionnaires were also administered during pre and post-tests, but were not used in this thesis. The questionnaires and other lab assessments will be used for future analyses of the main study. Blood samples are stored in a -80 degrees freezer for future analysis.

**2.6 Adherence**

I calculated the adherence to the HIIT protocol as the percentage of sessions completed (out of the intended 21). As a measure of compliance to the HIIT protocol of ≥ 90% individual HRmax, I calculated the mean percentage of HR during each individual 4 x 4 work bout and 10 x 1 work bout to find the mean HR for each individual 4 x 4 and 10 x 1 session. In the calculation, I used the average HR from the last 2 minutes of each 4 minute bout and the last 30 seconds of each 1 min bout. Adherence to the TRE protocol was estimated from the average self-reported eating-window duration and the average number of days per week with a window of ≤ 10 h.

**2.7 Outcomes**

The primary endpoint was the change in total fat mass from baseline to after the 7-week intervention period in the TREHIIT group compared with CON. The secondary endpoints were the change in body weight and $VO_2$peak from baseline to after the 7-week intervention period in the TREHIIT group compared with CON.

**2.8 Sample Size**

We calculated the sample size for the trial based on clinically meaningful difference in fat mass (primary outcome measure). A reduction of 5-10% is deemed clinically meaningful (31). In the calculations, we have used a 7% reduction. With this difference, a standard deviation of 6% (the observed variation in

Haganes et al) (27), significance level 0.05, and 85% statistical power, we will need 26 participants. To allow for up to 20% lost to follow-up, we aimed to include at least 34 participants.

### 2.9 Randomization and blinding

Randomization was conducted after the participants had completed the baseline testing. We used a random number generator, developed by The Unit for Applied Clinical Research, NTNU, Trondheim, Norway, to randomly allocate participants (1:1) to the two study groups, stratified by sex. Neither the investigators nor the participants were blinded to allocation.

### 2.10 Statistical Methods

I used a linear mixed model to estimate the effect of the intervention relative to the changes in the control group for each outcome variable. Time (pre and post) and the interaction between visit and group were included as fixed effects. The participant's ID was included as a random effect to account for repeated measurements. I visually inspected the distribution of residuals using Q-Q plots to check whether the data were normally distributed. I used paired samples t-test to assess within-group changes for total energy intake and energy intake window from baseline to post-intervention, and report observed values as means with standard deviation. I consider p-values $< 0.05$ as statistically significant with no adjustments for multiple comparisons. All statistical analysis were performed in IBM SPSS Statistics v.27 (SPSS Inc., USA) and I generated the figures in Graph Pad Prism 9.

## 3. Results

A total of 36 participants were enrolled and randomized for the main study. The participants were recruited between August 2022 and February 2023. I only used data from participants that completed post assessments on or before March 1, 2023 (n = 20). Figure 4 shows the flow of participants from the whole trial and specifies the participants included in my study and Table 1 shows the baseline of participants.

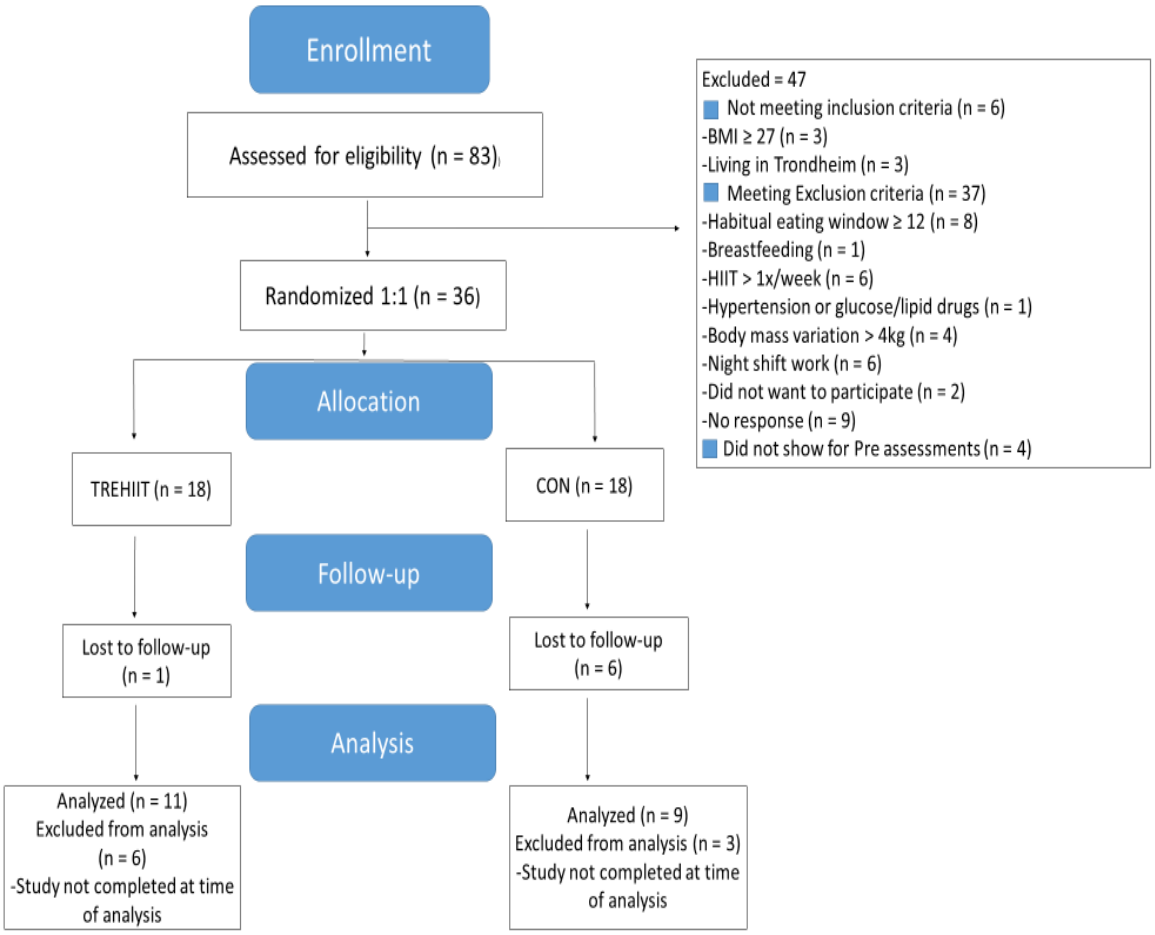


**Figure 4**. Flow chart of participants in the trial with specification of those included in this master project (n = 20). N = 7 participants were lost to follow up before March 1, 2023. The analysis was conducted on participants that completed the study on or before March 1, 2023.

**Table 1**. Baseline characteristics of participants according to group. Values are means ± standard deviation, or number of participants. TREHIIT = Time-restricted eating and high intensity interval training. CON = Control group.

| | TREHIIT (n = 11) | CON (n = 9) |
|---|---|---|
| Gender (men/women) | 6/5 | 5/4 |
| Age (years) | 35.5 ± 7.8 | 37.8 ± 4.3 |
| Height (centimeters) | 172. 8 ± 15.0 | 174.5 ± 10.8 |
| Body weight (kg) | 102.1 ± 26.9 | 102.8 ± 13.1 |
| BMI ($kg/m^2$) | 33.8 ± 5.0 | 33.8 ± 3.4 |
| Fat mass (kg) | 40.5 ± 14.6 | 38.3 ± 9.8 |
| $VO_2$peak (ml/min/kg) | 34.2 ± 3.7 | 38.8 ± 7.7 |

### 3.1 Effect of the intervention on fat mass, body weight and $VO_2$peak

There was no statistically significant difference between the groups in change in fat mass (primary outcome measure) or in body weight after 7 weeks (Table 2). Participants in TREHIIT increased their $VO_2$peak by 9% (95% CI, 2.82 to 6.36, p = 0.034), compared with CON after 7 weeks. There were individual differences in the changes in fat mass, body weight and $VO_2$peak from baseline to after the intervention period (Figure 5).

**Table 2.** Changes in fat mass, body weight and peak oxygen uptake ($VO_2$peak) from baseline to study completion. Observed values are expressed as means ± standard deviation. Effects of the intervention are derived from model-based estimates and are relative to change in the control (CON) group. The data are presented with corresponding 95% confidence intervals (CI), and p-values are for between group differences.

| | Baseline | At study completion | Estimated effect | 95% CI | p-value |
|---|---|---|---|---|---|
| Fat mass (kg) | | | | | |
| CON | 38.3 ± 9.8 | 38.3 ± 10.2 | | | |
| TREHIIT | 40.5 ± 14.6 | 39.4 ± 15.3 | -1.2 | -3.4 to 1.0 | 0.266 |
| Body weight (kg) | | | | | |
| CON | 102.8 ± 13.1 | 102.3 ± 13.8 | | | |
| TREHIIT | 102.1 ± 26.9 | 100.1 ± 27.1 | -1.6 | -3.8 to 0.7 | 0.159 |
| $VO_2$peak (ml/min/kg) | | | | | |
| CON | 38.8 ± 7.7 | 36.7 ± 10.4* | | | |
| TREHIIT | 34.2 ± 3.7 | 36.2 ± 4.3* | +3.3 | 2.8 to 6.4 | 0.034 |

TREHIIT = Time restricted eating and high intensity interval training. CON = Control. *Missing data from $VO_2$peak (TREHIIT = 1 & CON = 1).

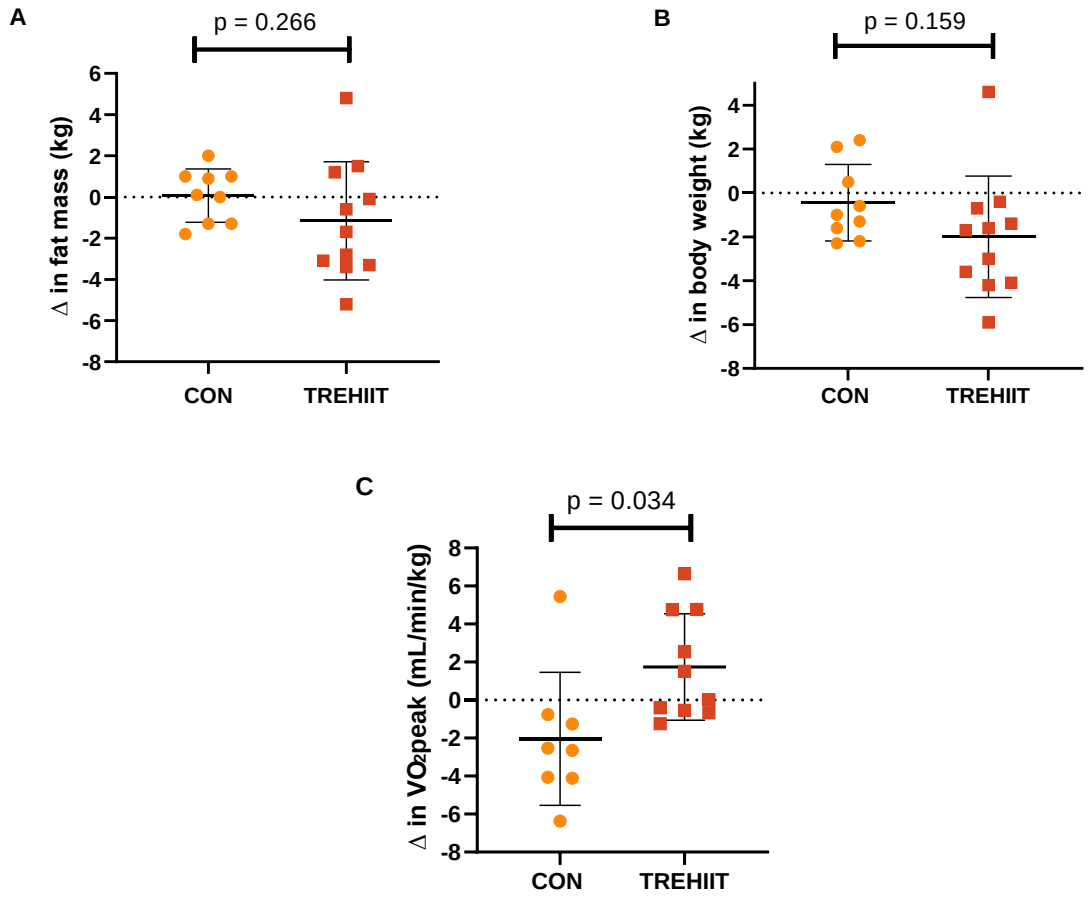


**Figure 5.** Observed data for A) Fat mass, B) Body weight, and C) Peak oxygen uptake ($VO_2$peak). Mean changes (Δ) for each group are presented as horizontal bars with corresponding standard deviation. Symbols represent individual participants. P-values are from linear mixed models comparing changes in the TREHIIT group with changes in the control group. TREHIIT = Time-restricted eating and high intensity interval training. CON = Control. Missing data from $VO_2$peak (TREHIIT = 1 & CON = 1).

### 3.2 Energy intake

Participants in TREHIIT decreased their total energy intake from 14,833 kcal (± 3,780) in the baseline week to 12,169 kcal (± 3,167) in the first week of the intervention (p = 0.002) (Figure 6). During the final week, TREHIIT reduced their total weekly energy intake by 4,051 kcal (± 3,096) (p = 0.016), compared with week 0. There were no changes in total energy intake in CON (Figure 6).

The participants in CON had a total weekly energy intake of 16,035 kcal (± 4,006) in the baseline week, 17,529 kcal (± 5,545) in week 1, and 16,687 kcal (± 4,957) in the final week.

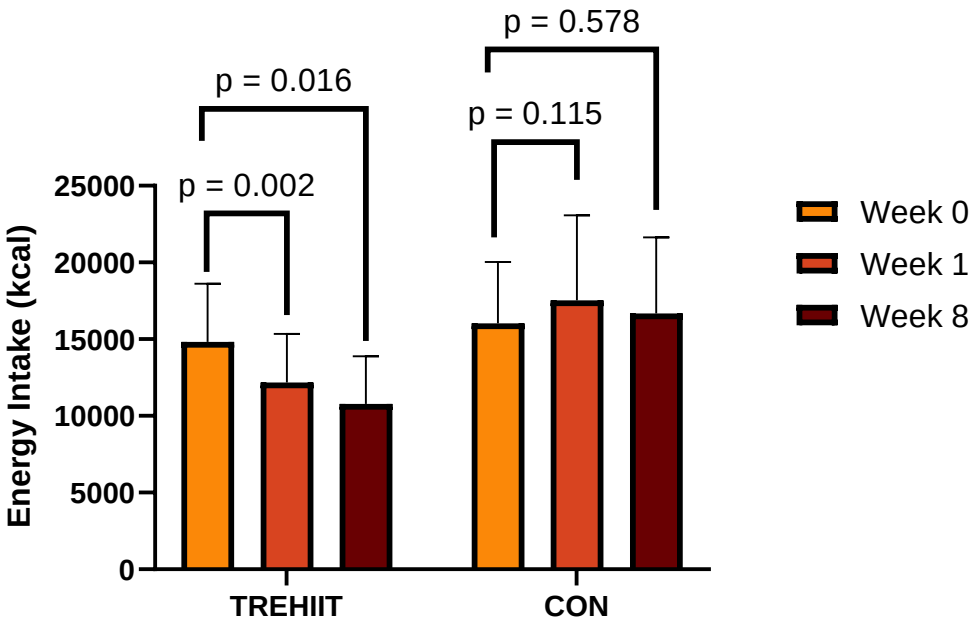


**Figure 6.** Weekly energy intake at the baseline week (week 0), week 1, and week 8 according to group. TREHIIT = Time-restricted eating and high intensity interval training. CON = Control. P-values are for within-group changes. Missing data (TREHIIT = 3 & CON = 2).

### 3.3 Energy intake window

Participants in TREHIIT reduced their time-window for energy intake from 12.3 h/day (± 2.2) in the baseline week to 9.1 h/day (± 0.9) during the intervention period ($p < 0.001$) (Figure 7). There was no change in the time-window for energy intake in CON (12.4 h/day (± 1.8) at baseline and 12.3 h/day (± 2.3) during the intervention period, ($p = 0.897$) (Figure 7). The participants in TREHIIT adhered to a ≤ 10 h/day time- window for energy intake for 6.1 days/week (± 0.8) during the 7-week intervention period. The participants in TREHIIT consumed energy intake ≤ 20:00 h 77% (± 0.2) of the days during the intervention period. Participants in TREHIIT consumed their last energy intake at 19:42 h (± 0.02).

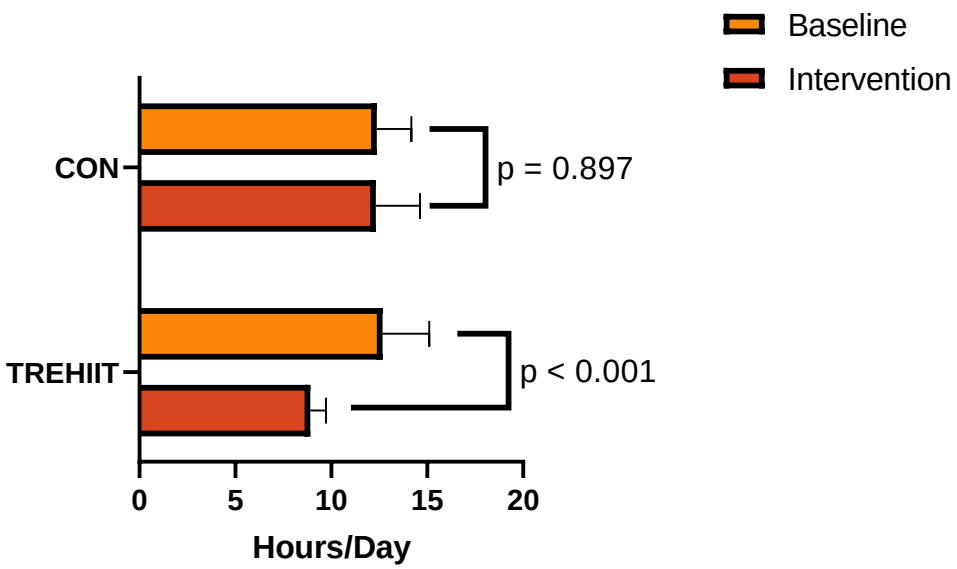


**Figure 7.** Self-reported energy intake window at baseline and during the intervention period, according to both groups. TREHIIT = Time restricted eating and high intensity interval training. CON = Control. P-values are for within-group comparisons. Missing data (CON = 1).

### 3.4 Adherence to HIIT

The participants in TREHIIT completed 16.6 (± 3.7) out of the total of 21 sessions (79% ± 0.2). The mean percentage of HRmax during each individual 4 x 4 work bout was 91% (± 0.02), and 90% (± 0.02) during each individual 10 x 1 work bout.

# 4. Discussion

### 4.1 Summary of main findings

The aim of my master's project was to investigate the effects of a TRE and HIIT intervention on fat mass loss, weight loss and cardiorespiratory fitness in adults with overweight or obesity. My findings did not support my primary hypothesis, which was that 7 weeks of TRE combined with HIIT would induce a greater decrease in fat mass, compared with a non-intervention control group. Secondary hypotheses were that the intervention group would have a greater decrease in body weight and a greater increase in $VO_2$peak compared with the control group. There was no difference in body weight change between the two groups, but a statistically significant increase in $VO_2$peak after TREHIIT, compared with CON.

### 4.2 Study findings in relation to other studies

*4.2.1 Fat mass & body weight*

The estimated effect of the intervention in my study on fat mass reduction was 1.2 kg and 1.6 kg in weight loss reduction, which are lower than the reported effect in the previous study in our research group on women only (27). My findings are also in contrast to other studies on the effect of isolated TRE-interventions on fat mass and body weight loss (23–26, 32). The studies by Moon et al, (2020), Regmi et al, (2020), Chow et al, (2020), Gabel et, (2018) and Steger et al, (2022) all indicated that TRE induces a reduction in fat mass, body weight or both. Steger et al, (2022) found that TRE reduced body weight by 3.7 kg similar to the 3.6 kg in body weight loss found by Haganes and colleagues (27). According to the aforementioned studies, the reduction in fat mass and body weight may be the result of the involuntary reduction in weekly intake of kcal due to the limited time-window for energy intake resulting in a reduction of daily eating occasions (23, 25, 26). My findings aligned with these studies when I found that TREHIIT reduced their weekly energy intake by 4,051 kcal, which was even more than the ~1,400 kcal reduction by Haganes et al, and the ~3,000 kcal weekly reduction found by Gabel et al, (26, 27). However, there was not a significant reduction in either fat mass or body weight in my study, and it may be the misreporting of energy intake by TREHIIT. Indeed, research has indicated that self-reporting energy intake is commonly underreported by 16%, and some has high as 20-30% (33).

Another cause for the insignificant change in weight and fat mass loss in my study could be the timing of the last meal of the day during the intervention period. When following a TRE protocol, people might find it easier to skip or delay breakfast rather than skipping dinner or eating dinner earlier (34). I advised the participants in TREHIIT to not eat after 20:00 h, but this was not strictly controlled. My findings indicated that the last time point for energy consumption in the intervention group was 23 minutes later than the last time point found in the Haganes et al, study (27). Due to the

energy intake window not being of a stringent nature, the participants adhered to the TRE window of consuming energy ≤ 20:00 h only 77% of the time. Research has indicated that eating after 20:00 h is associated with a higher BMI, and late meal timing limits weight loss and has been associated with increased body fat and obesity (35, 36).

Consuming energy after 20:00 h hinders weight and fat mass loss due to increased levels of glucose intolerance and insulin resistance, and a decrease in fat oxidation (18, 19, 37–39). A crossover trial indicated that glucose concentrations were 18% higher after a meal consumed at 22:00 h compared with when the same meal was consumed at 18:00 h impairing weight loss (18, 19). In another study the investigators reported that a small late night snack of 200 kcal at 23:00 h resulted in a decrease in 24 hour fat oxidation compared with the same kcal consumed in the daytime at 10:00 h with the latter consumption at night affecting weight loss (38).

An additional study has indicated insulin sensitivity decreases by 14% at night (39). The increase in insulin resistance at night causes a spike in glucose resulting in an excess storage of fat (37, 39). Furthermore, individuals that eat dinner later at night tend to consume twice the amount of fast food and soda, and half the amount of fruits and vegetables as adults that eat dinner earlier in the day (35). Therefore, it could be possible that consuming the last meal of the day at 20:00 h is also not sufficient to achieve the benefits of the circadian rhythm alignment of energy intake. In agreement with my findings, a study of 8 h/day of TRE with the last energy consumption at 20:00 h also failed to show a reduction in fat mass after 12 weeks in adults with overweight or obesity (34, 40). Therefore, a TRE protocol where the designated last energy intake time point is earlier than 20:00 h may be more ideal for weight and fat mass loss due to the effects from insulin, glucose and fat oxidation.

A study aligned with this statement when it was indicated that eating breakfast earlier in the day lowers the risk of type 2 diabetes and weight gain because of improved insulin sensitivity and glucose uptake in the morning (39, 41). Additionally, it was indicated that an earlier TRE window with the first meal at ~7:00 h and the last meal at 15:00 h improved insulin sensitivity and weight loss in adults with overweight or obesity (42, 43). Therefore, even though TREHIIT participants reduced their energy intake window from 12.3 to 9.1 h/day and adhered to the TRE protocol 6.1 d/week, the nightly energy consumption after 20:00 h 23% of the days may have affected insulin sensitivity, glucose tolerance and fat oxidation impeding weight and fat mass loss during the intervention period (37, 39).

In summary, a TRE window with the last energy intake being at 20:00 h may not be ideal for body weight and fat mass loss for adults with overweight or obesity. An earlier TRE protocol might be better to induce an optimal alignment of energy intake to the circadian rhythm. Eating earlier increases glucose tolerance, fat oxidation and insulin sensitivity regardless of the total daily energy intake, which may help to lose more weight and fat mass (37–39, 41–43). However, consuming energy earlier in the day, specifically breakfast or an early dinner may not be suitable for many people

due to the obligations regarding family life and their work schedule (44). Therefore, more research is needed to determine the cultural and social aspects of timing of energy intake.

*4.2.2 $VO_2$peak*

In my study, I found a 3.3 ml/min/kg increase in $VO_2$peak in TREHIIT compared with CON, which is similar to the previous study on supervised HIIT combined with TRE in our research group (27). The protocol in my study was similar to the former study, with an equal number of HIIT sessions over a 7-week period, with the only difference being the grade of supervision. TREHIIT participants had an adherence rate of 79% for HIIT sessions, which was less than the 93.4% and 94% adherence rate in Vella et al, and Haganes et al, respectively (27, 28). Both these former RCTs were conducted in a supervised laboratory setting. My results indicate that unsupervised HIIT might be more difficult to adhere to compared with supervised training in a laboratory setting, but that it can still positively affect cardiorespiratory fitness.

The ~15% less adherence rate in my study compared to the RCTs conducted in a laboratory setting may be the lack of supervision of the investigators during the exercise sessions. A research study agrees with my findings when it was indicated that the high adherence for exercise protocols in a laboratory setting may be due to professional exercise specialists observing each session to ensure correct performance and accurate intensity during each work bout increasing motivation among participants (45). However, even though the adherence rate in my study was lower, the participants in TREHIIT were still able to improve their $VO_2$peak by 9%. These findings are more than the 7.5% increase found in Vella et al, similar to the 10% increase in Helgerud et al, and identical to the 9% increase in TREHIIT in the Haganes et al, study (21, 27, 28). The reason for the 9% increase even with lower adherence could be that the compliance with the HIIT protocol during every completed HIIT session was very high. My findings are consistent with other research showing an increase of 7-24% in $VO_2$peak after 4-16 weeks of HIIT (28).

Many adults have indicated barriers for participating in PA, including lack of resources to access training facilities or training equipment resulting in less than 1 and 3 people adhering to WHO recommendations (4, 11). Therefore, my findings may be pertinent to people because the increase in $VO_2$peak by TREHIIT was achieved by participants having the option of performing HIIT by running/walking outside. The choice to perform HIIT outdoors indicates that a training facility nor equipment is needed to improve cardiorespiratory health for adults with overweight or obesity. Another barrier limiting adults to participate in PA is time constraint (10). However, my study revealed that adults with overweight or obesity can improve their cardiorespiratory health by undertaking HIIT for 109 minutes per week. Training that amount of time per week also helps adults meet the 75-150 minutes of vigorous activity recommended by WHO (5). Results such as these are vital because adhering to the WHO recommendations has helped to lower risks of a heart attack, type 2 diabetes and several forms of cancer (4, 6). My results additionally may be helpful to adults with

overweight or obesity because every 6% increase in $VO_2$peak has been associated with lowering the risk of all-cause mortality, reducing cardiovascular disease by 14%, reducing cardiovascular mortality by 8% and increasing insulin sensitivity by 6 % (46–48). My results highlight the potential value of an unsupervised HIIT intervention over a 7 week period for improving cardiorespiratory health in adults with overweight or obesity who are at a higher risk of heart and metabolic disease.

### 4.3 Study strengths

The RCT design is one strength of this study. RCTs are considered the gold standard for evaluating efficacy in clinical research. The major advantage of RCTs is that randomization minimizes systemic bias due to confounding factors, in investigations of cause–effect relationships (49). The direct measurement of $VO_2$peak is considered the gold standard for determining cardiorespiratory fitness (50). Furthermore, all exercise sessions were undertaken according to standardized protocols, which increases the reproducibility in future studies. Even if the training sessions were unsupervised, I could confirm that the participants trained with the correct intensity and followed the protocols for each bout via the digital registration of HR in each session.

### 4.4 Study Limitations

My study has several limitations which must be taken into consideration when interpreting the results. The timing of the energy intake window was not strictly enforced and the time points for first and last energy intake were self-reported. Therefore, I had to rely on participants being accurate in their recording of their total energy intake and timing of their energy intake window. Since participants were unsupervised, I was not aware of any issues with HR monitors until after the session was completed. Furthermore, the participants involved in the study during Christmas may have had more difficulty adhering to TRE and HIIT due to the cultural nature of celebrating over the holiday season. Participants may have indulged in more energy intake or energy consumption later at night compared to the other weeks. However, such effects of the Christmas season would likely impact both groups. Furthermore, there is also a risk of self-selection bias due to voluntary participation. Participants might have been inherently motivated to improve their health and it is not certain whether the participants made concomitant changes to their diet and/or physical activity in addition to the prescribed intervention. The inability to show a change in body weight or fat mass between TREHIIT and CON could be due to a type II error. Further analysis in the main study which includes all randomized participants might be needed to detect a significant between-group difference in fat mass loss. I observed a large standard deviation in fat mass change, and a potential explanation for this variation might be the rate of fat mass loss difference between men and women, due to men and women possibly responding differently to weight loss intervention.

## 5. Conclusion

Men and women with overweight or obesity who participated in time-restricted eating and high intensity interval training increased their $VO_2$peak but did not have a significant decrease in body weight or fat mass after 7 weeks.

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*Appendix:*

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V.2

# VIL DU DELTA I FORSKNINGSPROSJEKTET TIDSBEGRENSET SPISING OG INTERVALLTRENING – MED DIGITAL OPPFØLGING

## FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å undersøke effekten av å kombinere høy-intensitets intervall trening med tidsbegrenset spising på å redusere fettmasse og forbedre helsen hos voksne med kroppsmasse indeks (BMI) på 27 kg/m$^2$ eller mer. For å delta må du være mellom 18 og 50 år og ha et tidsvindu for når du spiser som er på 12 timer eller mer per dag (det vil si at det går minst 12 timer fra du spiser det første måltidet for dagen til du spiser det siste). Du må også være i stand til å gå eller løpe på en tredemølle eller sykle i minst 60 minutter og ikke trene intervalltrening med høy intensitet mer enn én gang i uka fra før. Du må forstå muntlig og skriftlig norsk eller engelsk for å være med. Du må også bo i Trondheimsområdet og ha mulighet til å komme inn til testing på St.Olav's hospital.

## HVA INNEBÆRER PROSJEKTET FOR DEG?

### Undersøkelser

Deltakelse i prosjektet innebærer to separate dager med undersøkelser ved oppstart og igjen etter 8 uker ved fullført studie. Den ene dagen vil vi ta en blodprøve av deg om morgenen etter at du har fastet (ikke spist eller drukket noe annet enn vann) siden kl. 22.00 kvelden før, hvor vi vil måle blodsukkeret ditt, samt insulin og fettstoffer i blodet. Vi vil også måle blodtrykket ditt og kroppssammensetningen din (andel muskler, fettvekt og fett rundt indre organer) med en spesiell vekt (bioelektrisk impedansanalyse). Du vil også bli bedt om å svare på noen spørreskjema om fysisk aktivitet, søvn og erfaring med prosjektet ved prosjektslutt. Den andre dagen vil bestå av å måle din fysiske form. Dette innebærer at du går eller løper på en tredemølle til du ikke orker mer mens du puster i en spesiell maske som måler oksygenopptaket ditt. Vi øker farten eller stigningen på tredemølla slik at du blir utslitt etter ca. 10-15 minutter. Undersøkelsene vil vare totalt ca. 60 min begge dagene, og alle undersøkelsene vil foregå på laboratoriene ved St. Olav's Hospital.

### Studie grupper og intervensjoner

Etter at du har fullført alle undersøkelsene ved oppstart vil du bli tilfeldig fordelt til en av to grupper. Det er like stor sjanse for å havne i den ene eller andre gruppen. Deretter skal du fortsette å leve som vanlig i syv dager. Etter den første uka, starter sju uker med tidsbegrenset spising og intervalltrening for de som havner i intervensjonsgruppen. De som havner i intervensjonsgruppen, får en trenings- og kostholdsveiledningstime ved oppstart. Tidsbegrenset spising vil si at du skal spise innenfor et 10-timers tidsvindu hver dag. Intervalltreningen vil bestå av tre ukentlige intervalløkter med høy intensitet som du kan gjennomføre ved å for eksempel gå, løpe, ro, sykle, ellipsemaskin, o.l., enten på treningssenter,

hjemme, eller ute. For å registrere treningsøktene, vil du bli bedt om å laste ned en gratis treningsapp (Polar Beat) på mobiltelefonen din. Du vil bli tildelt en pulssensor og et pulsbelte som kobles til appen via Bluetooth.

Det vil bli gitt ukentlig oppfølging via telefonsamtale eller videosamtale. De som havner i kontrollgruppen blir bedt om å fortsette å leve som vanlig i sju uker. Etter disse sju ukene vil de i kontrollgruppen bli tilbudt å følge intervensjonen med samme veiledning og oppfølging som de som først blir fordelt til intervensjonsgruppen.

Andre målinger under studieperioden

Gjennom studieperioden vil du bli bedt om å registrere tidspunkt for det første og siste måltidet hver dag i en studiehåndbok som du får med deg. I den første uken (uke 0), i uke 1 og i den siste uken (uke 7) ber vi deg om å registrere appetitt på en skala når du våkner og før du legger deg, og registrere daglig fysisk aktivitet og antall timer søvn per natt. Du vil også bli bedt om å registrere kosthold i en kostholds app (Fatsecret.com) i uke 0, 1 og 7.

Dine opplysninger

I prosjektet vil vi innhente og registrere opplysninger om deg. Dette omfatter: alder, vekt, høyde, kroppssammensetning (andel muskler og fett), hvor aktiv du er, blodtrykk, blodprøveresultater og fysisk form. I blodprøvene vi tar av deg vil vi måle kolesterol og blodsukker. Vi vil også fryse ned blod som vi skal analysere senere (analyser av insulin). Vi ber også om å få oppbevare noe av blodet til analyser som ikke er bestemt enda, men som trolig vil være appetitthormoner, andre markører for energiomsetning og for inflammasjon (betennelsesmarkører).

## MULIGE FORDELER OG ULEMPER

Fordelen for deg som deltaker er at du vil få undersøkt kroppssammensetning, blodsukkeret ditt, blodtrykk og fysisk form. Vi tror også det vil være en fordel for din generelle helse med veiledet trening og det å spise tidsbegrenset i en periode. Vi ser ikke at prosjektet innebærer noen ulemper for deg utover at du må avse tid til undersøkelsene og eventuelle ubehag du opplever med blodprøvetaking og fysisk anstrengelse. Om du skulle oppleve problemer med tanker og atferd knyttet til mat, kropp og vekt underveis i studien, kan du kontakte ROS (Rådgivning om spiseforstyrrelse) på tlf: 948 17 818 (innvalg 5) eller e-post: trondheim@nettros.no. ROS er en frivillig interesseorganisasjon som tilbyr støtte, råd og veiledning til alle som er berørt av problematikk rundt mat, kropp og selvfølelse. For mer informasjon, besøk www.nettros.no

## FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine opplysninger og ditt biologiske materiale. Du kan kreve innsyn i opplysningene som er lagret om deg, og disse vil da utleveres innen 30 dager. Du kan også kreve at dine opplysninger i prosjektet slettes og at det biologiske materialet destrueres.
Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser.

Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side).

## HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 2025. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder Trine Moholdt og prosjektmedarbeidere Kamilla La Haganes og Jared Criste Baker som har tilgang til denne listen.

Etter at forskningsprosjektet er ferdig, vil opplysningene om deg bli oppbevart i fem år av kontrollhensyn.

## DELING AV OPPLYSNINGER OG OVERFØRING TIL UTLANDET

Som en del av gjennomføringen av prosjektet kan det bli aktuelt å overføre innsamlede opplysninger om deg til andre land. Prosjektleder vil sikre at dine opplysninger blir ivaretatt på en trygg måte. Koden som knytter deg til dine personidentifiserbare opplysninger vil ikke bli utlevert.

## HVA SKJER MED PRØVER SOM BLIR TATT AV DEG?

Blodprøvene som tas av deg skal oppbevares i en forskningsbiobank tilknyttet prosjektet. Ansvarshavende for denne er prosjektleder Trine Moholdt. Blodprøvene vil fysisk være lagret ved Institutt for Sirkulasjon og Bildediagnostikk, NTNU. Biobanken opphører ved prosjektslutt.

Det kan bli aktuelt å sende prøver ut av landet for analyser i forbindelse med dette prosjektet. Det er på det nåværende tidspunkt ikke klart hvorvidt dette vil skje og i hvilket land prøvene i så fall vil analyseres. Hvis prøvemateriale blir sendt til utlandet vil rest-materialet etter analysering enten returneres til biobanken i Trondheim eller destrueres ved prosjektslutt.

## FORSIKRING

Deltakere er dekket av pasientskadeloven.

## OPPFØLGINGSPROSJEKT

Det kan bli aktuelt med et oppfølgingsprosjekt. Vi ber derfor om å få beholde dine kontaktopplysninger i tilfelle vi ønsker å kontakte deg igjen senere. Du kan bli med på prosjektet uten å gi oss tillatelse til å kontakte deg senere.

## ØKONOMI

Deltakelse i studien er gratis.

## GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet. [479143]

NTNU og prosjektleder Trine Moholdt er ansvarlig for personvernet i prosjektet.

Vi behandler opplysningene basert på EUs personvernforordning artikkel 6 nr 1a og artikkel 9 nr 2a og ditt samtykke.

## KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte prosjektleder Trine Moholdt, telefon 97098594, e-post: trine.moholdt@ntnu.no eller doktorgradsstipendiat Kamilla La Haganes, telefon 47316765, e-post: kamilla.l.haganes@ntnu.no .

Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: personvernombud@ntnu.no

## JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

*Vær vennlig og kryss av i **én** av boksene under:*

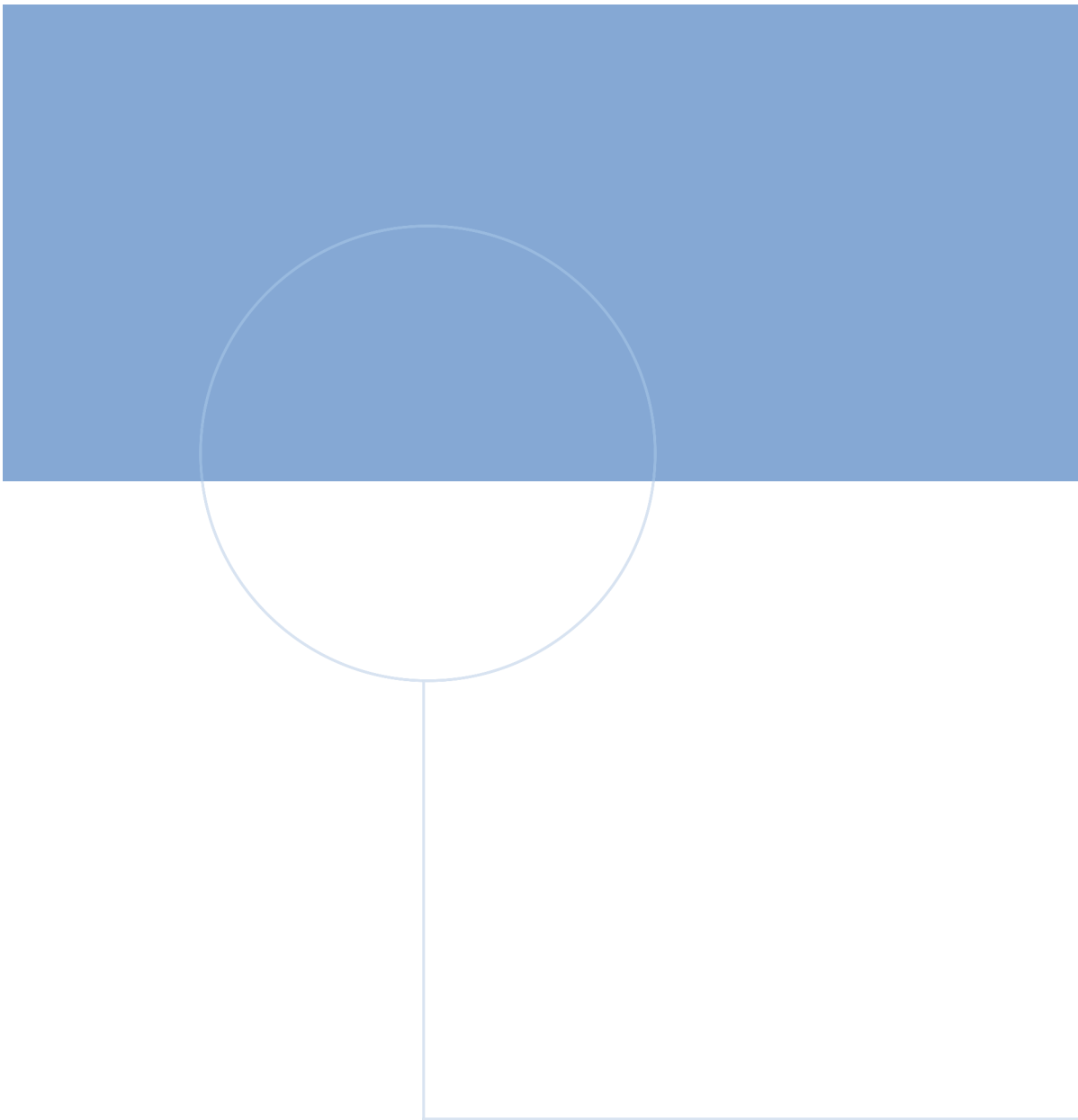
*Jeg **godkjenner** at mine kontaktopplysninger kan beholdes i tilfelle forskerne vil kontakte meg for eventuelle oppfølgingsstudier:* ☐

*Jeg **godkjenner ikke** at mine kontaktopplysninger kan beholdes i tilfelle forskerne vil kontakte meg for eventuelle oppfølgingsstudier:* ☐

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver



NTNU

Norwegian University of
Science and Technology