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Research Methodology of Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity

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Abstract

Exercise has been shown to improve insulin resistance, a key factor in mediating cardiovascular disease (CVD) risk, in both obese and healthy individuals. Aerobic training (AT) and resistance training (RT) have both been shown to improve insulin resistance, yet less research exists on RT's specific impact. Additionally, there is a lack of direct comparison of RT vs AT using standardized exercise programs, potentially confounding insulin resistance results. In "Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity", study participants were screened for eligibility, received baseline and post-intervention health assessments, randomized to a study arm, and received one of three treatments (AT, RT, or Control). REDCap software was used in designing and translating this longitudinal, stratified, and controlled study into an entirely digital format; effectively collecting data at each research stage, while creating a running database for subsequent analysis. Several REDCap features allowed for remote and in-person data collection, the stratification of participants to different intervention arms, generation and designation of data collection instruments (specific to each research phase and intervention arm), and longitudinal data collection for each participant. The specific drawbacks, challenges, and benefits to using REDCap in "Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity" will be investigated and discussed in detail. Using REDCap was an effective means of ensuring standardization in research protocol across participant arms, such that the study's results may be applied to the growing body of research on insulin resistance, physical activity, obesity, and CVD.

Keywords: REDCap, electronic databases, electronic data collection, text message health interventions, longitudinal data collection, insulin resistance, obesity.

Research Methodology of Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity

In the United States, approximately 2/3 of adults are overweight or obese, with 35% qualifying as obese. Obesity is associated with a decreased life expectancy and increased morbidity, and has been established as a risk factor for cardiovascular disease (CVD) - a series of cardiometabolic disorders and the United States' leading cause of mortality¹⁰. Additionally, obese individuals are at higher risk for cardiometabolic risk factors such as insulin resistance, hypertension, hyperlipidemia, hypercholesterolemia, and diabetes mellitus^{1,2}. Increasing evidence suggests that cardiometabolic risk factors have a stronger impact on cardiometabolic health independent of weight or obesity. However, obese individuals with cardiometabolic risk factors present are at 2-5x higher risk of CVD and generalized mortality than obese individuals without cardiometabolic risk factors³. It is therefore imperative to focus preventative measures for CVD on cardiometabolic risk factors, particularly in obese individuals where CVD risk and mortality rates are higher.

Insulin resistance has been identified as a key cardiometabolic risk factor, both as an independent CVD risk factor and as a precursor for other cardiometabolic risk factors⁴. Insulin resistant individuals experience an impaired biological response at insulin-dependent tissues - the liver, skeletal muscle, and adipose tissues - resulting in compensatory increases in endogenous insulin production. This increase in insulin production can result in further weight gain and exacerbated insulin resistance, consequently resulting in hyperglycemia, weight gain, and metabolic syndrome⁵, further compounding CVD risk. The metabolic consequences of insulin resistance can include hypertension, dyslipidemia, visceral adiposity, atherosclerotic plaque accumulation, skeletal or cardiac muscle abnormalities, endothelial dysfunction, and a

prothrombotic state, all of which can contribute to further development of CVD^{3,5}. Insulin resistance has been shown to be an independent predictor of CVD risk as well, as several studies have indicated changes in insulin resistance as profoundly associated with risk in coronary heart disease and CVD, over and above the presence of metabolic syndrome³. Insulin resistance thus is a key factor in mediating CVD risk, serving as both a precursor for cardiometabolic risk factors and an independent risk factor for CVD.

In general, physical activity has been seen to inhibit or reduce cardiometabolic risk, including insulin resistance. Evidence suggests that in both healthy and obese individuals, fitness is associated with more desired clinical outcomes, including decreased CVD risk, increased energy expenditure, and improved insulin sensitivity at skeletal muscle tissue^{5,6}. In a prospective study of ~15,600 “cardio-metabolically healthy” adults, it was found that increases in physical activity were associated with decreases in cardiometabolic risk, whereas decreases in physical activity in formerly active participants were associated with a relative increase in cardiometabolic risk⁷. Previous evidence also suggests that regular exercise training has desirable effects for obese individuals, including decreased insulin resistance and increased insulin sensitivity at skeletal muscle tissue⁸. Although the specific mechanism of obesity-induced insulin resistance remains unclear, this evidence suggests that exercise promotes higher insulin uptake at skeletal muscle, thus mitigating insulin resistance in obese individuals.

Yet, the majority of evidence available on exercise’s effect on the cardiometabolic health of obese adults focuses on aerobic training (AT), rather than resistance training (RT). AT is defined as exercise that exhausts the oxygen supply at the muscular level, yet without the need to derive energy from other sources (i.e. oxygen intake is sufficient). RT refers to exercise where oxygen consumption exceeds the rate of oxygen intake, resulting in skeletal muscle breakdown

of other energy sources (e.g. glycogen, fatty acids). A 2015 study by Jelleyman and colleagues compared the effects of high-interval intensity training (HIIT), continuous AT training, and no training (control) on insulin resistance, and found that both HIIT training and continuous AT reduced insulin resistance relative to control, with clinically significant decreases in insulin resistance among obese individuals⁹. RT regimens are typically indicated as improving skeletal muscle mass, size, and strength, yet considering skeletal muscle as an insulin-dependent tissue, RT has been investigated as a means of decreasing insulin resistance as well. However, no two prior studies have examined the same RT protocol or sample characteristics in doing so, and contain relatively small sample sizes, indicating a need for more research on RT's specific impact on insulin resistance among obese adults. Additionally, the respective impacts of AT and RT on insulin resistance have been directly compared by prior studies, yet lack standardization of intensity, frequency, and volume across exercise programs, potentially confounding prior results of insulin resistance.

In this study, "Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity", the effect of both RT and AT on insulin resistance in a population of obese individuals will be investigated through a simple, randomized control trial. Obese participants will be randomized to one of three groups: RT, AT, and a control group, with the aim of comparing insulin resistance across exercise groups and relative to a control group. RT and AT participants received training regimens, while control group participants received "health tips" via text message. Several parameters of cardiometabolic health were taken both before and after treatment.

Considering the need to standardize and match intensity, volume, and frequency across exercise treatments and their associated data collection instruments, along with creation of an

entirely unique set of data collection instruments and schedules for control participants, a particular database software was required to execute this study. In implementing “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity”, REDCap software was used to translate a longitudinal, multi-arm, randomized, and controlled study into a digital, computerized format. It was necessary that data collected by REDCap was accessible to a team of researchers, yet certain data collection instruments remain accessible to study participants to be completed remotely. Every aspect of this study presented a unique challenge in implementation, as several intrinsic REDCap features manifested themselves as obstacles to the original study design, and required critical thinking to resolve. Each of these obstacles, and the subsequent decisions made to solve them, will be identified and explored in detail in this paper.

In implementing “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity” into REDCap, a primary focus was ensuring standardization across exercise arms, as the data collection tools of the RT and AT programs were created such that intensity, frequency, and volume of exercise across both groups were matched. This proved that the primary findings of “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity” could not be attributed to differences in methodology or protocol across exercise arms, while also creating a running database for direct comparison of standardized data across exercise arms. Additionally, a secondary aim of using REDCap in implementation was to investigate the use of Twilio - a third-party service used to send out surveys via text message to study participants- within REDCap. In particular, the effect of using Twilio on participant adherence was examined.

Limitations due to COVID-19:

Due to the extenuating circumstances surrounding the COVID-19 pandemic at the time of this paper's writing, data and data analysis regarding participant adherence and standardization of measures were not possible, and are therefore not included in this paper. "Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity" lost 15 in-progress study participants, preventing complete data analysis on the effectiveness of using REDCap in its implementation.

Methods

Overview

REDCap, or "Research Electronic Database Capture", is an online platform that allows for secure entry of data and creation of databases for a given project, and is easily customizable to fit the needs of a specific research project. Each project contains data-collection web pages unique to a research study, in which data can be either directly inputted by researchers or inputted remotely by participants of a study. REDCap software is most frequently used for clinical and research purposes, but can be designed to fit a variety of projects.

The specific data collection tools within REDCap are referred to as "instruments", whereas specific questions within those instruments are referred to as "fields". A unique variable name is given to each field, allowing project managers to analyze data across participants following a research study. REDCap permits project managers to create their own data collection instruments, while also containing an extensive shared library of instruments, from which project managers can import instruments into their own study. Entering data in a REDCap project creates a unique, automated "Record ID" for a given participant, then used across instruments in a study as a means of participant identification. REDCap project managers can choose to analyze data through "Data Export and Reports", a function that creates a spreadsheet matching

participant Record ID with corresponding variable names and responses, allowing for subsequent data analysis.^{11,12}

REDCap projects can exist in one of two states, “Development” or “Production”. In the Development phase of REDCap, instruments are continuously created, data is inputted for the sake of testing how instruments and features work, and changes to a research design can easily be made. In the Production phase of REDCap, real participant data is inputted, instruments cannot be edited, and analysis of data is possible through a number of export features.

In addition to permitting creation of instruments and input of data, REDCap contains several intrinsic features that allow researchers to tailor their data collection to their project’s specific needs. In creating the data collection and research design portion of the “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity” study, specific features of the study, and how this translated into developing an appropriate REDCap project, will be examined.

Basic Study Features

“Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity” is a randomized, controlled trial, in which participants were assigned to one of three arms: a resistance training (RT) arm, an aerobic training (AT) arm, or a simple control group (SRC). 60 sedentary (i.e. ≤ 2 days per week structured exercise for >3 months), young to middle aged (18-45 years) male and female participants with obesity ($BMI: \geq 30 \text{ kg/m}^2; \leq 50 \text{ kg/m}^2$) were screened for eligibility, and eligible participants completed several pre-intervention health surveys as a baseline of comparison³. Data from interventions were collected longitudinally for each participant over a 12-week period, during which interventions were performed three days per week. To support data collection for this study, data collection instruments and schedules

were engineered for each respective intervention in REDCap, whereby each participant was assigned a certain record ID number.

Interventions

In examining the effect of RT and AT on insulin resistance for obese individuals, results were compared with exercise arms (RT and AT) as well as to a self-regulated control group.

The central goal of “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity” was to measure the efficacy of exercise in improving cardiometabolic health relative to a baseline control group; a secondary goal was to examine which type of exercise (RT or AT) had a more profound effect in doing so. It was hypothesized that both AT and RT will improve insulin resistance relative to the control group, whereas RT participants would display a more profound improvement in one metabolic marker (BCAA oxidation) and AT participants would display a more profound improvement in another metabolic marker (FFA oxidation).

Aerobic Training. The aerobic training program consisted of three, 65-minute sessions per week of moderate-vigorous aerobic exercise spanning 12 weeks, totaling 36 sessions. Each session consisted of a 5-minute warm-up, 55 minutes of aerobic exercise at a predetermined intensity, and a 5-minute cool-down. Participants had the option of using a treadmill, bike, or elliptical machine. Intensity was incrementally increased on a weekly basis, and heart rate and rate of perceived exertion were measured at ten-minute intervals during the aerobic training.³

Resistance Training. The resistance training program consisted of three, 60-minute sessions per week at a moderate-vigorous intensity for 12 weeks, totaling 36 sessions. Each session consisted of a 5-minute warm-up, 2-4 sets of 8-12 repetitions for 5-6 exercises, with a 2-3-minute interval of rest followed by a 5-minute cooldown. Participants were given the choice to

use weight lifting machines, supplemented with free weights, resistance bands, and/or bodyweight exercises. The weekly program adhered to a traditional split program so that each session would focus on one of the following: back/triceps/abs, quadriceps/chest/biceps, or shoulders/arms, respectively. Intensity was incrementally increased on a weekly basis, and heart rate as well as rate of perceived exertion were measured following each exercise³.

Control. The self-regulated control group did not undergo any in-person intervention, yet did receive health tips via text message three times a week. These text messages were sent through Twilio, a third-party service secured by UConn REDCap. Each health tip was designed to provide information about either physical activity, nutrition, or stress/mental health. Participants were encouraged to write responses to each text message as to how they could incorporate that tip throughout their day. The content of these responses, as well as their timestamps, were viewable to project managers within REDCap.

Longitudinal Design

An intrinsic aspect of this study was its longitudinal design, as results were continuously taken over a 12-week period for each study arm. For each participant, a certain “research schedule” existed, in which participants would undergo screening, pre-intervention testing, intervention data collection, and post-intervention testing. Each research phase contained unique data collection instruments; either collecting data between participants or within participants (i.e. over time).

In order to integrate the longitudinal design of this study into REDCap, several features of the REDCap software were used. REDCap allows for the creation of “repeatable measures” for a given instrument, meaning the same data collection instrument can be used for a given participant across different points in time. This allows the researcher to avoid recreating the same

instrument (and all fields within that instrument) for each participant on every occasion, saving a substantial amount of time and energy. Enabling the longitudinal feature of REDCap consequently required the creation of “events”, or specific occasions in which an instrument would be utilized. Events in REDCap typically refer to defined moments in time, such as clinical visits or performance of a task, for a given participant^{11,12}. Once a study has been designated as longitudinal and events have been created, specific instruments can then be assigned to any event and more than one event, allowing a project manager to collect the same data over time. In the scope of this project, this allowed the designation of specific instruments to events based on a participant’s research phase (i.e. screening-based instruments were assigned to screening events), while also allowing for repeatable measures within intervention arms (i.e. the same health surveys could be re-used for pre- and post-intervention, and RT/AT data recording sheets could be replicated from Session 1 to Session 2 and onwards).

A particular aspect of the longitudinal module investigated was the scheduling module, in which events were not only defined, but had designated points in time (i.e. groups of participants would be screened on the same day, then undergo pre-intervention testing on a predetermined later date). This could allow project managers to implement instruments and research phases on specific dates, ensuring a research project’s completion within a set period of time. However, using the scheduling module entailed each participant undergoing the study at the same time, with progression through the study being delayed until an adequate amount of data was collected at each research phase. Given our want for participant retention, the matriculation of participants into the study, and the large participant pool needed to undergo a schedule module, this module was soon nixed, and the timing of events were defined on an individual basis relative to participant’s initial screening, while maintaining their sequential order based on research phase.

Stratification of Participants

REDCap also permits a project manager to create study arms within their project, to which particular events and their corresponding instruments can be designated. This also allowed for the assignment of intervention-specific instruments to a given arm (i.e. RT-specific instruments could be applied to the RT arm, and not to participants in the AT arm or control group). Participant lists - REDCap's means of compiling Record ID's for a project - can exist for separate arms, allowing the manual designation of participants to a specific arm. Any number of events can exist within a given arm, theoretically permitting a project manager to create a "schedule" of events; allowing participants to undergo events specific to their arm of the study while also maintaining sequential order.

Initially, three arms were created, which stratified participants based on treatment: AT, RT, or Control. Each of these arms contained several events, which were standardized across arms (e.g. screening, pre-intervention assessment, "Day 1" of intervention), yet the instruments designated to each event differed for treatment-related instruments (i.e. the "Day 1" event was listed the same for RT, AT, and Control, yet all groups had different data collection instruments for these events). Theoretically, this would allow for participants to be assigned to an arm using a participant list, then proceed through each research phase by progressing from one event to the other at record-specific time points. However, after running several trial records, it was noted that the participant list that corresponded to the "screening" event/instrument was different from the participant list that ultimately underwent intervention; a substantial number of participants were excluded following screening and could not proceed with the study. Therefore, an entirely separate project in REDCap was created, dubbed "Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity: SCREENING". This implicates a very specific drawback

in using REDCap; participant lists cannot be modified extensively once in production mode, as being able to exclude specific participants from a participant list past a certain event could have proved beneficial to the study design. Additionally, creating a new project introduced the issue of identifying participants across studies, as the record ID generated for participants is project-specific, leading to difficulties in participant identification across REDCap projects. This issue was resolved by creating a separate “Master ID” REDCap project, in which record IDs across projects were inputted for a given participant in different fields.

Pre-Intervention and Post-Intervention

Following the creation of a separate screening project, the initial intervention project contained three separate arms (RT, AT, and SRC), each of which had a “baseline” event (pre-intervention health assessments), “treatment” events (Days 1-36 of receiving either resistance or aerobic exercise, or a health tip), and a “post-intervention” event (post-intervention health assessments). Theoretically, once participants were screened through the separate REDCap project and deemed eligible, each participant could be randomized to a specific arm and proceed with each event in the study, with the Master ID project identifying each participant’s different Record IDs.

Following several trial runs, a flaw in the REDCap system arose regarding chronological events and their associated instruments, particularly when surveys are used. Within the REDCap system exists an “auto-numbering” of Record ID’s, which provides an automated, unique Record ID for participants as they complete surveys. Surveys are a specific type of instrument in REDCap that allow participants to remotely input data, rather than having to be inputted in-person or by a project manager. Surveys are beneficial in their accessibility - either participants or project managers can directly input data - as well as their practicality, as project managers can

continuously update a participant list for a given survey. However, whenever using surveys within a longitudinal design, the “first” data collection instrument (i.e. assigned to the first event) must be a survey, since REDCap’s auto-numbering feature requires automating Record IDs for participants once they complete the initial survey. This likely exists so that REDCap can create a match between survey respondents from a participant list (usually identified using either email or phone number) and the REDCap system (identified by a Record ID number), so that longitudinal data at later points can be accurately matched to each participant. The auto-numbering feature is mandated when surveys are used in longitudinal design, and was a necessary feature in our design since surveys were used in screening, health surveys, and data collection (e.g. text tips for the control group). However, since surveys were used for the control group, yet the first event within the control group arm (pre-intervention visit 1) contained instruments that were not surveys, participant phone numbers or emails could not be continuously added to the control group’s participant list. This proved to be a major problem, as participants were intended to matriculate into the control group’s participant list after being screened, undergoing pre-intervention testing, and being randomized to the control arm. This issue was resolved by creating another separate project within REDCap, “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity: PRE- and POST-INTERVENTION TESTING”. Creating this fourth REDCap project allowed participants to continuously be added to the control group, while also ensuring that the health surveys given prior to and following intervention were repeatable (i.e. the same instruments were designated to multiple events within this project). The participant pool for this specific “Intervention Testing” REDCap project contained eligible individuals who passed screening, yet who had not yet been randomized to a study arm.

A specific drawback of REDCap's auto-numbering system with surveys pertains to longitudinal data, as introducing a temporal, longitudinal aspect to a study with surveys mandates auto-numbering of Record IDs to ensure participant identification, which in turn requires a survey be the first data collection instrument. While this feature was certainly an obstacle in creating the research design, the issue likely could only be resolved by creating a new project; the control group's health tips had to remain surveys in order to use text messages, yet other instruments assigned to the pre-intervention event could not be surveys, as only project managers could fill these out (e.g. a phlebotomy form).

Randomization

Following screening and pre-intervention assessment, individuals were randomized to one of three control groups, and were stratified on the basis of sex to prevent any participant bias. REDCap provides a randomization module, yet requires utilizing a third-party software (such as SAS, Stata, or R) to create a randomization table, which is then uploaded and used as a template for randomizing subjects within a REDCap participant list. Considering the vast complexity of doing so with a longitudinal project with participants matriculating in at various times, it was determined that a random number generator would be used to designate participants to each treatment arm based on when they entered the study.

Measures

General

Several instruments used were imported from the REDCap library, an online database containing thousands of prior-used, IRB-approved, and valid questionnaires and surveys. These instruments were all evaluated for the intended parameter to be measured, and the extent to

which each imported instrument would fit into the scope of this study. Variable names for imported fields were automatically generated by REDCap software.

A majority of instruments were created from scratch, using the “Online Designer” function of REDCap. This allows for the creation of instruments by building fields; each instrument consisted of anywhere from one to 203 fields. A vast majority of fields were a variety of questions (yes/no, multiple choice, “slider scale”, or short answer/open response), yet some fields contained section headers or images. Variable names for created fields were manually generated.

Screening

The Participant Screening Form was a novel questionnaire, created by Lauren Corso, which aimed to determine participant eligibility based on a number of specific characteristics. The Participant Screening Form was designated as a survey within the screening project, allowing participants to input data remotely while also continuously updating the participant list as recruitment continued. Fields within this instrument included multiple choice questions, yes/no questions, open-ended questions, and calculated questions (i.e. coding a calculation output using other variable’s input) For example, BMI was calculated using variables from prior fields in the questionnaire (“participant_height” and “participant_weight”) using a kg/m^2 formula. This required validation of the “height” and “weight” fields - only numerical responses were allowed - while also ensuring that participants did not have to calculate or estimate their own BMI’s.

The PARQ+ (or Physical Activity Readiness Questionnaire) is a prior established questionnaire which measures if participants require medical clearance to participate in an exercise program. The PARQ+ consists of seven yes/no questions, each of which contains sub-

questions that further specify the participant's physical condition if any answer is "yes".¹⁵ The seven questions of the PARQ+ were integrated into the Participant Screening Form, yet had to be novelly created within REDCap. Integrating the PARQ+ into the Participant Screening form resulted in a more convenient means of participant screening, as participants had to fill out only one survey rather than two.

In developing the Participant Screening Form, the "Branching Logic" function was utilized for several fields. Branching Logic is a specific function within REDCap that allows for certain fields/questions to be hidden under certain conditions, specifically dependent on inputted values from prior fields/questions. This minimized redundancy in the Participant Screening Form, as further elaboration was only required for participants who answered "yes" to an overarching health concern. For example, if a participant answered "yes" to the question "has your doctor ever said that you have high blood pressure?", the participant would be immediately prompted with a follow-up question regarding their high blood pressure; if the participant answered "no" to the same question, this second field would remain hidden. Branching logic was used between several fields within the Participant Screening Form, particularly asking for elaboration on "yes" responses to conditions such as high blood pressure, arthritis, cancer, diabetes, respiratory injury, stroke, spinal cord injury, significant mental health problems, or learning difficulties.

The Participant Screening Form was designed so that excluded participants would not know what criteria they failed to hit, or what caused them to be deemed ineligible. Therefore, each participant filled out the Participant Screening Form to its entirety, which helped create a more representative analysis of participants screened, useful for modifying exclusion/inclusion criteria in any study.

Pre-Intervention and Post-Intervention

A number of health surveys comprised the instruments within the “Pre-Intervention and Post-Intervention” REDCap project, each of which aimed to measure a certain parameter of physical or mental health for eligible participants.

Prior to and following intervention, events were scheduled as “Visit 1” and “Visit 2”. Visit 1 instruments included newly created questionnaires such as “The Liking Survey” (an 100-item self-report measure, where participants ranked on a scale of 1-100 how much they enjoyed certain foods or activities) and the Depression and Anxiety Stress Scales-42 (DASS-42, a 42-item self-report measure of anxiety, depression, and stress)¹³. Visit 1 also included imported surveys from the REDCap Shared Library, such as the Pittsburgh Sleep Quality Index (PSQI, used to measure the sleep quality and patterns of adults)¹⁴, the International Physical Activity Questionnaire (IPAQ; a short questionnaire used to obtain standardized and comparable estimates of physical activity in an international and interdisciplinary setting)¹⁶, the Positive and Negative Affect Scale (PANAS, a “psychometric scale” measurement of positive and negative states and traits in gauging psychological affect)¹⁷, as well as the RAND-36 Item SF Health Survey Instrument (RAND-36, a 36-item self-report of quality of life).¹⁸ All of these health assessments were generated as surveys, since most were self-administered, and all were compared pre- and post- intervention.

In addition to these health surveys, Visit 1 contained a “Contact Information” survey that collected participant emails and generated participant Record ID, as well as an “Informed Consent” instrument that ensured research assistants obtained informed consent from each participant. An instrument measuring Anthropometrics (40-items measuring participant height, weight, body composition, blood pressure, and heart rate) was also generated, and was

designated to pre-intervention visit 1 and post-intervention visit 1. A similar anthropometrics form (40 items measuring participant height, weight, body composition, and fat mass) was also generated and designated for pre-intervention visit 2 and post-intervention visit 2. A submaximal testing form (81 items measuring VO_{2max} and average 5-repetition max for bench press and leg press exercise) was generated and designated for both pre-intervention visit 1 and post-intervention visit 1. Finally, an 18-item phlebotomy form was generated and designated for pre-intervention visit 2 and post-intervention visit 2.

Using surveys at this portion of the experiment proved to be beneficial, as it minimized the need for participants to be physically present when filling out self-reported measures, providing a more accessible and convenient means of participant data input.

Resistance Training and Aerobic Training Interventions

For the two exercise treatments of the study, a single data recording sheet was generated that aimed to measure the same results, in the same procedural fashion, over 36 separate instances. Both sheets included a small information section regarding participant information and current physical state. Both sheets also included instruments asking for rate of perceived exertion (RPE), derived from the Borg Scale of Perceived Exertion.¹⁹

For the aerobic data recording sheet, heart rate and RPE were both measured in 10-minute intervals, each of which existed as a separate field within the instrument. Heart rate was measured using a “Wahoo” heart-rate sensor, whereas RPE was self-reported. Several open-response fields were created for research assistant’s notes on the session.

For the resistance data recording sheet, 3-5 sets of 4-8 repetitions of a variety of exercises were performed, with RPE being asked following the conclusion of each exercise. Each exercise set’s working weight (in pounds) and repetitions (“reps”) was given its own field, as well as an

RPE field following each exercise. RPE was self-reported using the Borg Scale of Perceived Exertion, and several open-response fields were present for notes.

Control Intervention

For the control group of the study, 36 individual, unique surveys were created that corresponded to the 36 days of treatment, and were sent to participants via text message. Sending a text message involved the third-party program Twilio, in which an account had to be created and funds had to be continuously updated.

Each control group survey was assigned to an event on a given day, and were programmed to be sent out at a specific time and date depending on participant schedule, using the “compose survey invitation” feature of REDCap. This reflected a drawback in the REDCap software; sending surveys out in a longitudinal, non-scheduled design, with different instruments for each event, requires coding different times for each survey invitation to be sent out for each participant. However, given the prior implicated issues with REDCap’s autonumbering system and surveys, as well as the need for the text tips to remain surveys, this method was still deemed the most effective way of coordinating text tips.

Conclusion

In considering obesity as an epidemic in the United States (needing new and unique intervention and treatment strategies), with insulin resistance as a key mediating factor, it is important to ensure reliability and validity within the study design of “Aerobic Compared to Resistance Training to Reduce Insulin Resistance in Obesity”, such that results may be applied externally in novel situations and research. REDCap research software allowed for the translation of this study’s design into an entirely digital format, without sacrificing any validity or standardization in research protocol. REDCap was used to standardize research protocol

across multiple arms of participants and multiple stages of research; allowing for the implementation of both new and old data collection instruments, completed either remotely by participants or in-person by research assistants, in this stratified, longitudinal, controlled research design. REDCap also allows for direct, continuous comparison of standardized data both across and within participant arms. Due to the loss of participants during the COVID-19 pandemic, data and subsequent data analysis were not possible.

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