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Weight loss among women and men in the ASPIRE-VA behavioral weight loss intervention trial

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STUDY IMPORTANCE:

- Because barriers to weight loss differ by sex, women Veterans may experience different weight loss outcomes with behavioral programs than do men Veterans.
- At 12 months after baseline, women in both group-based weight loss programs (the small-changes ASPIRE-Group program and the usual-care MOVE! program) lost weight.
- At 12 months after baseline, men in all three programs lost weight; they lost more weight weight with the ASPIRE-Group compared to the MOVE! program.
- Mixed-sex, group-based programs can result in weight loss for both women and men Veterans.

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Objective:

To examine weight loss among women and men Veterans in a clinical trial comparing ASPIRE, a "small changes" weight-loss program using either mixed-sex group-visit or telephone-based coaching, to MOVE![®], the usual mixed-sex group-based program.

Methods:

We used linear mixed-effects models to calculate adjusted percent weight change at 12 months by sex and compared outcomes across arms within sex.

Results:

Analyses included 72 women (ASPIRE-Phone = 26; ASPIRE-Group = 26; MOVE! = 20) and 409 men (ASPIRE-Phone = 136; ASPIRE-Group = 134; MOVE! = 139). At 12 months, women displayed significant weight loss from baseline in ASPIRE-Group (-2.6%) and MOVE! (-2.7%), but not ASPIRE-Phone (+0.2%). Between-arm differences in weight change among women were: ASPIRE-Group vs. ASPIRE-Phone, -2.8% (p=0.15); MOVE! vs. ASPIRE-Phone, -2.8% (p=0.20); and ASPIRE-Group vs. MOVE!, 0.0% (p=1.0). At 12 months, men lost significant weight from baseline across arms (ASPIRE-Phone, -1.5%; ASPIRE-Group, -2.5%; MOVE!, -1.0%). Between-arm differences in weight change among men were: ASPIRE-Group vs. ASPIRE-Phone, -0.9% (p=0.23); MOVE! vs. ASPIRE-Phone, +0.5% (p=0.76); ASPIRE-Group vs. MOVE!, -1.5% (p=0.03).

Conclusions:

Mixed-sex, group-based programs can result in weight loss for both women and men Veterans.



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Introduction

Despite the rigors of active duty service in the U.S. Armed Forces, the prevalence of overweight and obesity has continued to steadily increase over the past two decades among active duty personnel. Upon retirement, military personnel are particularly susceptible to significant increases in weight. Among Veterans who receive health care from the Veterans Health Administration (VHA), for example, nearly 78% are overweight or obese and 41% are obese.

To reduce the prevalence and long-term health consequences of overweight and obesity among Veterans, VHA developed MOVE![®], a nationally-implemented weight management program.^{4,5} Overall, participation in MOVE! is associated with clinically significant weight loss, but the impact of the program may differ by sex.⁶ In a study of MOVE! in four Western states, women Veterans were more likely than men Veterans to participate in MOVE!, but less likely to attain clinically meaningful weight loss.⁶

It is a clinical imperative to better understand what types of weight loss programs might best serve women Veterans receiving health care from VHA. The number of women using VHA services has nearly doubled in the last decade⁷, and women are projected to increase from 6.5% currently to over 14% of the VHA population by 2033. Although the prevalence of obesity is similar among women and men Veterans (21.2% and 22.2%, respectively), the prevalence of severe obesity (>=35.0 kg/m²) is higher among women Veterans compared to men Veterans (16.2% and 11.1%, respectively), representing a greater burden of disease among women. Furthermore, women Veterans have demonstrated interested in weight loss support through VHA. In a survey of women Veterans receiving behavioral health treatment in VHA, access to weight management programming was one of the top five health service priorities identified, and

62% of respondents indicated they were extremely likely to use this kind of service within the following six months.¹⁰

The literature suggests that barriers to weight loss among women and men differ, which may mean that different types of weight loss programs may be needed for women and men Veterans. For example, women Veterans are much more likely than men Veterans to have experienced military sexual trauma¹¹, which may undermine their willingness to join a mixed-sex, group-format weight loss program comprising mostly men.¹⁰ Anxiety is more common and regular exercise less common among women Veterans compared to men¹², representing additional differences in barriers to weight loss.

Studies among the general population describe additional ways in which weight-loss barriers differ between women and men. Women have more significant childcare and eldercare responsibilities compared to men; such responsibilities may represent competing priorities with self-care, and limit the time and energy available for weight loss efforts. Additionally, women with obesity have an inaccurately low perception of cardiovascular disease risk and worse self-reported mental health than do men with obesity. These factors may reduce interest in engaging or succeeding in any type of weight management efforts.

We conducted a secondary analysis of data collected from the ASPIRE-VA trial to understand weight loss outcomes among women and men at 12 months based on assignment to one of three types of behavioral weight loss programs. ASPIRE-VA was a pragmatic, randomized, controlled study that evaluated whether a "small-changes" weight-loss approach, using either group-visit or individual telephone-based coaching, could help Veterans who were overweight or obese lose significantly more weight over a 12-month period compared to the usual MOVE! weight-loss program. We previously reported that participants in all three arms

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of the ASPIRE-VA trial lost significant weight at 12 months. Those in ASPIRE-Group lost significantly more weight than those in the other two treatment arms (-2.8 kg ASPIRE-Group vs. -1.4 kg, p = 0.04 for both ASPIRE-Phone and MOVE!). ¹⁶

Methods

ASPIRE-VA compared three behavioral weight loss programs for Veterans, and has been described in detail elsewhere. Two of the programs were based on the ASPIRE (Aspiring for Lifelong Health) program, which used a small-changes approach that encouraged individuals to make small but cumulative changes in nutrition and physical activity. It was hypothesized that small changes could yield slower but more sustained weight loss compared to traditional behavioral treatments. Specifically, small changes were thought to reduce risk of weight gain over time by decreasing feelings of deprivation and satiation typically experienced with low-calorie diets. Tr,18

ASPIRE-VA was a pragmatic clinical trial¹⁹ which aimed to establish the effectiveness of the small-changes approach under "usual" conditions compared to the national referral process and weight loss program offered at all VHA facilities. This national program, MOVE!, was selected as the control arm for the study. Program specifications for MOVE! follow evidence-based clinical practice guidelines for obesity treatment disseminated by the VHA and the Department of Defense. ^{20,21} However, sites vary considerably in guideline implementation with respect to the design and delivery of programming, which has been attributed to local contextual constraints and priorities. ²¹

Veterans were randomized to one of three interventions: ASPIRE delivered individually via telephone (ASPIRE-Phone), ASPIRE delivered via in-person mixed-sex groups (ASPIRE-

Group), or the usual-care weight-loss program MOVE!, delivered via mixed-sex in-person groups. In both ASPIRE-Group and MOVE!, the majority of participants were men. Written informed consent was obtained from all participants. IRBs at both study sites approved all procedures.

STUDY SETTING AND POPULATION

ASPIRE-VA enrolled participants from two Midwestern VA medical centers. Eligible Veterans were men and women referred to the MOVE! program (body mass index (BMI) > 30 kg/m² or a BMI between 25-30 kg/m² with at least one obesity-related chronic health condition, without contraindications for weight loss). We excluded individuals already enrolled in a weight-loss study, receiving weight-loss treatment, or who were pregnant.

INTERVENTION

ASPIRE small-changes approach

The two ASPIRE programs (phone and group) used a small-changes approach. Rather than prescribing a pre-set goal such a daily calorie target²², the small-changes approach encouraged participants to set personalized goals for weight loss that were feasible within an individual's life context.²³⁻²⁵ Goals were designed to achieve a modest daily caloric deficit (100-200 fewer calories) through increased physical activity and modifications to eating patterns that were attainable and self-reinforcing.²⁶ Logbooks were provided to track food intake and pedometers were provided to track daily step count. Diet choices were guided by a modified Stoplight Food Guide, which categorized foods as "Green", "Yellow" and "Red" without having to count calories.²⁷ The small changes are designed to be cumulative over time, yielding slower but

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longer-term weight loss that is more likely to be maintained given participants' enhanced sense of self-efficacy and mastery of self-regulatory lifestyle habits. Both ASPIRE-Phone and ASPIRE-Group sessions were led by a trained Lifestyle Coach.

Lifestyle Coaches were non-clinicians with strong interpersonal skills and at least a bachelor's degree, but no psychology, behavior change, or coaching experience. Coaches attended a three-day in-person training workshop, and received ongoing continuing education and supervision in one-on-one, group and peer formats. Every six months the Coaches had inperson booster training sessions.

ASPIRE was a manualized intervention in which the Coach sought to elicit active engagement and discussion with participants regarding key self-regulatory topics and skills based on social cognitive theory³, problem-solving therapy²⁸, and motivational interviewing.²⁹ Sessions encouraged participants to receive feedback and support on self-monitored progress toward personal goal attainment. Those in ASPIRE-Group typically met in small groups with 5-8 participants and the Lifestyle Coach at prescheduled times at the medical center. These groups were closed to new participants after the program began. ASPIRE-Phone participants had individual phone calls with the Lifestyle Coach arranged at mutually convenient times.

ASPIRE-Group sessions were weekly for 90 minutes in the active treatment phase of the first 3 months. The maintenance phase in months 4-12 comprised bi-weekly 60-minute sessions for 6 months, and then monthly 60-minute sessions for the next 3 months. The total treatment dose was 33 hours. ASPIRE-Phone sessions were up to 30 minutes in the first 3 months and 20 minutes in the maintenance phase, for a total treatment dose of 11 hours. The small-changes intervention approach remained consistent over time.

MOVE! weight management program (control arm)

As noted, though national guidelines for MOVE! exist, local contextual features often determine specifics of the design and delivery of the program at individual sites. About three-quarters of MOVE sessions in VHA are delivered in group formats and MOVE! at our study sites were delivered predominantly via groups. Groups were open; new participants could join any time, though they were not included in our study sample. MOVE! provided individualized handouts on health behavior change topics, counseling and behavior modification support. Psychoeducation topics in MOVE! were discussed didactically. Sessions were led by an interdisciplinary group of providers, including dietitians, health psychologists, and physical therapists who rotated from session to session. A pedometer and an optional self-monitoring log were provided.

MOVE! participants were offered 90-minute 11-12 weekly sessions in the active treatment phase, during months 1-3. In the maintenance phase in months 4-12, both sites offered drop-in follow-up groups. Maintenance sessions in months 4-12 were 90 minutes every 3 months at one site, and 60 minutes every two weeks at the other site. Overall, Veterans in MOVE! were offered a total treatment dose of 22-35 hours. The intervention approach remained consistent over time.

DATA COLLECTION

Demographic and clinical data were collected at baseline. Medical diagnoses from medical records were used to compute the Charlson severity index.³⁰ At baseline, 3 months, and 12 months, we recorded anthropometric measures (height, weight, and waist circumference) and self-reported measures including a Food Frequency Questionnaire³¹, and downloaded pedometer

data. Satisfaction with the Lifestyle Coach/MOVE! leader was elicited via survey at 12 months. Questions included whether participants had confidence and trust in their Coach/leader (Yes, always; Yes, sometimes; No), the degree of Coach/leader courtesy (Excellent; Very Good; Good; Fair; Poor), whether participants were treated with respect (Yes, always; Yes, sometimes; No); and whether Coach/leader answers to the participant's questions were understandable (Yes, always; Yes, sometimes; No).

DATA ANALYSIS

Main Analysis: The primary outcome was percent weight change at 12 months. We used linear mixed-effects models to model weight at baseline, 3, and 12 months, using an intent-to-treat cohort of all enrolled participants (N=481). The models included each subject as a random intercept to adjust for within-patient correlation of the repeated measures and fixed predictors of sex, study arm indicators, 3- and 12-month time indicators, three way interactions of time by study arm by sex, and all lower two-way interactions. The summary measures were expressed as mean percent weight change (and its 95% confidence interval) at both 3 and 12 months for each sex by intervention group, estimated using predicted weights based on the model. Weights were compared across arms within sex at 3 and 12 months using appropriate interaction terms based on the model. Bonferroni correction was used to account for the three pairwise comparisons across study arms within each sex.

<u>Analyses of Secondary Outcomes:</u> We explored additional potential reasons for differences seen across arms in percent of weight lost among women and men. First, we calculated engagement as measured by the number of sessions completed by sex in each study arm, using ANOVA to

evaluate for differences across arms. Second, we examined differences in satisfaction with the Coach/MOVE! leader across the three programs using chi-square tests to generate a p-value for each question, by sex. Additional outcomes included diet and exercise measures, for which we calculated changes from baseline at 3 and 12 months for each arm by sex.

Results

481 Veterans were recruited and enrolled. There were 72 women (ASPIRE-Phone = 26; ASPIRE-Group = 26; MOVE! = 20) and 409 men (ASPIRE-Phone = 136; ASPIRE-Group = 134; MOVE!= 139) in the study sample (Table 1). Overall, women represented 15% of the sample. Compared to men, women were younger (46.5 vs. 56.5 years), more highly educated, had fewer comorbidities, and were more commonly depressed at baseline. Mean baseline weight was 99.3 kg among women and 115.4 kg among men. Of the 481 who were enrolled, 72 (15%) did not have any follow-up assessments at all over the study period. The remaining 409 participants (85%) had at either one or both follow-up assessments at 3 or 12 months.

Percent weight change

Table 2 shows the percent and absolute weight change in each study arm at 3 months and 12 months by sex based on the weight model. In Table 2, if the percent weight loss is negative and its 95% confidence interval does not include zero, it indicates significant weight loss from baseline. Figures 1 and 2 show the percent weight changes from baseline for women and for men, respectively.

At 3 months, women did not lose significant weight from baseline in any arm. At 12 months, women lost significant weight from baseline in ASPIRE-Group [-2.6% (-4.8%, -0.5%)]

and MOVE! [-2.7% (-5.2%, -0.1%)], but not in ASPIRE-Phone [+0.2% (-2.1%, +2.5%)]. The weight at 12 months did not vary across arms among women (p=0.14); though across-group difference was not significant, pairwise comparisons between groups are reported (Table 3).

Men lost statistically significant weight from baseline in all three study arms at both 3 months and 12 months. Weight loss at 12 months in the three arms was: ASPIRE-Phone [-1.5% (-2.4%, -0.7%)]; ASPIRE-Group [-2.5% (-3.3%, -1.7%)]; MOVE! [-1.0% (-1.8%, -0.2%)]. Percent weight loss differed across arms (p=0.04). In pairwise comparisons, the difference in weight change between ASPIRE-Group vs. MOVE! was significant (-1.5%, p = 0.03).

Secondary outcomes

Both women and men completed more sessions in the two ASPIRE programs than they did in MOVE! (Table 4). Differences across arms in sessions completed were significant among men (p < 0.001) but not among women (p = 0.21).

With respect to satisfaction measures (Table 5), women reported especially high confidence and trust in the Coach/leader and receiving understandable answers to important health questions for the ASPIRE programs compared to MOVE!. Diet and exercise measures were similar across the three programs among women and men (Table S1).

Discussion

Our findings, which examine weight loss outcomes separately among women and men, provide an important complement to the findings reported for the ASPIRE-VA study population as a whole. Those analyses included both women and men but did not examine weight loss outcomes by sex. In those analyses, Veterans lost weight in both ASPIRE programs, but not

MOVE!, at 3 months.¹⁶ At 12 months, Veterans lost weight from baseline in all three arms, with significantly greater weight loss in the ASPIRE-Group arm than in ASPIRE-Phone or MOVE!. In this study, we found that weight loss outcomes for men were similar to those in the overall analysis, except that at 3 months men lost weight in all three arms, and at 12 months, ASPIRE-Group was superior only to MOVE!.

The pattern of weight loss we observed among women contrasts with that reported among the ASPIRE-VA study population as a whole, and among men in our study. Women did not lose significant weight in any arm at 3 months. At 12 months, there was significant weight loss from baseline in both ASPIRE-Group and MOVE!, but not ASPIRE-Phone. There were not statistically significant differences across study arms, possibly due to the small number of women participants.

Better weight loss results for men with ASPIRE-Group as compared to MOVE! may be related to its small-changes approach. ASPIRE was initially designed predominantly for people who might be averse to traditional behavioral therapies emphasizing moderate to severe caloric restriction and "off-limit" foods. ASPIRE uses a "shaping" approach that is positive in its orientation to substitute obviously unhealthy behaviors with healthier choices that are acceptable and feasible within a Veteran's lifestyle relative to their current patterns. The coaching style of ASPIRE, which aimed to improve participants' sense of self-efficacy, may have been more effective than the more didactic psychoeducational approach used by MOVE! at the two study sites during the time of the ASPIRE-VA trial.

However, ASPIRE-Group and MOVE! differed in other ways that may explain the findings in men, including ASPIRE's smaller, closed group, expectation of self-monitoring, consistency of group leaders, and non-clinical group leaders. ASPIRE-Group may have provided

a more intensive and consistent experience, which facilitated better group cohesion and coachparticipant relationship satisfaction, leading in turn to better engagement as measured by sessions
completed, and subsequently greater weight loss. ^{16,32} While ASPIRE-Phone utilized the smallchanges approach, its individual, phone-based delivery mode, by design, did not have the
potential benefits accruing from having strong group cohesion. It needs to be noted that MOVE!
program guidance has been updated since the ASPIRE-VA trial and now encourages a more
interactive coaching approach, closed groups, and use of a consistent coach (see
www.move.va.gov).

We observed poor short-term (3-month) weight loss among women in each study arm. Recent studies of data from other behavioral weight-loss trials³³⁻³⁵ suggest that outcomes in the first few months predict clinically significant long-term weight loss. Clinically meaningful weight loss is important to reduce downstream problems from obesity-related morbidity and impairment. Women did lose weight in both group-based programs by 12 months, though, as among men, the modest percent of weight lost has limited clinical significance. Early weight loss may represent a promising target for future efforts to effectively treat obesity among women Veterans.

It is striking that women in the ASPIRE-Phone arm did not lose weight from baseline at either assessment point, despite similarly high levels of engagement and satisfaction in both ASPIRE arms. Given certain barriers to weight loss that are more common among women, such as caretaking responsibilities and military sexual trauma histories, we anticipated that women in ASPIRE-VA would engage better, be more satisfied, and lose more weight with individual phone calls as compared to prescheduled and mixed-sex (predominantly male) groups. However,

our findings, while not definitive, do not suggest any weight-loss benefit among women in a oneon-one phone-based program.

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In prior VHA research, women have reported a preference for sex-specific services for PTSD, depression, and coping with chronic medical conditions. ^{10,36,37} Our results suggest that sex-specific services for weight loss may not necessarily be a better approach than mixed-sex groups for women Veterans; our mixed-sex, group-based programs resulted in weight loss for both women and men Veterans. This outcome may be driven in part by the way the respective Coaches interacted with group participants e.g., by creating a safe environment for both sexes. Further research is needed to understand what attributes of Coaches or their interaction with groups contributes to equally positive weight outcomes. It may be that resources which would otherwise be spent on developing sex-specific weight loss services for women could be channeled instead into other sex-specific services with evidence of strong patient preference and/or demonstrably better clinical outcomes.

Limitations

This study is not without limitations. There were small numbers of women in each program and thus, the lack of significant differences for women must be interpreted with caution. While the low proportion of women in the ASPIRE-VA trial is slightly higher than the general population served by the VHA, our power to detect significant differences was limited. However, even with our small sample of women, we identified a trend towards better weight loss in both group-based programs, which is a plausible finding warranting further investigation in future studies. There was little variability in satisfaction with the Lifestyle Coach/MOVE! leader between ASPIRE study arms, which may be one explanation for similarities in weight loss

across these programs. Weight loss is believed to be mediated by improvements in diet and physical activity, but we did not find significant changes nor differences in these behaviors between sexes in these measures. It is possible that we lacked the power to detect differences in diet and exercise measures across study arms. Even though research grade pedometers, as used in the study, have been shown to be reliable and valid ³⁸⁻⁴⁰, participants may not have worn the pedometers consistently, which may have contributed to null findings. It is also possible that the magnitude of differences between groups is at the level of the composite changes in diet and exercise, as reflected in weight.

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Table 1 – Demographic and clinical characteristics at baseline in the ASPIRE-VA study

| | Women | Men | Total | p-value |
|--|--------|--------|--------|---------|
| N | 72 | 409 | 481 | |
| Baseline weight (kg, SD) | 99.3 | 115.4 | 113.0 | < 0.001 |
| | (19.8) | (22.2) | (22.6) | |
| Age (years, SD) | 46.5 | 56.5 | 55.0 | < 0.001 |
| | (9.5) | (9.3) | (10.0) | |
| Race (n, %) | , , | , , | , | 0.694 |
| Blac | k 33 | 163 | 196 | |
| | (45.8) | (39.9) | (40.7) | |
| Othe | er 1 | 8 | 9 | |
| | (1.4) | (2.0) | (1.9) | |
| Whit | te 38 | 238 | 276 | |
| | (52.8) | (58.2) | (57.4) | |
| Education (n, %) | , | , , | , | < 0.001 |
| <= HS Gra | d 7 | 101 | 108 | |
| | (9.9) | (25.3) | (23.0) | |
| Some Colleg | ge 32 | 222 | 254 | |
| | (45.1) | (55.6) | (54.0) | |
| College Gra | d 32 | 76 | 108 | |
| | (45.1) | (19.0) | (23.0) | |
| Arm (n, %) | | | | 0.59 |
| ASPIRE-Phon | e 26 | 136 | 162 | |
| | (36.1) | (33.3) | (33.7) | |
| ASPIRE-Grou | p 26 | 134 | 160 | |
| | (36.1) | (32.8) | (33.3) | |
| MOVE | E! 20 | 139 | 159 | |
| | (27.8) | (34.0) | (33.0) | |
| Charlson Index (n, SD) | 0.5 | 1.2 | 1.1 | 0.001 |
| | (1.2) | (1.5) | (1.5) | |
| Income < 20 K (n, %) | 27 | 169 | 196 | 0.33 |
| | (38.0) | (44.2) | (43.3) | |
| Substance use disorder (n, %) | 7 | 75 | 82 | 0.07 |
| | (9.7) | (18.3) | (17.0) | |
| PTSD (n, %) | 15 | 61 | 75 | 0.20 |
| | (20.8) | (14.9) | (15.8) | |
| Bipolar disorder or schizophrenia (n, %) | 7 | 24 | 31 | 0.22 |
| | (9.7) | (5.9) | (6.4) | |
| Depression (n, %) | 33 | 123 | 156 | 0.008 |
| • | (45.8) | (30.1) | (32.4) | |
| Other serious mental illness (n, %) | 1 | 6 | 7 | 0.96 |
| ` , , | (1.5) | (1.4) | (1.5) | |

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Table 2- Model-based* percent and absolute weight change† among women and men in each study arm at 3 and 12 months in the ASPIRE-VA study

| | ASPIRE-Phone | ASPIRE-Group | MOVE! | p-value |
|------------------------------|----------------------|-----------------------|-----------------------|---------|
| Women | N=26 | N=26 | N=20 | |
| Baseline | 96.1 | 102.6 | 99.0 | 0.50 |
| weight (kg) | (17.0) | (24.2) | (16.7) | |
| 3 months weight change fr | om baseline | | | |
| (%) | 0.1 | -0.6 | -1.0 | 0.83 |
| | (-2.2, 2.3) | (-2.8, 1.6) -0.6 | (-3.7, 1.7) | |
| kg | 0.0 | -0.6 | -1.0 | 0.82 |
| | (-2.1, 2.2) | (-2.8, 1.6) | (-3.7, 1.7) | |
| 12 months weight change from | om baseline | | | • |
| (%) | 0.2 | -2.6 | -2.7 | 0.14 |
| | (-2.1, 2.5) 0.2 | (-4.8, -0.5) -2.7 | (-5.2, -0.1) -2.6 | |
| kg | | | 0 | 0.12 |
| | (-2.0, 2.4) N=136 | (-5.0, -0.5) N=134 | (-5.2, -0.1) N=139 | |
| Men | N=136 | N=134 | | |
| Baseline | 115.7 | 114.3 | 116.2 | 0.76 |
| weight (kg) | (22.2) | (20.8) | (23.7) | |
| 3 months weight change from | om baseline | | | |
| (%) | -1.5 | -2.1 | -0.9 | 0.10 |
| | (-2.3, -0.7) | (-3.0, -1.3) -2 4 | (-1.7, -0.1) -1.0 | |
| kg | -1.7 | - . ' | 1.0 | 0.12 |
| | (-2.6, -0.8) | (-3.4, -1.5) | (-2.0, -0.1) | |
| 12 months weight change fi | om baseline | <u></u> | | |
| (%) | -1.5 | -2.5 | -1.0 | 0.044 |
| | (-2.4, -0.7) -1 8 | (-3.3, -1.7) -2.8 | (-1.8, -0.2) | |
| kg | 1.0 | _,, | 1.2 | 0.053 |
| | (-2.8, -0.8) | (-3.8, -1.8) | (-2.1, -0.2) | |

^{*} Estimated based on the linear mixed-effects model of weight at all assessment times

†mean (95% confidence interval)

Table 3 – Pairwise comparisons of weight loss from baseline at 12 months by study arm, based on linear mixed-effects models in the ASPIRE-VA study*

| d) | Mean difference in percent weight loss (95%CI) | p-value with Bonferroni correction |
|-------------------------------|--|---------------------------------------|
| Women | | |
| ASPIRE-Group vs. ASPIRE-Phone | -2.8 (-6.0, 0.3) | 0.15 |
| MOVE! vs. ASPIRE-Phone | -2.8 (-6.3, 0.6) | 0.20 |
| ASPIRE-Group vs. MOVE! | 0.0 (-3.4, 3.4) | 1.00 |
| Men | | |
| ASPIRE-Group vs. ASPIRE-Phone | -0.9 (-2.1,0.2) | 0.23 |
| MOVE! vs. ASPIRE-Phone | 0.5 (-0.6,1.7) | 0.76 |
| ASPIRE-Group vs. MOVE! | -1.5 (-2.6, -0.3) | 0.03 |

^{*} Estimated based on the linear mixed-effects model of weight at all assessment times

Table 4 – Intensive and maintenance sessions for weight loss completed for women and men Veterans by study arm* in the ASPIRE-VA study

| | AS | SPIRE-Phon | e | AS | ASPIRE-Group | | | MOVE! | | |
|-----------|---------|------------|-------|----------|--------------|-------|----------|-----------|-------|--|
| Women=26 | | Women=26 | | Women=26 | | | Women=20 | | | |
| | Men=114 | | | Men=115 | | | Men=119 | | | |
| Sessions | Inten- | Main- | Total | Inten- | Main- | Total | Inten- | Main- | Total | |
| | sive: | tenance: | | sive: | tenance: | | sive: | tenance: | | |
| | 1-3 mos | 4-12 mos | | 1-3 mos | 4-12 mos | | 1-3 mos | 4-12 mos | | |
| Planned | 12 | 16 | 28 | 12 | 16 | 28 | 6 | 18 | 24 | |
| number of | | | | | | | | | | |
| sessions | | | | | | | | | | |
| Women** | 6.8 | 4.6 | 11.4 | 5.9 | 3.8 (5.1) | 9.8 | 3.3 | 3.2 (5.0) | 6.4 | |
| | (3.9) | (4.7) | (7.9) | (4.8) | | (9.4) | (3.1) | | (6.4) | |
| Men† | 8.0 | 7.9 | 15.9 | 7.0 | 6.5 (6.1) | 13.5 | 3.2 | 2.2 (3.8) | 5.4 | |
| | (3.8) | (6.6) | (9.7) | (4.3) | | (9.7) | (3.3) | | (5.9) | |

^{*}mean, SD

 $[\]dagger$ p-value for total sessions completed across all arms = < 0.001



^{**} p-value for total sessions completed across all arms = 0.21

Table 5 - Satisfaction with Lifestyle Coach/MOVE! leaders in the ASPIRE-VA study

| | Female | Female | Female | l n | Male | Male | Male | n |
|----------------------------|---------|---------|--------|-------------|---------|---------|----------|-------------|
| | ASPIRE | ASPIRE | MOVE | p- value | ASPIRE | ASPIRE | MOVE! | p- value |
| | - Phone | - Group | WIOVE | varue | - Phone | - Group | WIO V L: | varue |
| | N=19 | N=18 | N=14 | | N=100 | N=103 | N=105 | |
| Did you have | 1, 1, | 1, 10 | 1, 1. | 0.03 | 11 100 | 11 100 | 1, 100 | 0.03 |
| confidence and | | | | 0.02 | | | | 0.02 |
| trust in the health | | | | | | | | |
| coach/MOVE! | | | | | | | | |
| leaders working | | | | | | | | |
| with you? (%) | | | | | | | | |
| Yes, always | 100 | 100 | 71 | | 94 | 93 | 89 | |
| Yes, sometimes | 0 | 0 | 21 | | 6 | 6 | 4 | |
| No | 0 | 0 | 7 | | 0 | 1 | 7 | |
| How would you | | | | 0.26 | | | | 0.14 |
| rate the courtesy | | | | | | | | |
| of your health | | | | | | | | |
| coach/the MOVE! | | | | | | | | |
| leaders? (%) Excellent | 89 | 88 | 64 | | 86 | 86 | 70 | |
| Very good | 11 | 12 | 29 | | 11 | 9 | 21 | |
| Good | 0 | 0 | 7 | | 3 | 7 | 7 | |
| Fair | 0 | 0 | 0 | | 0 | 1 | 1 | |
| Poor | 0 | 0 | 0 | | 0 | 0 | 17 | |
| Did you feel like | 0 | 0 | U | 0.07 | U | 0 | 17 | 0.41 |
| you were treated | | | | 0.07 | | | | 0.11 |
| with respect and | | | | | | | | |
| dignity during | | | | | | | | |
| your lifestyle | | | | | | | | |
| coaching sessions | | | | | | | | |
| [the MOVE! | | | | | | | | |
| sessions, visits, or | | | | | | | | |
| phone calls]? (%) | 100 | 100 | 0.5 | | | | 2.5 | |
| Always | 100 | 100 | 86 | | 97 | 98 | 95 | |
| Sometimes | 0 | 0 | 14 | | 2 | 2 | 5 | |
| No When you had | 0 | 0 | 0 | 0.002 | 1 | 0 | 0 | 0.05 |
| When you had | | | | 0.003 | | | | 0.05 |
| important questions to ask | | | | | | | | |
| your health | | | | | | | | |
| coach/MOVE! | | | | | | | | |
| leaders, did you | | | | | | | | |
| get answers you | | | | | | | | |
| could | | | | | | | | |
| understand? (%) | | | | | | | | |
| Yes, always | 100 | 94 | 64 | | 95 | 89 | 90 | |
| Yes, sometimes | 0 | 0 | 29 | | 5 | 8 | 4 | |
| No | 0 | 0 | 0 | | 0 | 0 | 4 | |



Figure 1 - Percent weight loss among women Veterans in each study arm from baseline to 12 months in the ASPIRE-VA study

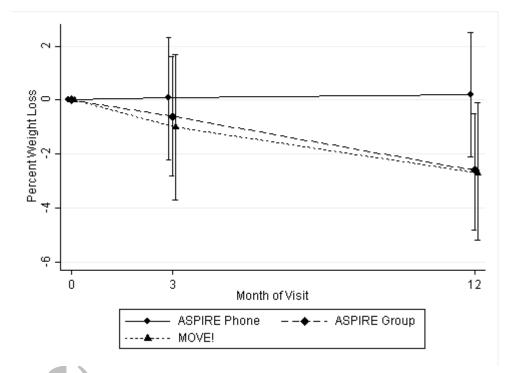
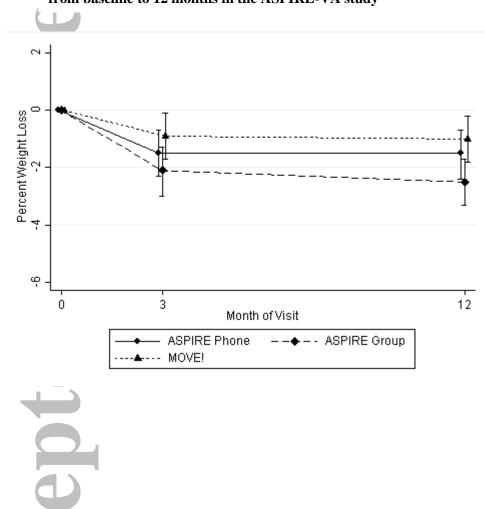


Figure 2 - Percent weight loss among men Veterans in each study arm from baseline to 12 months in the ASPIRE-VA study



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Sex differences in weight loss in the ASPIRE-VA behavioral weight loss intervention trial

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Table S1: Diet and exercise measures among women and men in each study arm at 3 and 12 months in the ASPIRE-VA study

| Outcome | Arm | Gender | N | Baseline | 3 mo Change | p v grp | p v move | 12 mo change | p v grp | p v move |
|---------------|-------|-----------|-----|-----------------------|----------------------|---------------|------------------|----------------------|---------|----------|
| | | | | (35.7 - 38.1) | (-0.6 - 0.0) | | | (-0.70.1) | | |
| Fruit Veg Pho | Phone | Female | 24 | 4.1 | -0.3 | 0.928 | 0.267 | 0.5 | 0.174 | 0.144 |
| | | | | (3.3 - 4.9) | (-1.1 - 0.5) | | | (-0.4 - 1.3) | | |
| | | Male | 105 | 4.7 | 0.6 | 0.736 | 0.203 | 0.6 | 0.978 | 0.116 |
| | | | | (4.3 - 5.1) | (0.2 - 0.9) | | | (0.2 - 0.9) | | |
| | Group | Female | 21 | 3.3 | -0.3 | | 0.914 | -0.3 | | 0.810 |
| | | | | (2.8 - 3.8) | (-1.2 - 0.5) | | | (-1.2 - 0.5) | | |
| | | Male | 104 | 4.7 | 0.7 | | 0.111 | 0.6 | | 0.114 |
| | | | | (4.4 - 5.0) | (0.3 - 1.0) | | | (0.2 - 1.0) | | |
| | MOVE | Female | 15 | 3.6 | -0.4 | 0.914 | | -0.5 | 0.810 | |
| | | | | (2.5 - 4.7) | (-1.5 - 0.7) | | | (-1.5 - 0.5) | | |
| | | Male | 105 | 4.5 | 0.2 | 0.111 | | 0.1 | 0.114 | |
| | | | | (4.2 - 4.8) | (-0.2 - 0.6) | | | (-0.2 - 0.5) | | |
| % Fat | Phone | Female | 22 | 33.8 | -0.1 | 0.221 | 0.775 | -0.8 | 0.933 | 0.857 |
| | | | | (32.2 - 35.4) | (-2.2 - 2.0) | | | (-3.1 - 1.4) | | |
| | | Male | 97 | 34.9 | -1.3 | 0.890 | 0.204 | -1.0 | 0.070 | 0.252 |
| | | | | (34.0 - 35.9) | (-2.30.4) | | | (-2.00.1) | | |
| | Group | Female | 21 | 33.8 | -1.9 | | 0.864 | -0.7 | | 0.794 |
| | | 3.6.1 | 102 | (31.5 - 36.1) | (-4.0 - 0.1) | | 0.150 | (-2.8 - 1.5) | | 0.002 |
| | | Male | 103 | 35.0 | -1.4 | | 0.159 | -2.3 | | 0.003 |
| | MOVE | F 1 | 1.5 | (33.9 - 36.2) | (-2.40.5) | 0.064 | | (-3.31.4) | 0.704 | |
| | MOVE | Female | 15 | 32.7 | -1.6 | 0.864 | | -1.1 | 0.794 | |
| | | 34-1- | 98 | (28.9 - 36.5) | (-4.4 - 1.1) | 0.150 | | (-3.7 - 1.5) -0.2 | 0.002 | |
| | | Male | 98 | 35.0 | -0.4 (-1.4 - 0.6) | 0.159 | | | 0.003 | |
| E'I | D1 | F 1 | 22 | (34.0 - 36.1) | | 0.000 | 0.101 | (-1.2 - 0.8) | 0.207 | 0.450 |
| Fiber | Phone | Female | 23 | 15.0 | -2.4 | 0.890 | 0.191 | -0.2 | 0.397 | 0.459 |
| | | Mala | 00 | (11.7 - 18.3) 21.4 | (-8.3 - 3.6) -1.0 | 0.275 | 0.125 | (-6.5 - 6.0) 1.3 | 0.642 | 0.624 |
| | | Male | 98 | (19.8 - 23.0) | -1.0 (-3.7 - 1.8) | 0.275 | 0.135 | (-1.5 - 4.1) | 0.643 | 0.624 |
| | Crown | Esmals | 21 | 13.9 | -1.8 | | 0.772 | -4.0 | | 0.983 |
| | Group | Female | 21 | (11.8 - 15.9) | (-7.8 - 4.2) | | 0.772 | (-10.1 - 2.1) | | 0.983 |
| | | Male | 101 | 21.3 | 1.2 | | 0.683 | 2.2 | | 0.980 |
| | | Iviaic | 101 | (19.5 - 23.1) | (-1.6 - 3.9) | | 0.063 | (-0.6 - 5.0) | | 0.980 |
| | MOVE | Female | 15 | 16.0 | -3.2 | 0.772 | | -3.9 | 0.983 | |
| | MOVE | remaie | 13 | (11.1 - 20.8) | (-11.0 - 4.5) | 0.772 | | (-11.4 - 3.6) | 0.983 | |
| | | Male | 100 | 20.9 | 2.0 | 0.683 | | 2.2 | 0.980 | |
| | | Iviaic | 100 | (19.3 - 22.6) | (-0.8 - 4.8) | 0.083 | | (-0.6 - 5.1) | 0.960 | |
| Steps | Phone | Female | 18 | 4,553.8 | 958.7 | 0.488 | 0.448 | -1,315.5 | 0.223 | 0.658 |
| steps | Thone | 1 Ciliale | 10 | (3,558.3 - 5,549.3) | (-432.9 - 2,350.3) | 0.400 | 0.440 | (-3,149.9 - 519.0) | 0.223 | 0.036 |
| | | Male | 89 | 4,812.9 | 925.9 | 0.706 | 0.246 | 1,161.8 | 0.633 | 0.882 |
| | | iviaic | 0,7 | (4,218.9 - 5,406.8) | (308.7 - 1,543.0) | 0.700 | 0.240 | (439.4 - 1,884.2) | 0.055 | 0.882 |
| | Group | Female | 17 | 4,045.8 | 241.7 | | 0.920 | 347.8 | | 0.544 |
| | Uroup | Temale | 1 / | ScholarOne. 3 | 375 Greenbrier Drive | e. Charlottes | ville. VA. 22901 | 341.0 | | 0.544 |

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| (3,069.9 - 5,021.6) | (-1,234.8 - 1,718.2) | (-1,600.4 - 2,296.1) | |
|---------------------|---|---|--|
| (4,105.8 - 5,424.4) | (75.7 - 1,423.8) | (171.7 - 1,649.2) | |
| 544 | | | |
| (2,550.7 - 6,127.3) | (-1,687.2 - 1,931.7) | (-3,082.4 - 1,836.9) | |
| | | | |
| (4,072.8 - 5,249.0) | (-420.6 - 1,108.0) | (199.6 - 2,319.3) | |
| | (4,105.8 - 5,424.4) 544 (2,550.7 - 6,127.3) | (4,105.8 - 5,424.4) (75.7 - 1,423.8) 544 (2,550.7 - 6,127.3) (-1,687.2 - 1,931.7) | (4,105.8 - 5,424.4) (75.7 - 1,423.8) (171.7 - 1,649.2) 544 (2,550.7 - 6,127.3) (-1,687.2 - 1,931.7) (-3,082.4 - 1,836.9) |