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Authors

Afari, Niloofar

Cuneo, Jessica Gundy

Herbert, Matthew

et al.

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Design for a cohort-randomized trial of an acceptance and commitment therapy-enhanced weight management and fitness program for Navy personnel

Niloofar Afari[a,b,c,*], Jessica Gundy Cuneo[a,b], Matthew Herbert[a,b,c], Isabel Miller[a], Jennifer Webb-Murphy[d], Eileen Delaney[d], Joshua Peters[e], Karla Materna[a], Erin Miggantz[a], Job Godino[b], Shahrokh Golshan[a,b], Gordon Wisbach[e]

[a] VA San Diego Healthcare System, San Diego, CA, USA
[b] University of California, San Diego, La Jolla, CA, USA
[c] Center of Excellence for Stress and Mental Health, San Diego, CA, USA
[d] The Naval Center for Combat & Operational Stress Control, San Diego, CA, USA
[e] Naval Medical Center San Diego, San Diego, CA, USA

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ABSTRACT

Overweight/obesity and inadequate fitness in active duty personnel impact the wellbeing of service members and have significant costs for military readiness and budget. ShipShape (SS), the Navy's weight management program, was designed to promote nutritional, behavioral, and exercise education to service members. Although SS is an evidence-based program, about half of those who complete the program pass the Body Composition Assessment (BCA), one part of the Navy's comprehensive Physical Fitness Assessment (PFA). SS may not fully address underlying behavioral, psychological, and emotional barriers that influence poor eating and exercise habits. A novel solution to improve outcomes is to incorporate acceptance and commitment therapy (ACT) to promote mindful awareness of present moment experiences, improve psychological flexibility, and support commitment to behavior change. This paper describes a cohort-randomized controlled trial of ACT-enhanced SS (ACT + SS) compared to the standard SS-only program. Active duty service members referred to the SS program are randomized to receive 8-weekly ACT + SS or SS-only group interventions. Our aims are to: 1) determine the effectiveness of ACT + SS compared to SS-only; 2) examine psychological flexibility as a mechanism underlying intervention response; and 3) explore potential moderators of intervention response. The primary outcome is weight, one of the key components of the BCA; secondary outcomes include Body Mass Index (BMI), body fat %, self-reported BCA results, physical activity, problematic eating, and quality of life. We have designed a cohort-randomized trial with interventions that are pragmatically implemented in a real-life military setting, and outcomes that are immediately relevant to service members and leadership.

1. Introduction

The rate of overweight and obesity among U.S. military service members has increased 61% since 2002, with the second highest rate being among U.S. Navy personnel [1]. In 2012, the overall prevalence of obesity (body mass index (BMI) $>$ 30 kg/m^2) in the Navy was 13.6% [2]. Obesity in military personnel is not limited to the U.S., as high rates have been reported in several countries across the globe [3–5].The prevalence of overweight and obesity has direct consequences for the health and wellbeing of service members, military readiness, and the costs associated with early attrition, reduced productivity, and medical care expenditures.

Regular physical examinations and fitness tests ensure military personnel are prepared for the physical and mental demands of military service. The Navy Physical Fitness Assessment (PFA) is an official evaluation of physical health, ability, and endurance conducted twice a year throughout each Sailor's career. The PFA consists of a medical screening, a Body Composition Assessment (BCA), and a Physical Readiness Test (PRT). Several indices including BMI, body fat %, and physical fitness are used to determine if a service member: a) is at risk of discharge from the Navy because of being overweight or poor physical fitness; and b) may benefit from health and wellbeing programs to

* Corresponding author. Department of Psychiatry, University of California San Diego, 9500 Gilman Drive, La Jolla, CA, 92093, USA.
E-mail address: nafari@ucsd.edu (N. Afari).

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increase the likelihood of passing the PFA. Among 313,513 Navy personnel who underwent the PFA in the first half of 2012, the overall BCA failure rate was 2.2% (2.0% for men, 3.4% for women) with substantially higher failure rates among those with higher BMI [2]. Within the Naval Medical Center San Diego (NMCSD), the PFA failure rate per cycle in years 2013–2014 was 4% (128 sailors on average), with the majority of failures resulting from BCA noncompliance [6]. There is a need for effective and easily deployable interventions to boost weight management and fitness efforts, increase the likelihood of passing the PFA, and help retain a valued and highly trained military force that can meet all mission demands.

The U.S. Navy has implemented the ShipShape (SS) program for addressing inadequate weight and physical fitness in military personnel. SS is an evidence-based weight management program that promotes healthy weight loss through nutritional, behavioral, and exercise education. The latest statistics available from January–June 2013 on SS across the country indicate that of the 393 sailors enrolled, 297 completed the program (76%), and only 45% of completers met the BCA component of PFA standards at 6-month follow-up [6]. We propose that SS falls short on meeting its goals because it does not adequately address underlying behavioral, psychological, and emotional barriers that influence problematic eating and poor exercise habits. Enhancing SS with novel strategies to address these barriers can close the current gaps in this intervention.

Acceptance and commitment therapy (ACT) is a *trans*-diagnostic cognitive-behavioral therapy that is designed to increase psychological flexibility, or the ability to behave consistently with one's values even in the face of unwanted thoughts, feelings, and bodily sensations [7]. ACT conceptualizes that many psychological and behavioral problems occur as a result of experiential avoidance, or an unwillingness to experience unwanted internal events (e.g., thoughts, emotions, memories, body sensations, etc.) and attempts to reduce the form, frequency, or situational sensitivity of these events [7]. Because ACT is based on the theory that negative internal events are an unavoidable aspect of the human condition, the intervention addresses thoughts, emotions, memories and bodily sensations by mindfully attending to and living with these experiences [8]. Intervention according to the ACT model typically consists of three components: a) awareness and nonjudgmental acceptance of all experiences, both negative and positive; b) identification of valued life directions; and c) appropriate action toward goals that support those values [8]. Building skills in these areas increase psychological flexibility (versus experiential avoidance).

Consistent with its *trans*-diagnostic approach, ACT has been successfully applied to a broad range of conditions in over 100 randomized controlled trials [9]. Specific to the aims of this study, ACT studies in the general population show improvements in weight, physical activity, problematic eating, quality of life, and psychological functioning [10–15]. Incorporating ACT into a 12-week behavioral weight management program contributed to weight loss and improved quality of life, and these changes were correlated with ACT constructs [10]. A 4-week ACT plus weight management protocol showed significant BMI reductions, increases in physical activity, and decreases in binge eating for those who reported using the strategies [12]. Compared to standard behavioral treatment, ACT resulted in greater weight loss with the best results found in participants who had more depression, disinhibition, and responsiveness to food cues at baseline [14]. Similarly, individuals who responded strongly to food cues found ACT strategies to be more effective at reducing eating and cravings compared to other psychological techniques [15]. Other studies have shown that ACT strategies reduce believability and distress associated with thoughts like “I'm fat” [16]. Even a brief, 1-day ACT workshop provided to participants that recently completed a weight loss program was shown to significantly impact outcomes at 3-month follow-up, including improvements in weight management, weight stigma, and quality of life with large effect sizes [11]. Thus, there is growing evidence for the benefits of ACT in weight- and fitness-related problems.

One solution to improving weight and fitness in the Navy's SS program is to incorporate ACT to: 1) promote mindful awareness of present moment experiences; 2) decrease experiential avoidance related to poor dietary choices and physical inactivity; and 3) support behavior change consistent with personal values. In this way, ACT can enhance the adherence to the dietary (e.g., portion control, meal preparation, weight loss tracking, behavioral weight loss techniques, stress and eating), and physical activity (e.g., Navy Operational Fitness and Fueling System, education on evidence-based physical activity guidelines) recommendations of SS to improve weight- and fitness-related outcomes. This paper describes the design, interventions, assessments, and analytic plan of a cohort-randomized controlled trial examining the effectiveness of ACT-enhanced SS (ACT + SS) compared to standard SS-only for Navy personnel.

2. Methods

2.1. Scientific aims and hypotheses

2.1.1. Aim 1

The primary aim is to examine the effectiveness of ACT + SS compared to standard SS-only in active duty service members at posttreatment (primary endpoint) and 3- and 6-months follow-up (secondary endpoints).

Hypothesis 1a. Participants in ACT + SS will experience significantly more weight loss (primary outcome) at posttreatment compared to those in SS-only.

Hypothesis 1b. Participants in ACT + SS will experience significantly greater improvements on secondary outcomes, including BMI, body fat %, self-reported BCA results, subjective indices of physical activity, problematic eating, and quality of life at posttreatment compared to those in the SS-only condition. An exception to time point of assessment are subjective indices of physical activity and self-reported BCA, which are collected at baseline and 6-month follow-up only.

Hypothesis 1c. Participants in ACT + SS will experience significantly greater improvements in objective measures of physical activity (i.e., actigraphy) at 6-month follow-up compared to those in the SS-only condition.

2.1.2. Aim 2

The second aim is to examine psychological flexibility as a mechanism underlying intervention response.

Hypothesis 2. Changes in psychological flexibility will mediate intervention response on outcomes of interest.

2.1.3. Aim 3

The third aim is to explore potential moderators of intervention response between and within groups. This will include sociodemographic variables (e.g., gender or marital status), weekly intervention attendance rates, weight loss readiness, and baseline distress factors.

2.2. Study design and timeline

2.2.1. Study design

This is a cohort-randomized controlled trial of ACT + SS compared to the standard SS-only program. The trial is pragmatically incorporated into the Health and Wellness Department of NMCSD where SS is provided as the main approach to addressing weight and fitness for service members who fail or are at risk of failing the PFA. Interested and eligible active duty service members who are referred to the SS program at NMCSD due to failing or being at risk of failing the PFA are cohort-randomized to receive 8 weekly ACT + SS intervention groups or 8

weekly standard SS-only intervention groups. As with the standard SS program, participants complete the 8-week series of classes in cohorts of 10–15 participants with 6–8 cohorts per year. A computer generated randomization schedule has been developed prior to the start of the data collection by the study statistician, and each cohort is randomly assigned to ACT + SS or SS-only with equal probability.

Initially, BCA pass/fail rate at 6-month follow-up was proposed as the primary outcome, given its immediate relevance to the military. However, in early 2016 prior to initiation of data collection, the Navy's PFA requirements were changed to incentivize sailors to meet standards for weight control and fitness through a variety of options. As a result of these changes, the BCA pass/fail rate was no longer the optimal outcome. In consultation with the Navy Marine Corps Public Health Center, the NMCSD Health and Wellness Department, the study DSMP Safety Officer, and the study statistician (S.G.), the primary outcome was changed to weight (loss). Weight is directly relevant to the Navy's BCA and also is typically the primary outcome in intervention trials of overweight and obesity. Therefore, weight as the primary outcome also has the added benefit of allowing comparison of this study to previous studies.

We have purposefully designed a cohort-randomized trial with interventions that are pragmatically implemented in a real-life military setting, and outcomes that are immediately relevant to service members and leadership. Cohort randomization is necessary because it fits with the current structure of the standard SS program at NMCSD and therefore is essential to the feasibility and acceptability of the research in this setting. The military-relevant and generalizable findings are more likely to have expeditious impact within the military. SS provides an ideal comparison arm that is the current standard of practice in the Navy. Integrating ACT with SS in this setting overcomes many of the logistical, practical, chain-of-command, and other challenges that have typically impeded the roll out of research throughout the military. The primary and secondary outcomes are theoretically linked, and additional assessments are empirically-based and will allow us to better understand mediators and moderators of intervention response in active duty service members. The overall study design is in Fig. 1.

2.2.2. Timeline

Conducting research with active duty service members and in a military context has many challenges [17] and few randomized clinical trials rely solely on active duty study participants [18]. Challenges include but are not limited to onerous regulatory and data sharing processes, need to obtain ongoing support from department heads due frequent leadership changes, and limits to what is possible for recruitment and retention of participants due to rules and regulation, clinic flow, frequent changes in duty station, deployments, assignments, and retirement. Therefore, feasibility and successful completion of this study requires flexibility and research and clinical staff across multiple institutions (NMCSD, VA San Diego Healthcare System, University of California, San Diego (UCSD), and Naval Center for Combat & Operational Stress Control) that collaborate extensively but have clearly delineated responsibilities. A substantial initial hurdle that impacted the timeline of the study was obtaining regulatory approval for the study across two institutions. Once institution-specific research responsibilities were clearly delineated, two separate IRB protocols were approved by each institution (NMCSD and VA San Diego Healthcare System). This process took approximately 1.5 years from initial funding in June 2016. Recruitment and enrollment began in January 2018 and is anticipated to end in November 2020, with final 6-month assessments completed in May 2021.

2.3. Participants and recruitment

Active duty service members who are obese or overweight, or whom have failed or at risk of failing the PFA are referred to the SS program at NMCSD. Being at risk of failing the PFA is determined by the Navy's

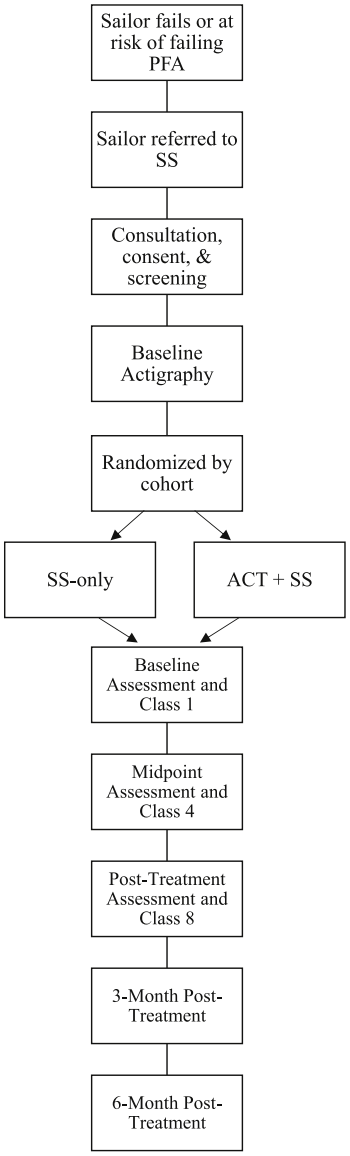

Fig. 1. Randomized controlled trial design.
Note: PFA = Physical Fitness Assessment; SS = ShipShape; ACT = Acceptance and Commitment Therapy.

Command Fitness Leaders, who help ensure overall fitness and readiness of Sailors. Service members who are not obese or overweight would likely not fail the BCA component of the PFA; however, they may still fail or be at risk of failing the PRT component (e.g., push-ups, curl-ups, and a 1.5 mile run), and thus may be referred to the SS program. All active duty service members who are eligible for participation in the NMCSD SS program are eligible for participation in the study. The only exclusion criteria for study participation are pregnancy or physical limitations (e.g., injury) that preclude engagement in the physical fitness recommendations of SS.

The SS program is advertised throughout NMCSD through the facility intranet page, banners and flyers at various locations, and attendance of the SS coordinator at fitness enhancement briefs. The study is advertised online and in the local community at sites frequented by active duty service members. Participants are self-referred, referred by their Command Fitness Leaders or Associate Command Fitness Leaders, medical providers, and word of mouth. Interested participants meet with the SS coordinator for screening and consent. Separate consenting for the study is conducted by a study coordinator.

Table 1
Treatment protocols.

	NMCSD ShipShape Content	ACT Enhancements
All Classes	- Weekly Action Plan - Action Plan check-in	- Mindfulness exercise - Orientation to the ACT matrix
Class 1	- Motivation - Weight management tacking methods - Hunger and satiety signals - Introduction to NOFFS	- Introduction to ACT matrix - Introduction to mindfulness - Values and values-congruent ("toward") and values-incongruent ("away") action
Class 2	- Nutrition education - Portion control - Building healthy habits	- Values clarification - Cost-benefit analysis of "away" moves - Determining "toward" moves (workability)
Class 3	- Meal preparation - Kitchen essentials - Food log	- The limitations of control - Acceptance as an alternative to control
Class 4	- Stress management - Relaxation - Sleep education	- Buying into vs observing thoughts - Identifying with a transcendent self
Class 5	- Time management - Weight loss management and progress check - NOFFS review	- Willingness to be with food urges and cravings - Noticing and distancing from thoughts during weight loss progress check
Class 6	- Cognitive distortions and restructuring* - Mindful eating - Social support	- Acceptance, distancing from thoughts, and values - Workability and emotional eating - Committing to values-congruent action
Class 7	- Educational video on obesity ("The Skinny on Obesity")	- Noticing and distancing from ongoing thoughts - Committing to values-congruent action
Class 8	- Maintaining motivation - Weight loss progress and results - Intuitive eating - Long-term maintenance	- Acceptance, distancing from thoughts, and values - Workability and long-term commitment to health

* Not covered in ACT + SS protocol.
Note: NMCSD = Naval Medical Center San Diego; ACT = Acceptance and Commitment Therapy; NOFFS = Navy Operational Fitness and Fueling System.

2.4. Interventions

2.4.1. Standard ShipShape

The standard SS-only protocol at NMCSD (Table 1) is delivered in eight 2-h weekly group sessions. The materials and format of the SS-only protocol are based on guidelines from the Navy and Marine Corps Public Health Center. These include: a) education for nutrition and physical activity; b) creating and documenting goals for weight loss and physical fitness; c) a food diary to track eating habits throughout the program; d) developing behavioral strategies to initiate/maintain an exercise program; e) monitoring of physical activity; and f) identifying and overcoming personal triggers for overeating. Homework is assigned to practice the materials and tasks discussed in class.

2.4.2. ACT-enhanced ShipShape

The ACT + SS intervention (Table 1) is also delivered in eight 2-h weekly group sessions. In developing this protocol, we extensively reviewed the 6-h workshop protocol by Lillis and colleauges [11] that was focused on weight loss maintenance as the primary outcome, and the 4-session protocol by Tapper and colleauges [12] that measured weight loss and binge eating, as well as other acceptance-based protocols for problematic eating, obesity, and diabetes [10,13–15,19]. The ACT + SS protocol integrates ACT concepts and strategies within the standard SS protocol. The ACT components focus on: a) thoughts, feelings, and bodily sensations that are often present in the context of efforts to lose weight or improve fitness; b) limitations of previous efforts to control or eliminate negative thoughts or emotions, stress, or food cravings; c) changing expectations and goals from elimination of stress or cravings to living as well as possible with such feelings; d) mindfulness exercises to increase awareness of experiences; and e) identification of personal values and setting and pursuing values-consistent goals in order to achieve improved quality of life.

The major components of the standard SS-only protocol are all represented in the ACT + SS protocol. The ACT material within a given ACT + SS class typically ranges from 10 to 40 min within the 2-h class. Some of the ACT material is integrated within the SS content (e.g., integrating values into the discussion of motivation to lose weight), while some ACT material stands alone. To accommodate the stand-alone ACT material, some contents of the SS-only protocol (e.g., nutrition information) are covered in less detail in the ACT + SS protocol. However, participants in both treatments receive similar information in their handouts. Class 6 is where the two protocols differ significantly. For this session the SS-only protocol contains information that is considered contradictory to the philosophy behind ACT, including a focus on recognizing negative thoughts, challenging these thoughts, and replacing them with more adaptive thoughts. In contrast, class 6 of the ACT + SS protocol focuses on teaching strategies to notice and distance from thoughts, accept negative thoughts without struggle, and move in a valued direction regardless of the presence of negative thoughts.

In the ACT + SS protocol, participants are first introduced to a simple tool to help explain the ACT model called the Matrix [20]. Briefly, the Matrix classifies behavior as "toward" moves (i.e., values-consistent behaviors) vs. "away" moves (i.e., avoidance behaviors). Group members then discuss their challenging internal experiences (thoughts, feelings, memories, bodily sensations) related to diet and exercise, strategies they have used to control or avoid these internal experiences, and the ultimate outcome of these strategies (i.e., if they helped move towards or away from values). In subsequent sessions, various metaphors and experiential exercises are used to help participants skillfully respond to internal experiences in order to facilitate "toward" moves. As an example, if a participant values health, yet the experience of embarrassment prevents them from exercising at the gym, an in-session experiential exercise such as the 'tug-of-war' [8], covered in session 3, would promote acceptance of the feeling of embarrassment such that it no longer functions as a barrier to exercising at the gym. Homework to develop the skills taught is also stressed.

2.5. Study measures

Assessment focuses on domains that are typically measured in weight management and fitness trials or implicated as important factors in weight management. Some measures are expected to be affected by

Table 2
Schedule of assessments for addressing study aims.

	Screen	Baseline (week 1)	Mid (week 4)	Post (week 8)	3-Mo Post	6-Mo Post
Aim 1						
Hypothesis 1a						
Weight		x	x	x	x	x
Hypothesis 1b						
Other weight-related variables						
BMI		x	x	x	x	x
Body fat %		x	x	x	x	x
Self-reported BCA results		x				x
Subjective physical activity						
IPAQ		x				x
Problematic eating						
TFEQ		x	x	x	x	x
Quality of life						
SWLS		x	x	x	x	x
SF-12 (1st question only)		x	x	x	x	x
Hypothesis 1c						
Actigraphy		x				x
Aim 2						
Hypothesis 2						
Psychological flexibility						
AAQ-W		x	x	x	x	x
Comp-ACT		x	x	x	x	x
Aim 3						
Exploratory Moderators						
Demographics	x					
Attendance (weekly)		x	x	x		
Medical history	x					x
PSS-4		x	x	x	x	x
PHQ-4		x	x	x	x	x
PC-PTSD		x	x	x	x	x
WLRT-II	x					
Weight loss motivation/ confidence		x	x	x	x	x

Note: BMI = body mass index; BCA = Body Composition Assessment; IPAQ = International Physical Activity Questionnaire; TFEQ = Three Factor Eating Questionnaire; SWLS = Satisfaction With Life Scale; SF-12 = 12-Item Short Form Health Survey; AAQ-W = Acceptance and Action Questionnaire for Weight-Related Difficulties; Comp-ACT = Comprehensive assessment of Acceptance and Commitment Therapy processes; PSS-4 = Perceived Stress Scale; PHQ-4 = Patient Health Questionnaire for Depression and Anxiety; PC-PTSD = Primary Care Screen for Posttraumatic Stress Disorder; WLRT-II = Weight Loss Readiness Test.

the interventions and are considered outcomes, while others are included to describe the sample, control for any potential baseline differences between groups, and explore as potential personal or health-related moderators of intervention effect. Table 2 provides a detailed view of measures used to address study aims and the time point at which each measure is administered. The entire battery of questionnaires takes approximately 30 min to complete. Participants are compensated for their time and effort in completing and returning the 3-month ($30 gift card) and 6-month ($50 gift card) follow-up assessment packets that are mailed to them and completed at home or competed over the phone.

2.5.1. Sociodemographics and weight

Sociodemographic and service history information by self-report is used to characterize participants and to explore personal characteristics as potential moderators of intervention response. These include: age, gender, race/ethnicity, relationship status, years of education, income, living situation (e.g., on-base, off-base), occupation/duty assignment (e.g., technician, corpsman), work status (e.g., full duty, limited duty, medical board), current military rank (e.g., petty officer, commander), number and location of deployments, and combat exposure. Examinations at baseline and each assessment time point obtain weight and body fat %. Height is obtained at baseline in order to calculate BMI for each time point. Further, self-reported BCA results are examined at baseline and 6-months post-intervention to measure changes in pass/fail rates.

2.5.2. Medical history

Medical history is obtained via self-report at the screening assessment and 6-months follow-up to determine medical and mental health diagnoses, use of health services, including pharmacotherapy (e.g., psychotropic or weight loss), psychotherapy, complementary and alternative approaches, and hospitalization. This information is used to describe the participants and as potential covariates.

2.5.3. Physical activity

The International Physical Activity Questionnaire (IPAQ) is used as a self-report subjective measure of physical activity. This survey was developed to obtain comparable estimates of physical activity cross-nationally, and has been shown to be a valid and reliable method for measuring physical activity in diverse settings [21]. The short form is used in this study at baseline and 6-month follow-up to measure levels of activity in the seven days leading up to completion of the questionnaire. IPAQ outcomes include 3 measures including vigorous and moderate physical activity, light activity (e.g., walking), and sitting.

Actigraph accelerometers (ActiGraph GT9X Link) are used to objectively measure the duration, frequency, and intensity of physical activity [22] to address Hypothesis 1c. The unobtrusive activity monitor is worn around the non-dominant wrist to continuously measure physical activity and sleep. The small size makes it acceptable for most users because it does not interfere with movement or clothing. The Actigraph has excellent validity for quantifying activity levels in laboratory and field settings [23], and has been used extensively by the research team. No difficulties have been reported with the procedure and compliance has been greater than 90%. For this study, data are collected for two 1-week periods at baseline and 6-month follow-up.

2.5.4. Problematic eating

The Three Factor Eating Questionnaire-R18 (TFEQ-R18) is a shortened version of the 51-item survey developed by Stunkard and Messick in 1985 [24]. It measures three aspects of eating behavior including cognitive restraint, uncontrolled eating, and emotional eating. It has been shown to be a valid method of distinguishing among different eating behaviors [25].

2.5.5. Quality of life

The Satisfaction with Life Scale (SWLS) was developed to assess whole life satisfaction by measuring subjective well-being, including feeling that one's life is close to ideal and contentment in what one has achieved [26]. It is a short, 5-question survey that has been shown to be a valid and reliable measure of overall subjective quality of life [27]. In addition to the SWLS, the first question of the SF-12, a short-form scale that assesses general health, is used to determine the subject's perception of their overall health ranging from poor to excellent [28].

2.5.6. Psychological flexibility

The Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQ-W) is a 20-item questionnaire developed to measure experiential avoidance of thoughts related to food as control, weight as a barrier to living, and weight-stigma [29]. The AAQW has been shown

to be sensitive to changes in attitudes around weight that occur during a targeted ACT intervention [30]. In addition, the Comprehensive Assessment of ACT Processes (Comp-ACT) is used as a measure of general psychological flexibility. This questionnaire was designed to fit with the ACT model and has been shown to correlate with wellbeing and distress measures [31].

2.5.7. Emotional distress and other potential moderators

Given the rates of emotional distress and posttraumatic stress symptoms in service members [32] and the interaction of these symptoms with weight management [33], it is important to understand the level of such symptoms in our sample. The Percieved Stress Scale (PSS-4) is a 4-question self-report survey used to measure the degree to which situations in life are considered stressful [34]. The Patient Health Questionnaire for Depression and Anxiety (PHQ-4) is a brief, 4-question screener for depression and anxiety [35]. The Primary Care Screen for PTSD (PC-PTSD) is a brief, self-report measure of distress related to posttraumatic stress symptoms [36]. Together these measures will aid us in determining emotional distress at each assessment time point. In addition, the Weight Loss Readiness Test-II (WLRT-II), a 27-item questionnaire that measures six factors related to readiness: motivation, expectations, confidence, hunger and eating cues, binge eating and purging, and emotional eating [37], is administered at screening as part of standard NMCSD procedures. Two items from the WLRT-II are administered at all 5 assessment points to assess changes in weight loss motivation and confidence.

2.5.8. Expectancy and satisfaction

Expectancy after the first intervention session is measured with the Credibility and Expectations for Improvement scale (CEI) which is designed to assess how logical the intervention seems and how much the participant expects to benefit from it [38]. Satisfaction after the completion of the intervention is measured with the Client Satisfaction Questionnaire (CSQ), a widely used measure of satisfaction with physical and mental health treatment [39].

2.6. Sample size and power

Due to the change in the primary outcome from a dichotomous (pass/fail) to a continuous outcome (weight), the initial assumptions underlying power analyses were no longer valid and sample size had to be re-calculated prior to initiation of recruitment. For continuous outcomes of Aim 1, power was estimated using methods for mixed effects models [40]. Previous studies of ACT for weight management suggest medium effect sizes (i.e., Cohen's d of 0.5) for between group differences. Using this effect size and an estimated dropout rate of 20%, we have a minimum of 80% power at $p = 0.05$ with a sample size of 160 participants for all continuous outcomes. For the dichotomous secondary outcome, the sample size of 160 will provide us with minimum 80% power to detect a 15–20% difference in PFA pass/fail status (Power Analysis and Sample Size Software 13; NCSS, Inc.). We used the same method used for Aim 1 to estimate power for Aim 2. Indices of psychological flexibility will be added to the linear mixed models. Because this method only includes adding an additional covariate into the model, a sample size of 160 still provides 80% power to address Aim 2. Due to the exploratory nature of Aim 3, power estimates are not calculated for this aim.

2.7. Analytic plan

Preliminary analyses will examine the distribution of variables to assess their characteristics, provide descriptive statistics, and allow assessment of randomization. Continuous measures will be tested for normality and homogeneity of variance. Non-normally distributed variables will be transformed as necessary. Preliminary analyses will also determine if there are any participants who are not considered obese or overweight. Randomization will be tested by performing a series of Analyses of Variance (ANOVA) and chi-square tests to compare groups on demographic and initial clinical variables. Any variables on which the groups differ initially may be used as covariates in subsequent analyses. Because of cohort randomization, intra-class correlation (ICC) within cohorts will be examined for each cohort [41]. ICC in the medical literature typically ranges from 0 to 0.1 [42], and we do not expect ICC larger than 0.05 based on prior research [43]. CSQ and CEI ratings will be compared between groups using ANOVA or a non-parametric test if the variables are not normally distributed, and these ratings may be used as covariates. Due to multiple testing for secondary outcomes under Hypothesis 1b, type I error rate will be corrected for each of the four outcome domains (see Table 2) using the Bonferroni procedure. Each domain contains either two or three outcomes (either full scale or subscales); thus adjusted alpha level for Hypothesis 1b will be either 0.025 or 0.017, respectively. Hypothesis 1a and Hypothesis 1c each contain only one outcome, and therefore requires no alpha level adjustment. Primary analyses will be conducted with data from all randomized participants; sensitivity analyses will be conducted excluding participants who are not considered obese or overweight, if necessary. SPSS release 25 (IBM, Inc.), SAS 9.4 (SAS Institute, Inc.), and Mplus version 4.0 will be used for these analyses. Results will be reported according to the recommended CONSORT guidelines.

2.7.1. Aim 1

The analytic strategy for the primary (Hypothesis 1a) and continuous secondary outcomes (Hypothesis 1b) is the same, using linear mixed-effects models to examine treatment differences. This method allows us to account for all levels of clustering (e.g., cohort and assessment time). Further, because linear mixed-effects modeling retains all participants regardless of missing data, no imputation procedures are required to handle missing data. The main effect of cohort and intervention-by-cohort interaction will be included and tested as "nuisance parameters," which will be removed from final models if found to be non-significant. The model will include a random effect for assessment time, fixed effects for intervention and intervention-by-time interaction and a random intercept. A fully saturated intervention-by-time model will be used for inference. Akaikes Information Criterion will be used to choose co-variance structure. For the primary comparison, the first three time points (baseline, mid-point and end of treatment) will be included to evaluate the main effect of the treatment on weight as the primary outcome as well as the secondary outcomes. These analyses will be followed by testing the long term effect of treatment by comparing baseline with 3-months and 6-months follow-up on weight (and secondary outcomes). For self-reported BCA results at 6-month follow-up, mixed-effects models for binary or count outcome data will be used [44]. Because the timing of the official BCA might vary in relation to the completion of interventions, the time from intervention completion to date of official BCA will be examined and used as a covariate in analyses if necessary. For Hypothesis 1c, the objective physical activity outcome is the average daily minutes of physical activity for the seven days of actigraphy at baseline and 6-month follow-up. In this random effects model, the average minutes of activity per day during the two time points will be nested within a participant; intervention, time, and the intervention-by-time interaction will be added as fixed effects, and cohort and cohort-by-intervention interaction will be added as random effects.

2.7.2. Aim 2

To address aim 2, the AAQ-W and Comp-ACT as indicators of psychological flexibility are obtained at all five time points. We anticipate that increases in psychological flexibility will be related to improvement in outcomes among those receiving ACT + SS. Mediators are intervening variables that are necessary to complete a cause-effect pathway between an intervention and an outcome [45]. We will build longitudinal mediation models as specified by Kraemer and colleagues

[46]. First, we will test the effect of group and the group-by-time interaction on the mediator; we expect a statistically significant group-by-time interaction. Second, we will test the effects of AAQ-W/Comp-ACT change-by-group interaction on the outcome in the model that includes group and time; we expect a statistically significant AAQ-W/Comp-ACT change-by-group-by-time interaction.

2.7.3. Aim 3

The limited research on obesity in military personnel suggests that sociodemographic (e.g., gender or marital status) and baseline distress factors may be fruitful to explore as potential moderators [47–49]. We also will explore other potential moderators, such as weekly attendance rates, medical history, and motivation level. A series of exploratory linear mixed-effects models will be used to explore moderator-by-time and moderator-by-group-by-time effects.

3. Discussion

This study is designed to examine whether an ACT-enhanced intervention to improve weight- and fitness-related outcomes is more effective than the Navy's existing weight-management program. Improvement in weight and physical fitness among U.S. Navy Service Members has the potential to increase military readiness, resilience, and overall wellbeing. This study has several unique features: 1) this is the first study to use an ACT-enhanced intervention for weight management with an active duty population; 2) the pragmatic, cohort-randomized nature of the study allows us to compare SS-only and ACT + SS in a real world setting, increasing its generalizability; and 3) the study brings together investigators and clinicians across multiple institutions to address an important topic relevant to the U.S. military.

We have developed a novel ACT intervention protocol that incorporates ACT principles and strategies with standard SS strategies that are designed to address the specific needs of active duty personnel. ACT focuses on facing challenging situations in accordance with one's values, which is consistent with the military's culture and core principles that help service members remain resilient when confronted with the challenges associated with combat, operations, and training. A burgeoning theoretical and empirical literature supports using ACT within military populations [50]. For example, ACT-consistent strategies have been used to enhance the performance of military personnel by promoting focused attention to performance tasks and values-driven commitment to behaviors that support operational goals [51]. Further, a brief ACT intervention used as resiliency training in Navy submariners pre-deployment found better task performance and engagement in valued behavior compared to matched controls who did not receive ACT [52].

This growing area of research highlights the potential relevance of ACT to active duty personnel and further supports the use of ACT to improve health behaviors and weight management in service members. As the newest wave in cognitive-behavioral strategies, ACT offers a *trans*-diagnostic psychosocial approach that involves acceptance of stressful experiences, negative thoughts, and emotions in order to increase values-based action that can be readily applied to weight management and physical activity. ACT incorporates a distinctive values component to help individuals explore their sense of life meaning and purpose. Values provide an ongoing guide for actions and a powerful mechanism for behavior change that is consistent with the military's core principles. For instance, illuminating the value of commitment to military duty and staying fit and healthy is critical to achieving peak performance and may incentivize healthier eating and exercise choices to optimally perform in line with this value.

This study is also designed specifically for ideal integration within a real-world Navy setting, making the findings immediately relevant to active duty personnel struggling with weight management. The pragmatic approach to incorporate a randomized clinical trial into the Health and Wellness Department of NMCSD where SS is provided allows us to reach a much broader and more diverse population of individuals. Further, the unique cohort randomization design ensures the study does not disrupt the flow of Navy personnel entering this program. The design is also more suitable due to challenges in recruitment and follow up assessment that may result when active duty participants are deployed or change duty stations as is common in this context. If successful, outcomes from this trial can inform the next steps in an evidence-based approach to weight management and physical fitness in the military.

There is an urgent need for innovative and easily deployable interventions that can boost the effectiveness of SS and similar official weight loss programs for active duty service members. Conducting randomized clinical trials in the military context to generate an evidence base for interventions specific to active duty is challenging. Our multidisciplinary study team of researchers and clinician across multiple institutions is uniquely situated to overcome these challenges and add to the scant literature on weight management in the military. Findings from this study can inform and define the future of evidence-based weight management and physical fitness programs within the military, and ultimately enhance the readiness of U.S. and international service members and the military at large.

Trial registration number

This trial was registered with ClinicalTrials.gov (NCT03029507).

Conflicts of interest

There are no conflicts of interest to declare.

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