Effects of eight weeks of concurrent exercise training and time-restricted feeding (16/8 hr) on body composition, muscle endurance, metabolism, cardiovascular risk factors, and dietary intake in overweight, males and females

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Purpose

- Investigate the feasibility and efficacy of time-restricted feeding (TRF) as a dietary approach for weight loss and health improvement in overweight individuals.

Background

- Overweight and obesity prevalence in adolescents and adults continues to remain significantly high in the United States[1,2]. While diet and exercise improve many consequences of obesity[3], dietary restriction strategies are not always nutrient sufficient and manageable long-term.
- Time-restricted feeding (TRF) may be an ideal dietary approach for reducing fat mass and cardiovascular disease risk, while diminishing the loss of muscle mass and strength associated with obesity and aging[4,5].
- TRF, unlike continuous energy restriction, does not require a restrictive energy intake[6]. TRF requires individuals to consume calories within a set window of time (example = 8 hours), inducing a fasting window of 16 hours per day[7].
- There are few human studies on TRF that measure their effects in combination with both aerobic and resistance training. One recent study found an 8-hour TRF program (16-hour fast) improved insulin sensitivity, decreased fat mass, and maintained muscle mass in resistance-trained males after 8 weeks[7].

Aims

Aim 1: To determine whether time-restricted feeding (TRF) is an effective dietary strategy for reducing fat mass while preserving fat-free mass in combination with aerobic and resistance training.

Aim 2: To evaluate potential changes in health-related biomarkers (cardiovascular profile and anabolic-catabolic hormones) and muscle health indicators (mass, strength and quality) after 8 weeks of resistance training with TRF.

Aim 3: To examine the influence of caloric intake and macronutrient distribution on muscle health in TRF and normal feeding (NF) pre- to post-aerobic and resistance training.

Approach

- The study will recruit 40, overweight (determined by body mass index between 25.0-29.9 kg/m^2) male and female participants between the ages of 35-60 years old who are not currently following a structured aerobic or resistance training program or dietary plan.
- Participants will be randomly assigned to a TRF group or a NF group. The TRF group will be required to consume all their energy intake in an 8-hour feeding window (12:00pm to 8:00pm), inducing a fasting window of 16 hours. The NF group will maintain their typical dietary habits. Exercise training (Table 1) for the TRF and NF group will be completed within the feeding window.
- This study will be a randomized, controlled trial with assessments made pre- and post-intervention.
- All study protocols will be approved in advance by the NDSU IRB (approval #HE18247) and written informed consent for all subjects will be obtained.

Approach

Table 1. Experimental Design.

Pre-Testing		Concurrent Training RT: 3 sets, 12-15 repetitions; AT: ≥55% HRR			Post-Testing	
Visit 1	Visit 2	Training Week	Collection Materials	Exercise Prescription	Visit 1	Visit 2
DXA Body Composition	Muscle Function	Week 1	3-Day Food Diary	Aerobic training (15 minutes); Load assignment	DXA Body Composition	Muscle Function
Dried Blood Spot Testing	3-minute Step Test	Week 2	Accelerometer Recording	Aerobic training (20 minutes)	Dried Blood Spot Testing	3-minute Step Test
Saliva Testing		Week 3		Aerobic training (25 minutes)	Saliva Testing	
Grip Strength		Week 4	3-Day Food Diary	Aerobic training (30 minutes)	Grip Strength	
3-Day Food Diary		Week 5	Accelerometer Recording Blood pressure & Body Mass	Aerobic training intensity ↑ 5-10%		
		Week 6				
		Week 7	3-Day Food Diary	Aerobic training intensity ↑ 5-10%		
		Week 8	Accelerometer Recording			

Muscle & Fat Tissue Mass

Dual energy X-ray absorptiometry (DXA) scans (Figure 1) will be completed using a GE Healthcare Lunar Prodigy, Model #8915.

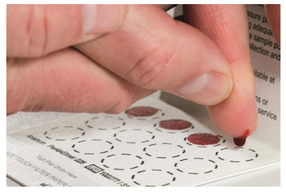
Figure 1. DXA assessment.

Strength and Cardiovascular Function

Assessment of lower body muscle strength and endurance will occur using the Biodex Pro4 system dynamometer (Biodex Medical Systems, Shirley, NY). (Figure 2A). Upper body strength will be assessed using a hand-grip dynamometer (Figure 2B) and cardiovascular fitness will be measured using the 3-minute step test.

Figure 2. A) Biodex, B) Hand dynamometry.

Cardiometabolic and Endocrine Function



Blood spot (Figure 3) and saliva testing (Figure 4) will be performed in collaboration with ZRT Laboratory. Correlations between blood spot and venous blood are shown in Tables 2 and 3.

Figure 3. Blood spot testing.

Figure 4. Endocrine Testing.

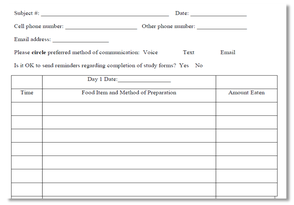
Table 2. Dried blood spot biomarker assay and correlations

Biomarker	Assay Method	Correlation (R)
Insulin	ELISA	0.9300
Hs-CRP	ELISA	0.9900
Hemoglobin A1c	Immunoturbidimetric	0.9700
Triglycerides	Enzymatic	0.9700
Cholesterol	Enzymatic	0.9000
HDL	Enzymatic	0.9200

Table 3. Saliva biomarker assay and correlations

Hormone	Sample Type	Assay Method	Correlation (R)
Estradiol	Saliva	ELISA	0.9725
Progesterone	Saliva	ELISA	0.9877
Testosterone	Saliva	LIA	0.9995
DS	Saliva	ELISA	0.9996
Cortisol	Saliva	EIA	0.9955

Energy intake and macronutrient distribution



Subjects will document their food intake on 2 typical days and 1 untypical day for several weeks during the study. The food intake logs will be analyzed using the Food Processor [ESHA, Salem, OR].

Figure 5. Self-reported dietary intake

Statistical Analysis

Analytic plan. For age, body mass, and height, descriptive statistics will be used. For dependent variables (grip strength, DXA fat mass and fat-free mass, blood spot testing, muscle function, dietary factors, aerobic capacity), separate 2 (Dietary Plan: TRF and NF) x 2 (Time: pre- and post-training) ANOVAs with repeated measures will be used. An alpha level of $p < 0.05$ will be used to determine differences. If a significant interaction is found, independent and paired t-tests with Bonferroni corrections will be used to compare the post-training adaptations.

Sample Size and Power. A sample size of 20 subjects per arm will provide 81% power to detect a between-arm effect size of 0.40 in primary outcome measures, assuming a two-tailed α of 0.025. Assuming a 20% attrition rate, the final sample size is estimated at 16 subjects per arm. This is consistent with previous work in resistance-trained males[8].

Next Steps / Deliverables

- NDSU IRB approval granted (approval #HE18247).
- Awaiting funding support.
- NDSU provided start-up funds to initiate study (n=10).
- Currently recruiting and screening subjects for eligibility.
- Projected first batch of subjects: October to December 2018.
- Second batch: January to March 2019.
- Third batch: March to May 2019.
- Analysis of data: May to August 2019.

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