Title: Flipped Classroom for Weight Management
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Study Title: Flipped Classroom for Weight Management.
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I. Purpose, Background and Rationale

A. Aim and Hypotheses

The pedagogy of weight management education has received little investigation, despite health education being considered an essential aspect of weight loss interventions. We propose a 24-week study in which adults will engage in weekly, group weight management classes via Zoom utilizing the flipped classroom teaching methodology. All participants will receive a standard weight management diet and exercise prescription. The aims of this study are to:

1. Determine the feasibility and effectiveness of a 24-week, weight management intervention in adults (ages 18-75) for improving lifestyle habits and weight reduction
2. Measure changes in weight, physical activity, and behavioral outcomes across a 24-week weight management intervention

B. Background and Significance

There is an overall lack of pedagogy (i.e., approaches to teaching and learning) behind weight management programs. We have conducted multiple searches in NIH RePORTER and PubMed and have found no studies on pedagogy for weight management education, despite educational content being a staple in weight management interventions and programs (Franz et al., 2007; Maula et al., 2020). Investigation of pedagogy in weight management education is virtually absent in the literature and it is warranted to investigate given the rising obesity epidemic.

An educational model used in academic institutions, deemed the active learning model, may serve as a feasible educational model used in weight management interventions. In a traditional education model, the educator reviews educational materials during class times, then the students independently complete skills-based homework assignments outside of class (Ayaz & Sekerci, Oct 2015; Mayasari et al., Mar 2018; Persky & McLaughlin, 2017). In contrast, the active learning model requires students to independently review educational material before class, and class time with the educator is spent engaging in group and individual skills-based activities and problem-solving assignments (Ayaz & Sekerci, Oct 2015; Mayasari et al., Mar 2018; Persky & McLaughlin, 2017). The theoretical basis for the development of active learning is to elicit higher cognitive learning, according to the revised Bloom's taxonomy (Bloom et al., 1956; Krathwohl, 2002) and shift independent student time to passive learning (remembering and understanding) and collaborative student and educator time to active learning (applying, analyzing, evaluating, and creating) (Krathwohl, 2002). When utilized in academic institutions, the active learning model has been shown to increase student test scores, learning, engagement, and skill acquisition across a variety of health and science- related topics (McLaughlin et al., 2014; Persky & McLaughlin, 2017; Simpson & Richards, 2015). Investigators believed mechanisms behind the improvement in student learning were ownership of learning and flexibility (Simpson & Richards, 2015), self-efficacy and preparation (Alt, 2015; McLaughlin et al., 2014), and self-awareness and problem-solving (Freeman et al., 2014). Previous research shows enhanced weight loss with improved self-efficacy (Nezami et al., 2016) and self-awareness via self-monitoring (Painter et al., May 2017) in adults during a weight management intervention, supporting the inference that an educational model with outcomes which enhance student learning in academic institutions may be an effective pedagogy for weight management education.

C. Rationale

Establishing effective weight management education techniques may help improve intervention adherence and improve lifestyle habits that can assist with long-term weight reduction.

II. Research Plan and Design

A. Study Objectives

The purpose of this study is to examine the feasibility and initial efficacy of a pedagogy applied in a weight management intervention for adults with overweight/obesity.

B. Study Type and Design

This study is a 24-week, single-arm trial investigating the feasibility of a flipped classroom behavioral intervention for weight management. We will recruit up to 30 adults ages 18+ with a body mass index greater than or equal to 25 kg/m2 to participate in weekly, 1-hour group weight management education delivered remotely via Zoom with a trained health educator. Participants will receive a dietary prescription of 1200-1500 calories/day (5 portion-controlled meals and 5+ servings of fruits and vegetables) and exercise prescription of 150-300 minutes exercise/week. Additionally, participants will be asked to self-monitor diet and exercise adherence weekly. Feasibility outcomes will be collected at baseline, 12-weeks, and 24-weeks.

C. Subject Criteria

Inclusion: 1) Body Mass Index greater than or equal to 25 kg/m^2. 2) Age: 18-75 yrs. 3) Wireless internet connection in the home. 4) Ability to engage in moderate to vigorous exercise. *Exclusion*: 1) Unable to commit to weekly group education. 2) Food allergy/intolerance that would hinder ability to adhere to dietary prescription.

D. Specific methods and techniques used throughout the study

1. Intervention:

Virtual, group instruction: Participants will be complete a total of 24, 1-hour group education sessions with a trained health educator. The group size will be 15-18 participants with continuous recruitment until reaching a total of 30 participants. Sessions will be delivered virtually (Zoom®). Prior to each group meeting, participants will be provided hard copy and audio/visual versions (podcasts and YouTube®) of the lesson to be covered in the upcoming meeting. group session will follow a pre-determined structure: group discussion, review of adherence, 5 to 10 minutes of physical activity, and an active learning-based education. Thus, active learning-based education will include: case vignettes, group debates/discussions, think-pair-share activities, gamification of health-related topics, creation of meal and physical activity, problem-solving barriers to a healthy diet and physical activity, and hands-on worksheets.

i. Diet Prescription. Participants will receive a diet prescription of 1200-1500 kilocalories (kcals), consisting of 5 portion-controlled meals [(PCMs); 3 shakes and 2 entrees], 5 servings of fruits and vegetables, and zero-calorie beverages. All PCM shakes will be prescribed from the company Health Management Resources (HMR), consisting of 100 kcals and 10g of protein/shake. PCM entrees are available either via HMR or approved outside entrees for purchase at the grocery store as determined by the RD. Guidelines for the approved outside entrees are <300 kcals, <10g sugar, and <3g saturated fat per PCM. Participants will be encouraged to consume at least 65 ounces of zero-calorie beverages per day. Adherence to the diet prescription will be monitored via weekly self-monitoring sheets submitted to the RD by email prior to the educational session for review and feedback.

ii. Exercise Prescription. Participants will be asked to engage in 45 minutes of moderate- to-vigorous exercise 5 days per week or 50,000 steps per week. A pedometer will be available for purchase if desired, but participants may use personal step counting devices (e.g.,

phone apps, watches). Adherence to the prescribed MVPA and steps will be assessed using weekly self-monitoring sheets submitted to the RD via email prior to each session.

b. *Self-Monitoring of Health Behaviors:* Once a month (Baseline, Month 1, Month 2, Month 3) the participant and their caregiver will meet with the health educator via the tablet computer using Zoom video conferencing for approximately 20 minutes to discuss individual healthy lifestyle goals related to nutrition and physical activity and review Fitbit data. Health educators will discuss with participants any further adaptations/modifications needed to help participants reach their goals.

2. Schedule of Evaluations

	Screening Visit: (Day-30 to Day-1)	Baseline (Day-30 to Day-1):	Weekly	End of Study (Week 24)
Informed Consent	**X**			
Enrollment	**X**			
Anthropometrics	**X**		**X**	
Health History		**X**		**X**
Quality of Life		**X**		**X**
Self-Efficacy		**X**		**X**
Diet Behaviors		**X**		**X**
Session Attendance			**X**	
Diet Adherence			**X**	
Exercise Adherence			**X**	

3. Description of Evaluations

a. Anthropometrics (Weight, Height, Waist Circumference): Participants will be weighed at the KU Weight Management Clinic location in Kirmayer Fitness Center on the main KU Medical Center campus. Anthropometrics will be collected in a private room by a registered nurse prior to the participant seeing a clinic physician. Weight will be collected to the nearest 0.1 kg. Standing height will be measured using a stadiometer. Body Mass Index will be calculated as weight (kg) divided by height (cm) squared. Waist circumference will be measured at the midline level between the inferior margin of the ribs and the superior border of the iliac crest.

b. Health History: A health history developed by the study team will be completed online via the REDCap database. Questions include a comprehensive assessment of previous weight loss attemps, current and previous medical conditions, current medications, and previous medical procedures.

c. Quality of Life: Quality of life will be assessed using the Short Form 36 Health Survey Questionnaire (SF-36). The SF-36 is a validated and commonly utilized survey ($\alpha > 0.85$) that relies on self-report of 8 domains: limitations in physical activities because of health problems, limitations in social activities because of physical or emotional problems, limitations in usual role activities because of physical health problems, bodily pain, general mental health, limitations in usual role activities because of emotional problems, vitality, and general health perceptions (Brazier et al., 1992).

d. Self-Efficacy: Self-efficacy will be assessed using two tools: the Health Eating and Weight Self-Efficacy (HEWSE) scale and the Self-Efficacy for Exercise (SEE) scale. Both surveys will be completed at baseline and post-intervention via REDCap. The HEWSE is an 11-item scale to measure heatlhy eating and weight-selficacy with good internal consistency ($\alpha > 0.80$) and test-re-test reliability ($r = 0.72$) (Wilson-Barlow et al., 2014). The SEE is a 9-item scale that measures confidence engaging in exercise 3 times per week for 20 minutes ($\alpha = 0.9$) (Resnick & Jenkins, 2000).

e. Diet Behaviors: Diet behaviors will be assessed using the Eating Attitudes Test, 26-item version (EAT-26) completed via REDCap survey. The EAT-26 is a self-report of general and risky eating behaviours as a screening measure for disordered eating behaviors (Garner et al., 1982) that clinicians can use as a screening tool prior to engaging in a lifestyle intervention.

f. Session Attendance: Attendance to the group education sessions will be measured weekly and evaluated by the health educator. Attendance records will be entered into the study REDCap database.

g. Diet Adherence: Adherence to the diet prescription will be measured weekly via participant self-report. Participants will report daily total number of shakes, number of entrees, servings of fruit and vegetables, and days off plan. The self-monitoring sheet will be submitted via email to the health educator prior to each group session. The health educator will provide individual feedback based on self-reported diet adherence.

h. Exercise Adherence: Adherence to the exercise prescription will be measured weekly via participant self-report. Participants will report daily minutes of moderate to vigorous physical activity and steps. The self-monitoring sheet will be submitted via email to the health educator prior to each group session and individual feedback will be provided.

F. Risk/Benefit Assessment

Risks to the participant from participation in this study are minimal. Participants will be cleared by a board-certified obesity physician to participate in moderate to vigorous exercise and follow the diet prescription. Participants will be asked to gradually increase their exercise by 15-20 minutes per week. The benefits to the participants are the well-established benefits of weight reduction, including reduced risk of chronic disease and improved health outcomes. The information obtained from this study will increase our understanding regarding pedagogy for weight management and its impact on intervention components, such as adherence. The risks to participants in this study are minimal while the benefits are large.

G. Location Where Study Will Be Performed

Research activities will take place at the University of Kansas Medical Center weight management clinic located in Kirmayer Fitness Center. All data will be saved on a KUMC redcap database, and all study related documents will be saved on a KUMC P-Drive.

H. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Elements of the plan include:
    a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB): Study Team
    b. Data/events that will be reviewed: Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion) and Adverse Event Rates
    c. Frequency of review: Monthly
    d. Types of analyses to be performed: Means
    e. Safety-related triggers that would cause the PI to stop or alter the study: The most likely scenario indicating the need to stop the investigation would be a failure to recruit or deliver the intervention as planned. Another issue relating to stopping rules for this trial would be new information. It is unlikely that any new information will become available during this trial that would necessitate stopping the trial
2. Data on adverse events will be reported monthly to the PI throughout this trial. We anticipate that most adverse events will be mild in nature and will allow a complete return to the same activities after a short period of time; that is, later that day or a day or two later.
3. We anticipate most adverse events (if not all) will allow a complete return to the same activities after a short period of time; that is, later that day or a day or two later. However, if a serious adverse event that prohibits participation moving forward, the participant will be terminated from the intervention.

Measurement and Reporting of Subject Accrual, Adherence to Inclusion/Exclusion Criteria
Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur monthly to assure that participants meet eligibility criteria.

Measurement and Reporting of Adverse Events
Data on adverse events will be reported monthly to the PI throughout this trial. We anticipate that most adverse events will be mild in nature and will allow a complete return to the same activities after a short period of time; that is, later that day or a day or two later.

Measurement and Reporting of Participant Compliance to the Treatment Protocol
Compliance to the program will be monitored by attendance to the group sessions. Compliance to the intervention protocol will be reviewed monthly by the PI.

Stopping Rules
We believe this trial conveys minimal risk. It is unlikely that any new information will become available during this trial that would necessitate stopping the trial.

III. Subject Participation

A. Recruitment
We will recruit adults through the KU Weight Management clinic at KU Medical Center. Adults are primarily referred to the clinic via KU Health System physicians and contacted via phone or HIPAA-compliant messaging in their medical record to schedule an initial appointment with a clinic physician. The physician will conduct a comprehensive evaluation of the patient health status, including pertitent medical history. A study coordinator will assist with explaining a basic overview of intervention components in-person to evaluate initial interest. If interested, potential participants will participate in group Zoom® sessions with a study coordinator to obtain consent.

B. Screening Interview/Questionnaire:
The pre-screening for ability to participate in moderate to vigorous exercise and follow the diet prescription will be completed in the initial appointment with the clinic physician. Following the physician appointment, participants will be screened for other eligibility (e.g., commitment to study components, access to wifi) by a study coordinator.

C. Informed Consent Process And Timing Of Obtaining Of Consent
Mary Hastert will obtain written informed consent. Remote video chat sessions (Zoom) will be scheduled with participants who are deemed to be initially eligible to participate. This video chat session will provide an opportunity to describe the project in detail, answer questions, verify eligibility, and to obtain consent and assent. Prior to the consenting session, the participant will be sent the consent form and cover letter through The University of Kansas Medical Center's (KUMC) secure email system. The study team will use the "share screen" option on Zoom to walk through each section of the consent document while noting questions that arise and answering these questions fully. Participants who are willing to participate in the study will sign and date the consent and/or assent forms electronically via REDCap.
Participants/caregivers will be given unlimited time to make the decision on whether to participate. The study team member who conducted the consent meeting will also sign and date after reviewing the signed consent forms and verifying completeness. Study staff will provide the participant with a fully signed consent form for their records.

D. Alternatives to Participation
Participants may join other weight management programs.

E. Costs to Subjects
There will be no costs to the participant or their family for this study.

F. How New Information Will Be Conveyed To The Study Subject And How It Will Be Documented
New information will be told to the participants before, during, or after their participation in the study by email that will be sent to all participants.

G. Payment, Including a Prorated Plan for Payment
Participants will not receive any payment for their participation in the study.

H. Payment for a Research-Related Injury
There will not be any payment for a research-related injury.

IV. Data Collection and Protection

A. Data Management and Security: Data base creation and management will be performed by experienced research staff. Research staff that enters data will be supervised and will be blinded to condition. The PI and study coordinator will have access to study data. We have extensive experience in data entry, data checking, and quality control from previous and current projects. The primary database will be maintained through KUMC's Redcap. Additional data (Fitbit Data) will be maintained a KUMC P-Drive. Prior to transfer of data files to non-study personnel (i.e., for statistical analysis), the files will be de-identified. Data will be categorized and entered into separate tables within a database, all linked by participant number. All key personnel have current Human Subjects/HIPPA certificates. Physical files will be stored in a locked filed cabinet, in a locked office, in our space in the KUMC endowment building suite 100.

B. Procedures to Protect Subject Confidentiality
Confidentiality for participants may be at risk during data collection, entry, and storage. However, we will use a secure, HIPAA compliant system (i.e., REDCap) to serve as the study database to store all the demographic information that may lead to subject identification. The output from the Fitbit will be stored in the KUMC protected drive and only identified by a unique participation identification number to maintain confidentiality. All paper records will be kept in a locked file cabinet and information will not be released without written permission of the participant, except as necessary for monitoring by the KUMC IRB

C. Quality Assurance / Monitoring: At logical time points, the data will be checked for outliers and normalcy. Questionable data (e.g., >3 standard deviations from the mean) will be re-checked for accuracy and re-entered if necessary.

V. Data Analysis and Reporting

A. Statistical and Data Analysis
The effectiveness of the intervention will be assessed by estimating a confidence interval for weight loss percent at 3 months. If the 95% CI includes 5% and the observed weight loss exceeds 2.5%, we will consider that the clinical effectiveness of the intervention is plausible and will seek to confirm this in a larger trial. We evaluated the operating characteristics of this decision rule through simulation with n = 36 and assuming 15% attrition. When the true weight loss percentage is at least 5% we will have a 97.5% probability of proceeding, while if the true weight loss was not clinically significant, e.g., weight loss of 4% or 2.5% we would have a 57% and 1% chance of proceeding respectively. This will ensure that we do not proceed when the true effectiveness is much less than has been determined clinically relevant. We will compare our observed recruitment, attendance, and adherence to observed values from our traditional weight management program (88 ± 5% recruitment, 75 ± 8% attendance, 80 ± 3% adherence) and previous studies utilizing the same diet plan, we expect to see similar rates in this intervention and will evaluate any characteristics of this trial which led to lower than expected rates for potential modification for a follow-up trial. The recruitment goal is set at 30 participants to account for 10-15% attrition and statistical analysis of a sample size of at least 24 participants. All statistical analyses will be conducted using SAS software version 9.4 or higher with a significance level set at 0.05.

B. Outcome
We except to know the feasibility of the intervention and determine if we should apply for external funding to complete an adequately powered trial.

C. Study results to participants

Study results will not be sent to the participants.

D. Publication Plan

The research results will be presented at a conference and published in a peer-reviewed journal upon completion of the pilot study.

VI. References

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