



HHS Public Access

Author manuscript

Contemp Clin Trials. Author manuscript; available in PMC 2019 January 01.

Published in final edited form as:

Contemp Clin Trials. 2018 January ; 64: 58–66. doi:10.1016/j.cct.2017.11.006.

Design and Rationale of the Medical Students Learning Weight Management Counseling Skills (MSWeight) Group Randomized Controlled Trial

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Competing interests

The authors declare that they have no competing interests with this study.

Author Contributions

JO conceived the study and developed the protocol with RH, LC and AG. JO led the writing of the first draft of the paper, with contributions from KA, LC, MB, SC, LP, BO, DJ and AG. All authors contributed to editing and redrafting, and have read and approved the manuscript for submission.

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Abstract

Physicians have an important role addressing the obesity epidemic. Lack of adequate teaching to provide weight management counseling (WMC) is cited as a reason for limited treatment. National guidelines have not been translated into an evidence-supported, competency-based curriculum in medical schools. *Weight Management Counseling in Medical Schools: A Randomized Controlled Trial (MSWeight)* is designed to determine if a multi-modal theoretically-guided WMC educational intervention improves observed counseling skills and secondarily improve perceived skills and self-efficacy among medical students compared to traditional education (TE). Eight U.S. medical schools were pair-matched and randomized in a group randomized controlled trial to evaluate whether a multi-modal education (MME) intervention compared to traditional education (TE) improves observed WMC skills. The MME intervention includes innovative components in years 1–3: a structured web-course; a role play exercise, WebPatientEncounter, and an enhanced outpatient internal medicine or family medicine clerkship. This evidence-supported curriculum uses the 5As framework to guide treatment and incorporates patient-centered counseling to engage the patient. The primary outcome is a comparison of scores on an Objective Structured Clinical Examination (OSCE) WMC case among third year medical students. The secondary outcome compares changes in scores of medical students from their first to third year on an assessment of perceived WMC skills and self-efficacy.

MSWeight is the first RCT in medical schools to evaluate whether interventions integrated into the curriculum improve medical students' WMC skills. If this educational approach for teaching WMC is effective, feasible and acceptable it can affect how medical schools integrate WMC teaching into their curriculum.

Keywords

Weight management counseling; 5As; patient-centered counseling; medical education; group randomized controlled trial; medical schools

1.0 INTRODUCTION

Obesity has reached epidemic proportions and is one of the most compelling health problems facing Americans. Slightly more than 70% of U.S. adults have overweight or obesity, [1] placing them at increased risk for diabetes, heart disease, and cancer [2]. National surveys demonstrate that only 20–40% of adult patients with obesity receive weight management counseling (WMC) from a physician [3–6]. This results in missed opportunities to engage patients in weight management, diet, and physical activity

promotion, [3] ultimately increasing their risk of morbidity and premature mortality. Given that physicians can effectively assist patients with weight management, [7–15] the U.S. Preventive Services Task Force recommends that physicians “screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote weight loss for adults” [16].

Physicians, however, lack adequate education in WMC [6, 17, 18] and report low perception of their skills or self-efficacy regarding their ability to perform WMC [19, 20]. The 1985 report from the National Academy of Sciences recommends at least 25 – 30 hours of nutrition education in medical school [21]. A recent survey of U.S. medical schools found that the average required hours of nutrition were 20.4 in 2000 and 19.0 in 2012; [22, 23] however only about one-third of surveyed schools achieve the recommended minimum hours [22]. A larger gap exists for skills-based practice for WMC with only 2% of the schools in the noted survey reporting patient assessment and counseling [22].

The most prominent organization of medical schools, the Association of American Medical Colleges (AAMC), seeks to address the noted deficit by recommending that WMC be strongly emphasized within the medical school curriculum [24]. They have developed curriculum guidelines providing competencies and learning objectives related to the biologic, population health, and clinical training aspects of WMC. These guidelines [16, 25] have not been translated into an evidence-supported, competency-based curriculum [24, 26]. To help close the gap we have developed a WMC curriculum for counseling adults, “MSWeight” (Medical Students learning Weight management counseling skills). We are evaluating its efficacy compared to traditional medical education on students’ WMC skills and their perception of their skills in a group randomized controlled trial. This pair-matched RCT is similar in design to our prior study, MSQuit (Randomized Controlled Trial (RCT) for Smoking Cessation in 10 Medical Schools-5R01 CA136888) [27].

This research is the first of its kind to develop and evaluate the effect of a WMC medical school curriculum intervention on fostering WMC skills acquisition in a multi-site RCT. If efficacious, MSWeight can have an important public and clinical health impact by providing foundational education to enable physicians-in-training to help patients who have overweight or obesity achieve a healthier weight. This research is timely and critical for addressing the obesity epidemic.

2.0 METHODS

2.1 Study Design

MSWeight is a multi-modal educational intervention (MME) guided by Social Cognitive Theory, [28] Gagne’s Conditions of Learning,[29] and Socio-Ecological Theory [30]. An eight-school pair-matched group RCT design is used to compare MME to traditional medical education (TE) for the primary and secondary outcomes. The primary outcome of observed WMC skills is measured by an Objective Structured Clinical Examination (OSCE), the standard method for observing and evaluating medical student skills at all U.S. medical schools [31]. WMC OSCE scores will be compared between MME and TE schools for the graduating class of 2020 measured during the students’ core clerkship rotation (either

Family Medicine or out-patient Internal Medicine). The secondary outcome of student perceived WMC skills and self-efficacy in delivering WMC is measured by changes in scores for medical students from their first year to during their core clerkship rotation. In addition to our primary aim of comparing efficacy of MME to TE for teaching WMC, we will address the potential influence of individual, interpersonal and institutional factors on observed student WMC skills and student perceived WMC skills. The noted constructs are included in our three guiding theories [28, 29, 30] (see Figure 1). We also will evaluate the feasibility and acceptability of implementing the MME across medical schools. If the MME approach improves students' WMC skills and is acceptable to students, faculty and school administration, then it can support integration of national recommendations for training future physicians in WMC.

It employs a nested cross-sectional study design to compare OSCE scores between MME and TE schools. The MME curriculum developed and modeled from previous on-line tested instruction [32] includes: 1) an evidence-supported and competency-based web-course; 2) a role play exercise guided by a WMC OSCE-based checklist; 3) novel use of standardized WebPatientEncounter [33] technology to provide practice and structured feedback to students on their WMC skills; and 4) an enhanced Family Medicine or outpatient Internal Medicine clerkship that provides WMC skill building experiences. A web-based patient encounter is an innovative addition that was not used in the MSQuit intervention and was added to potentially increase the impact of the intervention on WMC skills. This combination of the web-course, role play exercise, WebPatientEncounter, and preceptor facilitated teaching during an enhanced clerkship provides repeated exposure to the WMC curriculum during the first three years of medical school. The curriculum is intended to provide a structured and reinforcing foundation for helping medical students build and practice WMC skills, and to build confidence in their skills and self-efficacy [28] (i.e. belief in their ability to perform WMC) for implementing WMC (see Figure 2 for the Study Timeline).

To capture school pre-intervention OSCE scores, a comparison cohort of students (graduating class of 2018) at each school who are not part of the intervention will complete the OSCE (see Figure 2). The study cohort is comprised of students from the graduating class of 2020. MME students will have completed the enhanced clerkship activities during their core clerkship rotations. The study cohort (MME and TE) OSCEs will be administered after completion of the same pre-determined clerkship. To determine the impact of the intervention on our secondary outcomes, perceived WMC skills and self-efficacy for delivering WMC, students in the eight schools in the Class of 2020 will complete a 16 item survey assessing their perceived WMC skills and an additional item assessing their WMC self-efficacy as first year students (i.e. "Baseline Survey") and after their core clerkship rotation and following their WMC OSCE ("Follow-up Survey"). (See Table 1).

Evaluation of the feasibility and acceptability of implementing the MME intervention is measured through interviews with each MME school study PI or designee, participation rates (feasibility) and satisfaction scores (acceptability) for each intervention component.

2.2 Participants and Randomization

Eight medical schools are participating in the MSWeight RCT. Six of the eight schools previously participated in the NCI-funded trial, MSQuit [27]. The two remaining schools were recruited through networks with colleagues. Schools are from each U.S. region (e.g. North, South, West, Midwest) and met the following criteria at the time of recruitment: 1) includes a Family Medicine or out-patient Internal Medicine clerkship; and 2) is willing and able to offer a WMC OSCE for students following the completion of a core clerkship, the Family or out-patient Internal Medicine Clerkship rotation, or as part of a cumulative OSCE. The University of Massachusetts Medical School coordinates the study. MSWeight was submitted and determined to be exempt at the University of Massachusetts Medical School and by each participating medical school's Institutional Review Board.

Prior to randomization, the eight schools were surveyed about the presence of curricula and number of hours addressing behavior change and WMC in medical school years 1 through 3. In addition, a Matching and Randomization Survey was administered to the Class of 2017 for both TE and MME schools, during their core clerkship rotations (See Table 1 for measures and when they were administered).

The survey was designed to include questions built on content and format used in previous research [35]. Measures include student demographics, attitudes, and questions to assess perceived skills for WMC (16 items; responses 1=not at all skilled, to 5=very skilled) and self-efficacy for delivering WMC (1 item; responses 1=strongly disagree to 4=strongly agree). The survey was pilot tested for ease of understanding with medical students from the University of Massachusetts Medical School and site PIs. Results from the pilot test were used to refine the final self-administered survey. Schools were stratified into high (four schools) or low (four schools) WMC and behavior change curriculum hours based upon reports from the school faculty or PI. Within each institutional curriculum stratum, the four schools were then rank ordered based on school mean score for student perceived WMC skills from the Matching and Randomization Survey. This resulted in four strata with two schools each. These pair matched schools were randomly assigned to either MME or TE. Randomization was accomplished using a random number generator (See Figure 3).

Following randomization first year students from the study cohort (class of 2020 students) at the eight schools were informed that their medical school was participating in a study to test the effectiveness of different teaching methods to facilitate medical student skill development in WMC. By completing the survey the student is agreeing to take part in the research study. Each medical school PI obtained the current roster of the class of 2020 from its Office of Student Affairs or the registrar. For sites with multiple campuses the school selected the medical students at the campus who would be able to complete the study OSCE and take part in the intervention if randomized to the MME. Altogether, from the eight medical schools combined, 1307 medical students in the class of 2020 will be eligible to participate in the study.

2.3 Medical School Education Arms

2.3.1 Traditional Education (TE) Comparison Arm—The TE arm represents “usual care” and includes the current content and mode for WMC teaching weight management among schools randomized to TE. Modes of learning mainly include WMC lectures interspersed among basic science and behavior change classes, with some use of small group discussions or communication skill-building exercises and clinical experiences for health behaviors.

2.3.2 Multi-Modal Education (MME) Intervention Arm—The MME intervention targets *student individual factors* (WMC knowledge, obesity bias, WMC observed skills, and WMC perceived skills and self-efficacy), *interpersonal factors* between faculty and student (modeling and provision of WMC feedback), and *institutional factors* (exposure to WMC curriculum, including clinical experiences) to support WMC skill building for medical students. The MME intervention is modeled on the protocol we have used for diet, alcohol, and smoking behavior change interventions, using patient-centered counseling integrated into the 5As framework (Ask, Advise, Assess, Assist, and Arrange) [36–38] as well as incorporating content from the obesity guidelines noted in Section 2.3.2 [25]. The MME is designed to give students repeated and sequential exposure to WMC curricula over the course of the first three years of medical school.

2.3.2.1 Web-Course “MSWeight: Building Weight Management Counseling Skills”: Our team of experts in behavioral health, medical practice and nutrition reviewed existing online courses such as New Lifestyle [39] and Nutrition in Medicine [40] for teaching WMC. Other selected resources include the American Heart Association/American College of Cardiology/The Obesity Society Clinical Guidelines for the Management of Overweight and Obesity in Adults, [41] Center for Disease Control and Prevention, [1] American College of Sports Medicine’s Exercise is Medicine®, [42] the U.S. Department of Health and Human Services’ Physical Activity Guidelines, [43] the American Heart Association’s Fitness Basics, [44] and the 2015–2020 Dietary Guidelines for Americans [45]. Using these resources as a guide the team selected key goals for the web-based didactic component of the intervention. The web-course includes 14 modules that range from epidemiology of overweight/obesity and the role of the physician in WMC to providing tools that physicians can use to partner with patients to make dietary and physical activity behavior changes. Since obesity bias is prevalent in society and can be present during a medical student-physician-patient interaction [34], the web-course incorporated content to raise awareness about obesity bias and increase knowledge for effectively counseling patients with obesity.

To facilitate the web-course completion, the course is self-paced. Each module is designed to be completed by students in approximately 15 minutes with an overall time commitment of 4 hours. Medical education deans and course directors agreed to include the course in the first year curriculum and to record course completion among their students. At the end of the web-course, students will complete a short quiz. Upon completion of the quiz students will receive a certificate of completion. The web-course is promoted as a prerequisite for the role play exercise.

2.3.2.2 Role Play Exercise: The goal of the role play exercise is to provide students with hands-on practice conducting WMC. The one-hour session is facilitated by school faculty instructors and includes a brief video demonstration of a physician-patient encounter for WMC that incorporates the 5As framework followed by a brief discussion of the video and WMC challenges such as initiating the conversation about weight management and goal setting. Subsequent to the discussion, students break into dyads and practice two physician-patient encounters.

2.3.2.3 WebPatientEncounter: The WebPatientEncounter [33] is an innovative addition to the intervention that provides students with WMC skills practice during the second year. In this intervention, students interact with a standardized patient (SP) with obesity in a formative WebPatientEncounter, using a video-conferencing system developed and administered by investigators at Drexel University College of Medicine - in alignment with our OSCE checklist. It provides a two-way video that can be recorded and stored. After a 15-minute encounter the SPs (hired and trained by Drexel University) guide the student through our structured OSCE WMC behavior checklist, noting behaviors and communication skills the student successfully implemented and those the student could have employed for a more effective encounter. The SP provides feedback by playing back relevant parts of the encounter to show the student what they did. Students can access their interview for continued reflection. Total time with the SP is 40 minutes; staff at Drexel University along with staff at each MME institution schedule student/SP meetings.

2.3.2.4 Enhanced Clerkship and Faculty Development: Clinical preceptors are in the position to teach, model, provide practice opportunities, give constructive feedback to students during the clerkship experience, and can have a positive impact on students' clinical skills development [46, 47]. In MSQuit, we involved academic detailers to conduct the faculty development. Such educational outreach has demonstrated effectiveness for teaching physicians various intervention skills [36, 38, 48–52]. However, the educational level, experience, and skill level of the academic detailers varies between schools. We were concerned that academic detailers [27, 52] are not on the front line with preceptors or medical students and may not adequately teach them WMC. For the current study, the clerkship director (CD) delivers the intervention because the CD is on the front line with faculty and students. Clinical faculty also play a major role in student education, precepting students during their core clerkship rotations. For this reason the clerkship directors in this study work with the UMass team to develop preceptor faculty development materials, designing the educational session to be brief, 30 minutes, to enhance preceptor engagement.

Clerkship directors facilitate the group educational session for the preceptors. Preceptors are strongly encouraged to: (1) conduct WMC with their patients for students to observe, as modeling is an effective training technique, [53] and (2) actively observe students with patients and give critical feedback related to their WMC skills. The clerkship directors' educational program for preceptors includes principles of patient engagement and use of the 5As and patient-centered counseling for WMC. For preceptors who are not on-site, a recorded session is sent out electronically. Preceptors and medical students receive pocket guides to reinforce intervention concepts. Through use of a checklist, preceptors and medical

students verify that the medical student was observed and given feedback on their WMC skills. The checklist is forwarded to the study coordinator at the site. Materials are provided in multiple formats including one easy to access by smartphone.

2.4 Intervention Implementation and Fidelity

To maximize implementation of the MME intervention, site PIs are encouraged to tailor implementation of the intervention to their institution's unique characteristics and needs within their organizational and educational context. While the curriculum content is standardized across schools, each school has flexibility to choose the specific course in which the educational intervention is to be implemented and when to implement it (e.g. during the Doctoring and Clinical Skills course). Schools are provided with guidelines for implementation timing so that students across schools receive the intervention within a common and specific timeframe. These guidelines are as follows: 1) the web-course is implemented when medical students in our intervention study cohort are in their first year; 2) the role play is implemented after the web-course during the study cohort students are in their first year of medical school; 3) the WebPatientEncounter takes place during the second year after the role play exercise and prior to the clerkship; and 4) the clerkship director/preceptor teaching experience takes place prior to the study cohort entering the outpatient internal or family medicine clerkship rotation.

To maximize intervention fidelity specific steps are implemented. First, we ensure that all MME site PIs and key staff for a particular intervention have a role in its refinement. They or their designee (e.g. whoever implemented the intervention component) are therefore familiar with the intervention content, goals, and objectives. Next, our team made sure the content and structure of the intervention components (e.g. role play exercise, enhanced clerkship) were standardized and semi-guided with written instructions and examples of discussion points provided for faculty instructors. The web-course is directly implemented by the UMass team remotely as it requires student login and registration to ensure participation. The UMass team facilitates standardized orientations for each intervention component. Finally, conference calls with MME faculty are held monthly and individually as needed to address challenges in real time and to enhance fidelity to program implementation.

3.0 MEASURES

3.1 Primary Outcome: Observed Weight Management Counseling Skill

OSCEs for assessing clinical skills consist of a series of stations (cases) intended to simulate a component of a clinical encounter [31]. This rigorous assessment was used to evaluate medical students' tobacco dependence treatment skills in our prior trial [54] and will be used in the MSWeight trial. As noted in Section 2.1, for the primary outcome we will compare MME school and TE school scores on the WMC OSCE using a nested cross-sectional design. As with MSQuit [27] the OSCE will be used to objectively measure skills among medical students who have completed their core clerkship.

Student scores on the WMC OSCE are determined by an OSCE checklist consisting of 23 items assessing WMC skills integrating 5As behaviors (15 items) and patient-centered

counseling skills (8 items). The WMC skill items integrated into the 5As framework were based on the 2013 Guideline for the Management of Overweight and Obesity in Adults published by The Obesity Society and American College of Cardiology/American Heart Association [25]. The communication skill items were developed based on patient-centered counseling models and guidelines. Examples of 5As items include: “Asked permission to discuss diet and physical activity history and current behaviors” (Ask); “Advised that weight loss is recommended based on the patient’s personal health information (e.g. BMI and risk factors)” (Advise); “Assessed the patient’s level of readiness to make lifestyle changes to achieve weight loss” (Assess); “Assisted the patient by discussing behavior change strategies that will help achieve their goals” (Assist); and “Recommended or referred the patient to weight management resources in the clinic or in the community and scheduled a follow up appointment” (Arrange follow-up). An example of communication skills items include “Used a majority of open-ended questions during the encounter”. The OSCE checklist was refined based on application of the checklist to videotaped encounters and reviewed and approved by behavioral health and weight management experts, practicing clinicians and medical students prior to finalizing.

The 8 Patient-Centered items are scored 0–2 (max = 16) and the 15 5A items are scored Yes/No (max = 15), for a maximum score of 31 for each OSCE. The final scores will be computed as total points earned. One coder will score each OSCE tape. To check for consistency a 'gold standard' coder and supervisor will code 10% of the completed checklist for each coder. This verification process will be conducted on an ongoing basis to detect and correct any discrepancies. This method is consistent with scoring in the MSQuit where consistency was very high [54]. Although students are not expected to complete all 23 checklist behaviors, higher overall scores may be indicative of better WMC performance. Similar to MSQuit, we anticipate that the 8 patient-centered items also will be used to create a separate outcome from the total OSCE score indicating number of completed behaviors.

All WMC OSCEs are videotaped and blinded. Trained coders will score them. The coders will not be members of the research team and will be blinded to school and its intervention assignment (MME or TE). Coders will complete a series of trainings and follow-up booster trainings led by our research team and will have several opportunities to practice coding WMC OSCE performances from a pool of practice UMass students.

3.1.1 WMC OSCE Case Refinement and Checklist Development—We adapted a WMC-specific OSCE case that has been used previously as a teaching tool within a medical school curriculum. The OSCE case was reviewed and refined with input from each school’s site PI, clinical skills course director, and SP trainer. The OSCE checklist was developed using the WMC perceived skills and patient-centered counseling items from the baseline survey, and refined through a process of co-investigators, clinicians, and weight management experts reviewing four SP WMC OSCE videotapes and coding the tapes using the checklist. Once the checklist was revised and refined it was reviewed by the PI and the investigative team, practicing physicians, and medical students. The checklist was finalized when consensus was reached.

3.1.2 Standardized Patient Training—As in MSQuit [27] our research team trained each school’s SP trainer in the details of the case through a series of half-day trainings. Trainers were then responsible to train the SPs at their school. The number of SPs at each school is dependent upon the number of concurrent sessions scheduled. An expert SP trainer reviewed a training video for each SP and the school’s trainer coached the SP with any corrections required (see ref [55] for discussion of this training).

3.2 Secondary Outcomes: Self-Reported WMC Skill and Self-Efficacy

For our secondary outcomes, student perceived WMC skills and self-efficacy, students in both MME and TE schools complete surveys at baseline (“Baseline Survey”) and follow-up (“Follow-up Survey”, post intervention). The baseline and follow-up surveys include 15 items to assess perceived skills in WMC using patient-centered counseling and integrating the 5As framework. Students are asked to rate their skill level in carrying out each of the WMC steps with patients (1=Not at all skilled to 5=Very skilled). Examples of items are similar to the OSCE items in the primary outcome (section 3.1). The total score is the average among WMC skills using patient-centered counseling and integrating the 5As framework. The secondary outcome of *student perceived WMC skills is calculated as the average of the ratings across these items*. A separate, single item global self-efficacy question was included in the baseline and follow-up survey: “I feel confident in providing weight management counseling for my patients with overweight and obesity”, (1=Strongly disagree to 5=Strongly agree) to assess self-efficacy in conducting WMC with patients.

3.3 Other Outcomes of Interest: Proposed Mediators

Several intrapersonal, interpersonal, and organizational variables are hypothesized as mediators and are measured for students in MME and TE schools through the matching and randomization and the follow-up surveys. Intrapersonal mediators include perceived WMC skills and self-efficacy (as described above) and include the frequency of instructional and observational experiences in WMC received by students. In the noted surveys the core clerkship medical students are asked the number of times that they have been instructed how to do WMC. Students also report how frequently they observed a physician or preceptor perform WMC 5As behaviors with a patient with obesity or overweight. Finally, organizational mediators are assessed in the baseline and follow-up surveys, including counseling prompts, reminders, or clinic/system changes.

3.4 Process Evaluations: Feasibility and Acceptability of the MME

Feasibility and acceptability data will be gathered on MME conference calls, debriefing with PIs and other key personnel about implementation of each component, and through student and preceptor evaluations. The research team at each medical school document feasibility, that is, participation rates for student intervention components and faculty development. Acceptability data are collected via satisfaction surveys students complete after each MME component. Finally, we will determine curriculum and institutional changes at both TE and MME schools that may affect student training in WMC. In order to capture institutional curricula changes over time, we will assess school curricula on nutrition, WMC, and

behavior change after completion of the intervention using the same approach that we used for matching and randomization prior to intervention initiation.

3.5 Sample Size and Power Calculation

Our primary outcome is WMC skills measured by the study cohort post-intervention OSCE score. Adjusting for school-specific mean baseline OSCE score, the detectable MME-TE mean difference is given by $\Delta = [2(\sigma_m^2 \Theta_m + m\sigma_g^2 \Theta_g) (t_{\alpha/2} + t_\beta)^2 / mg]^{1/2}$ where σ_m^2 and σ_g^2 indicate school and intervention group components of total variance of OSCE score= σ_y^2 , respectively; Θ_m and Θ_g reflect reductions in those variance components from covariate adjustment; m =number of students per school and g =number of schools per condition; and t_c indicates a critical value with right tail probability c from a t-distribution with degrees of freedom= $2(g-1)$ [55, 56]. To be conservative, we take $\Theta_m=1$. $\Theta_g = 1 - R^2_{y,x}$ where $R^2_{y,x}$ =proportion of outcome variance explained by baseline school mean, estimated as the square of the over-time correlation. Also, $\sigma_g^2 = \sigma_y^2 \times$ intra-class (intra-school) correlation (ICC) and $\sigma_m^2 = \sigma_y^2 \times (1-ICC)$. Using values from our prior randomized clinical trial of MME versus TE for tobacco counseling as a guide, [57] the observed over-time correlation in school means = 0.87 and ICC=0.12. Standardizing the outcome ($\sigma_y^2=1$), and taking $m=125$, two-sided hypothesis testing with 0.05 Type I error rate, 80% power, and $g=4$ schools per condition, the projected detectable MME-TE difference in mean OSCE score=0.42 standard deviations; this difference is in line with the prior study's observed between-group difference of 0.35 standard deviations, and we anticipate a larger difference in MSWeight given the more intensive intervention. Power for the secondary outcome, perceived WMC skills, will be higher than for the primary outcome given the anticipated positive correlation over time for both individual students and schools. The ICC indicates within-school correlation of OSCE scores from students in the same school. We have used results from MSQuit [57] as a guide for anticipated magnitude of the intervention effect given that the components of the intervention are similar in both studies.

3.6 Data Management and Data Analysis Plan

3.6.1 Data management, confidentiality, and blinding—Each eligible student is assigned an ID by school personnel which is used in all study data files; no study investigators outside the school have access to student identifying information that can be linked to their ID. All study data are entered into REDCap (Research Electronic Data Capture), a secure web-based application for research studies, either directly by students (survey data) or by study personnel. OSCE scoring will be conducted by coders blinded to school and randomization arm.

3.6.2 Data analysis plan—Analyses of the primary outcome will compare post-intervention MME and TE schools' WMC OSCE scores, adjusting for pre-intervention scores. To account for the nested cross-sectional design, with students measured at two time points in the same schools – pre-intervention = Comparison Cohort students (class of 2018), post-intervention = Study Cohort students (class of 2020)– we will use a two-stage mixed model analysis of covariance (ANCOVA) [55, 56]. In the first stage, 16 (8 schools \times 2 time points) mean scores will be estimated from an ANCOVA for student-level WMC OSCE scores as a function of school, time point, and their interaction. In the second stage, the eight

post-intervention school-mean scores will be regressed on intervention assignment and the corresponding pre-intervention school mean. This approach adjusts for any MME-TE differences in baseline school mean WMC OSCE scores while accounting for within-school correlation. The secondary outcome, perceived WMC skills, will be measured twice in the same study cohort students, both pre- and post-intervention, allowing the assessment of change within individual students. Depending on the distribution of this outcome, MME-TE differences post-intervention will be estimated using linear mixed models (continuous) or random effects logistic regression (categorical), adjusting for the student's own pre-intervention report and treating school as a random effect to account for within-school clustering. The latter models will adjust for relevant student-level covariates, such as gender, age, and planned specialty.

3.7 Ethics and Dissemination

Site PIs obtained school approval to participate in the research (both MME and TE schools) and to incorporate WMC MME intervention components into the existing medical student curriculum (MME schools only) well in advance of project implementation. All surveys, OSCE scores, and MME evaluation component data will be de-identified before being given to the UMass Coordinating Center research team, who will manage databases and analyses.

All IRBs noted that completing surveys was voluntary. Three of the eight IRBs required a consent information sheet, not requiring documentation of written consent. One IRB required a consent information sheet noting that participation in the intervention was voluntary. Two of the three medical schools included language about releasing their de-identified videotaped OSCE to the research team noting that the research team would code the OSCE. Data sharing and the timely release of sharing the final research data are essential. The dissemination plan includes publications, presentations at and distribution to organizations to which our project members currently belong. We will use NCI's Cancer Control Planet that we have used previously for distribution of all project materials in other projects led by current investigators. The plan includes sharing the use of research tools, such as project surveys and OSCEs, curricula materials such as web-based training and enhanced clerkship materials, and results from surveys collected in multiple years of the study. Our findings will be highly relevant to individuals in medical education and obesity behavior change fields.

4.0 DISCUSSION

Guidelines for the treatment of obesity recommend intensive behavioral counseling [16, 25]. The US Preventive Services Task Force recommends that physicians screen and offer intensive behavioral counseling to patients with obesity; [16] and the Centers for Medicare and Medicaid Services (CMS) approved covering intensive behavioral counseling by primary care physicians using the 5As model [58]. Although research is limited, WMC delivered by a variety of trained interventionists in the primary care setting is recommended and is consistently associated with patient weight loss [59–61]. However, WMC training is limited and not standardized across medical schools [6, 22, 26]. Learning is optimal when knowledge is acquired and experience occurs early, skills are reinforced consistently, and

teaching is integrated into all aspects of a curriculum [29, 62–67]. Therefore, early exposure to WMC through didactic sessions, skill building exercises, and preceptor modeling, observation, and opportunities to practice WMC with patients and receive feedback from preceptors has great potential to benefit medical students. Additionally, the opportunity to methodically learn behavioral skills such as WMC may be most beneficial when trainees can observe, be observed, and receive immediate critical feedback from preceptors during medical school.

The MSWeight study is the first group randomized controlled trial that seeks to establish whether a MME intervention compared to TE methods will influence medical student WMC skills and self-efficacy. It has many strengths in design and outcome implications. The MME intervention incorporates components of a known effective web-course [39] and the role play exercise. It also includes the novel use of the WebPatientEncounter [33] and methods to train clerkship directors and preceptors to provide instruction in WMC. The MME intervention is grounded in learning theory, implemented early in the medical school curriculum, and integrated throughout a student's medical school experience. Finally, because the MME intervention was developed with the goal of possible and eventual national medical school dissemination, the curriculum was refined through input from medical students, medical school administrators, medical faculty, education specialists and WMC specialists. In addition the MME was designed to be delivered in a standardized manner yet allow for flexibility to tailor the MME components to a school's specific curriculum.

One other notable strength of this research is its use of scores from observed WMC OSCEs for its primary outcome. This rigorous method of evaluation reduces potential student and school-level biases as independent and blinded coders code the OSCE videotapes in the current study in order to objectively evaluate WMC skills. Prior research has shown that medical students evaluate their experience positively with health behavior change trained SPs, [68] and that SPs are trained in a variety of health behavior change cases. However, little research, if any, has objectively used a weight management-specific case and OSCE scores to measure intervention impact on student WMC skills. If feasible to implement, our OSCE WMC case may be used for additional training purposes or could be used for required undergraduate medical student standardized evaluation (e.g. Clinical Skills Exam (CSE) of USMLE Step 2) [69].

Potential limitations of the current study include the need for flexibility in implementation given the challenges associated with implementing a multi-modal intervention across multiple medical schools with varying school resources, institutional policies, prior WMC curricula, and community obesity rates. Through our process evaluation we will be able to better understand some of the contextual factors affecting implementation. Real world medical education is changing at a very fast pace, continuously allowing for more flexibility and options for students and our pragmatic approach reflects these trends. Although we have matched for school-level differences in student perceived WMC skills, differences in the ability to feasibly implement the study across medical schools exist. For example, school-related policies that allow faculty to make curriculum components graded or required versus optional differ among institutions and potentially can affect student participation rates and

study outcomes. Schools also may differ in the number of faculty who have interest or expertise in WMC which also may affect school-level outcomes.

In summary, a WMC intervention that can effectively help physicians-in-training, their clerkship directors and their preceptors learn WMC skills could make an important contribution to medical education, clinical medicine and population health.

Acknowledgments

We acknowledge all school site PIs, research coordinators, evaluators, directors of standardized patients, medical directors of clinical education and simulation center, research assistants, support staff, participating medical students, course directors, clerkship directors, preceptors and our weight bias consultant who have and will implement and participate in the study.

Funding: This work is supported by the National Institutes of Health, National Cancer Institute, 5R01CA194787.

Role of the Funding Source: The funding source has had no involvement in the conduct of the research or preparation of the article.

Abbreviations/Definitions

5As

Ask, Assess, Advise, Assist, Arrange

MME

Multi-modal education

TE

Traditional education

OSCE

Objective Structured Clinical Examination

Pre-clinical coursework

occurs prior to core clerkship rotations and timing varies by school

Core clerkship rotation

occurs after pre-clinical coursework is completed (2nd or 3rd year of medical school)

SP

Standardized patient

WMC

Weight Management Counseling

RCT

Randomized Controlled Trial

MSQuit Medical Students

Medical Students Helping Patients Quit Tobacco

MSWeight

Medical Students Learning Weight Management Counseling Skills

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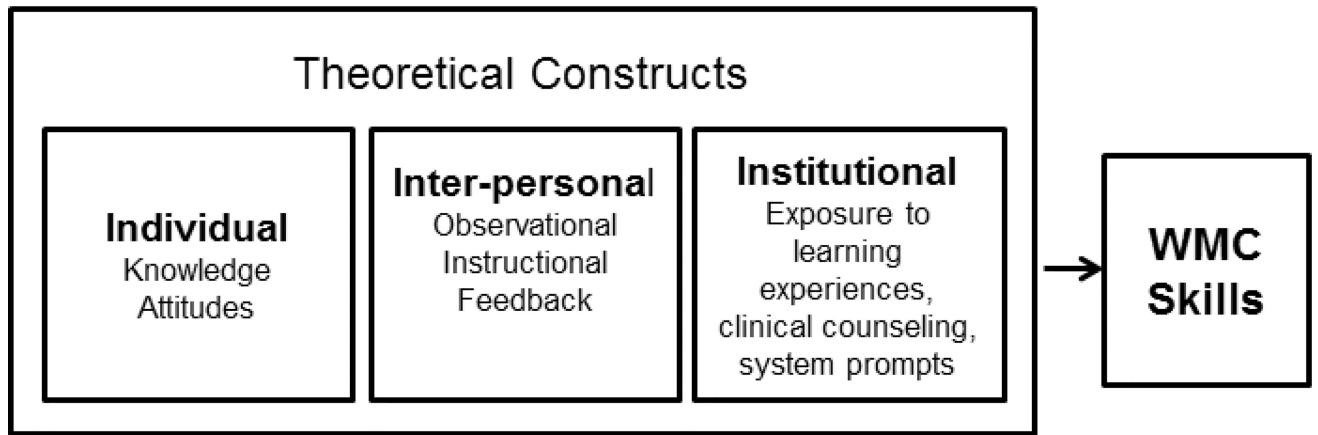


Figure 1. Theoretical Constructs that Potentially Influence WMC Skills
Theoretical constructs represent the constructs that are applicable to individual, interpersonal and institutional levels.


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Grant Year	1	2	3	4	5
Academic Year	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Coursework	----	Preclinical	Preclinical	Core clerkship rotation	----

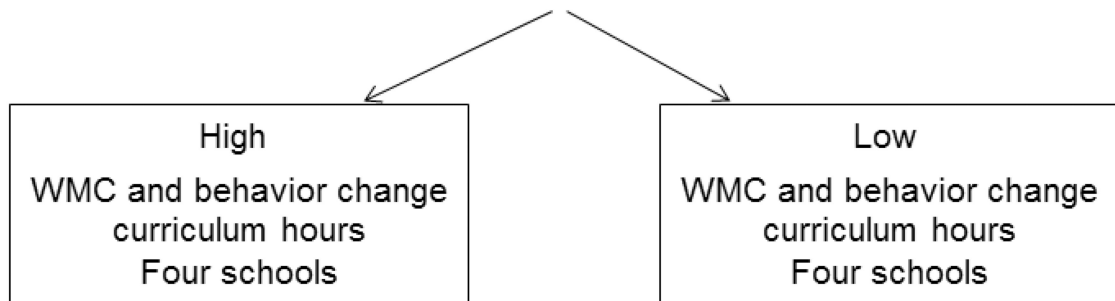
Traditional Education (TE) Intervention	Usual Curriculum 				
Multi-Model Education (MME) Intervention	----	Web-course Role-playexercise	WebPatientEncounter	Enhanced clerkship	----

Outcome Measures	Matching & randomization survey administered to the graduating class of 2017	Comparison cohort completes OSCE (graduating class 2018) Baseline survey administered to graduating class of 2020	----	Study cohort completes OSCE (graduating class of 2020) Follow-up survey administered to graduating class of 2020	----
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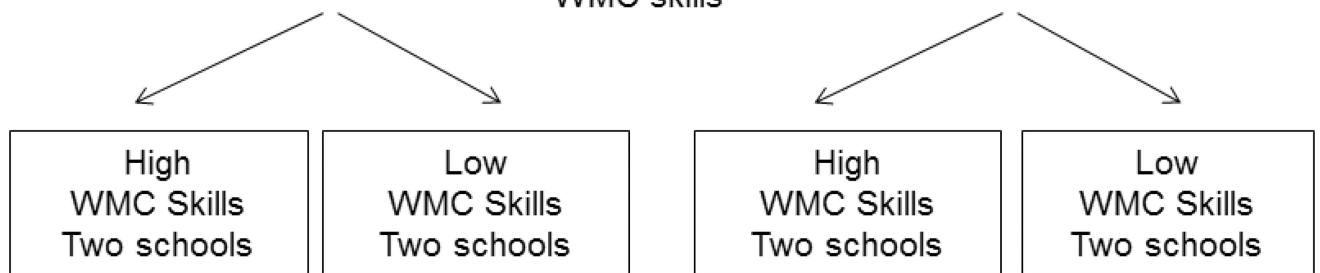
Figure 2. Study Timeline

OSCE=objective structured clinical exam; Pre-clinical=medical student academic year 1 and year 2; Core clerkship rotation=occurs after pre-clinical coursework is completed (2nd or 3rd year of medical school); RCT=randomized controlled trial; MME=multimodal education; TE=traditional education; CD=clerkship directors; SP=standardized patient.

Eight U.S. Medical Schools
Self-report institutional curriculum for WMC and behavior change



Mean score for student perceived
WMC skills



Within each pair of schools matched on institutional curriculum and student perceived WMC skills, randomize 1 school to MME and 1 school to TE

Figure 3. Randomization Schema

WMC = weight management counseling

MME = multi-modal education

TE = traditional education

Table.1

Study Measures -

Year	2015–2016	2016–2017	2018–2019
Objective Measure: OSCE	-----	Comparison cohort completes the OSCE class of 2018	Study cohort completes the OSCE class of 2020
Self-Report Measures: Student Surveys	Matching and Randomization Survey administered to the class of 2017	Baseline Survey administered to the class of 2020	Follow Up Survey administered to the class of 2020
WMC perceived skills	X	X	X
Self-efficacy to deliver WMC	X	X	X
Attitudes about PD-WMC	X	X	X
Obesity Bias [34]	X	X	X
Intention to Treat	-----	X	X
Perception of Impact on Patient Motivation	X	-----	X
Prior experiences in WMC	X	-----	X
Personal Health Habits	X	X	X

OSCE=Objective standardized clinical exam; WMC=weight management counseling; PD=physician delivered.

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