Behavioral Treatment for Veterans with Obesity: 24-Month Weight Outcomes from the ASPIRE-VA Small Changes Randomized Trial

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BACKGROUND: Small Changes (SC) is a weight management approach that demonstrated superior 12-month outcomes compared to the existing MOVE!® Weight Management Program at two Veterans Affairs (VA) sites. However, approaches are needed to help graduates of treatment continue to lose or maintain their weight over the longer term.
OBJECTIVE: The purpose of the present study was to examine the effectiveness of a second year of low-intensity SC support compared to support offered by the usual care MOVE! programs.
DESIGN: Following participation in the year-long Aspiring to Lifelong Health in VA (ASPIRE-VA) randomized controlled trial, participants were invited to extend their participation in their assigned program for another year. Three programs were extended to include six SC sessions delivered via telephone (ASPIRE-Phone) or an in-person group (ASPIRE-Group), or 12 sessions offered by the MOVE! programs.
PARTICIPANTS: Three hundred thirty-two overweight/obese veterans who consented to extend their participation in the ASPIRE-VA trial by an additional year.
MAIN MEASURES: Twenty-four-month weight change (kg).
KEY RESULTS: Twenty-four months after baseline, participants in all three groups had modest weight loss (−1.40 kg [−2.61 to −0.18] in the ASPIRE-Group, −2.13 kg [−3.43 to −0.83] in ASPIRE-Phone, and −1.78 kg [−3.07 to −0.49] in MOVE!), with no significant differences among the three groups. Exploratory post hoc analyses revealed that participants diagnosed with diabetes initially benefited from the ASPIRE-Group program (−2.6 kg [−4.37 to 0.83]), but experienced significant weight regain during the second year (+2.8 kg [0.92–4.69]) compared to those without diabetes.
CONCLUSIONS: Participants in all three programs lost weight and maintained a statistically significant, though clinically modest, amount of weight loss over a 24-month period. Although participants in the ASPIRE-Group initially had greater weight loss, treatment was not sufficient to sustain weight loss through the second year, particularly in veterans with diabetes. Consistent, continuous-care treatment is needed to address obesity in the VA.

KEY WORDS: veterans; obesity; behavioral medicine; weight management; clinical trials.

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INTRODUCTION

While obesity remains at historically high levels in the US adult population,[1,2,3] rates are even higher among veterans. Nationwide, 32% of veterans live with obesity,[4] and for those who have received care in the Veterans Health Administration (VHA), the rate is even higher, at 41%.[5] The Department of Veterans Affairs (VA) provides healthcare to patients that are predominantly male, older, of lower socioeconomic status, and often burdened by multiple physical and mental health comorbidities compared to patients in other healthcare systems, which creates challenges for obesity treatment.[6]

In 2006, the VA introduced the MOVE!® Weight Management Program to meet the urgent need to address obesity and its subsequent effects on health.[4,7,8] While MOVE! encompasses multi-level behavioral interventions consisting of treatments delivered in different modalities (e.g., group, individual, telehealth), the majority of treatment (72%) is delivered via in-person group sessions.[9] Despite evidence of weight gain prior to participation,[10,11] single-site and system-wide analyses of participant outcomes have consistently revealed significant, though modest, weight loss at 6 and 12 months.[9,10,12]

However, the problem of long-term weight loss maintenance has been argued as the greatest challenge in treating obesity.[13] Though clinically significant weight loss has been achieved in a sizable portion of participants across many randomized controlled trials,[14–16] weight loss often peaks at 6–12 months, with subsequent weight regain. Successful maintenance of weight loss is generally defined as minimal weight gain for at least 12 months after intensive treatment.[17] A systematic review[18] and other trials[19] have found that patients who received long-term follow-up or "continuous-care" treatment were more likely to retain more of their weight loss over a 24-month period than those who did not receive follow-up care.

Small Changes (SC) is an evidence-based treatment approach[20–23] for addressing obesity that encourages and supports participants in making modest changes to their dietary intake and level of physical activity *relative* to their current behaviors and attitudes, which differs from other approaches that have prescribed goals.[24] The Aspiring to Lifelong Health in Veterans Affairs (ASPIRE-VA) trial tested the SC approach among 481 veteran participants in a 12-month program.[25] The year prior to enrolling in the trial, participants experienced an average weight gain of 2.7 kg. At enrollment, participants were randomized to 1) group-based delivery of SC (ASPIRE-Group), 2) individual phone-based delivery of SC (ASPIRE-Phone), or 3) the usual care in-person group-based MOVE! program in two VA medical centers in the US Midwest.[25] Twelve months later, participants in the ASPIRE-Group had lost twice the amount of weight (−2.8 kg) as participants in ASPIRE-Phone or MOVE! (−1.4 kg for both groups), and session attendance was markedly higher in the two SC arms compared to MOVE!.[26]

The aim of the current study was to extend the 12-month ASPIRE-VA trial into another year of low-intensity support to examine the impact of SC over the long term in this complex, underserved population compared to the usual care MOVE! program. Additionally, through post hoc exploratory analyses, we sought to identify factors that might impact weight trajectory over 24 months, including diabetes because of its high prevalence among veterans.[27,28]

METHODS

Study Design

The full design and rationale of the original ASPIRE-VA weight management study[25] and 12-month treatment outcomes[26] are reported elsewhere. In the original trial, participants were randomized to one of three treatment arms (described above) for a period of 1 year. Participants who completed the 12-month assessment were invited to participate in an additional 12 months of treatment. Institutional review was obtained for the original and extended studies at two Midwestern VA medical centers.

Participants and Procedures

In the initial trial, participants were provider- or self-referred for weight management services and were eligible for the MOVE! program (BMI $\geq$ 30 kg/m^2, or BMI of 25–30 kg/m^2 and at least one obesity-related health condition). Other inclusion criteria were capacity to consent, reliable access to a telephone, and ability to communicate in English. Exclusion criteria included current enrollment in another weight loss or physical activity trial, inability to complete a 6-min walking test, and pregnancy. Of the 481 participants originally randomized in the trial, 332 (69%) consented to a second year of follow-up treatment (Fig. 1). Enrollment in the first year began in January 2010, and the last of the extended assessments (out to 24 months) were completed in November 2013. Participants received additional remuneration for completing additional assessments at 18 months ($50) and 24 months ($50) after their initial enrollment.

Small Changes (SC) Intervention Programs

The two ASPIRE SC arms were designed based on the SC model of behavior change,[24] which draws from social–psychological goal–conflict theories and encourages patient-chosen behavioral goals, the benefits of which (e.g., weight loss) would accumulate slowly over time.[25] Participants were encouraged to set new goals only after previous behaviors were successfully maintained.

During the first year, both ASPIRE SC treatment arms consisted in weekly sessions for 3 months, followed by 6 months of biweekly sessions, and then 3 monthly sessions (28 sessions total). Non-clinician lifestyle coaches conducted the ASPIRE SC sessions. Coaches had at least a bachelor's degree and did not possess any specific psychology, behavior change, or coaching training/experience. A licensed clinical psychologist (LDL) and master's-level social worker (LG) facilitated ongoing supervision and feedback based on patient data and supervisor reports. These coaches and the supervision continued in the extended second year.

For the current study, which focuses on the second year, participants were offered the opportunity to continue with their same coach in the same program as during the first year (i.e., phone for ASPIRE-Phone, in-person groups for ASPIRE-Group). However, coaching sessions were less frequent; rather than monthly, they were scheduled every other month ($n = 6$ sessions). Both SC arms had the same number of sessions, but total contact time was different: phone sessions lasted 20 min and group sessions lasted 60 min. As in the last 3 months of the first year, sessions consisted in 1) checking in on progress toward patient-selected goals, 2) problem-solving any issues related to barriers and challenges to making dietary and physical activity changes, and 3) setting goals for the following 2 months.

Usual Care: MOVE! Weight Management Program

In the first year, individuals who were randomized to the MOVE! program had 11-12 weekly sessions delivered by a team of leaders in each of the two study sites.[25] After completion of the weekly sessions, the sites offered a range of options: quarterly 90-min or biweekly 60-min group sessions, repeating the initial series of 11 or 12 weekly sessions, or engaging in other programs (e.g., TeleMOVE, an in-home technology-based program).[29] These offerings continued, unchanged, into the second year. Study staff contacted MOVE! participants only to obtain consent for participation in the study's second year and to schedule and conduct their 18- and 24-month assessments.

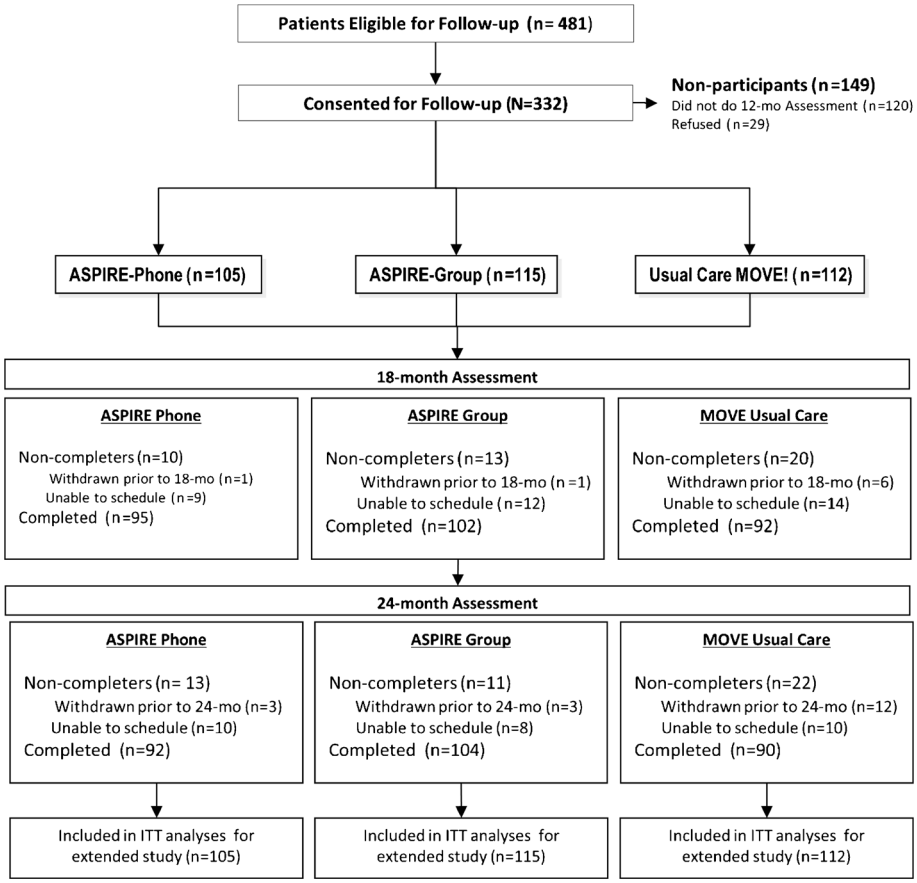

Figure 1 CONSORT diagram of patient flow and retention for follow-up.

Outcome Measure

The primary outcome for the present study was weight at 24 months, measured as a continuous variable. Results are presented in absolute *weight change* (kg) from baseline to 3, 12, 18, and 24 months.

Statistical Analyses

Analyses were performed in Stata version 13.1 software (StataCorp LP, College Station, TX). The chi-square test and *t* tests were used to examine differences in baseline characteristics between those who consented ($N = 332$) and those who did not consent to the second follow-up year ($n = 149$). The primary analytic cohort included all participants consenting to participate in the second year of follow-up who continued with the same treatment arm assigned at the start of the first year. We examined treatment engagement across the three intervention arms, and report the mean number of completed sessions by arms. Weight changes across the three arms at each follow-up time were analyzed using linear mixed-effects models with baseline and 3-, 12-, 18-, and 24-month weight as dependent variables. The model included participants as random intercepts to adjust for within-participant correlation of the repeated measures, fixed predictors of study arm, 3-, 12-, 18-, and 24-month time indicators, and time by study arm indicators. This model enables the inclusion of all participants with at least one weight measure at any time point. Expected weight changes at follow-up times from baseline were estimated using parameter estimates from the model.

Furthermore, as diabetes prevalance is high in Veterans, and has been identified as a potential moderator of weight outcomes, exploratory post-hoc analyses were conducted to assess the role of diabetes in long-term weight change.[25–28] The analytic model described above was extended by adding the interaction terms of the potential moderator by intervention arm indicators by follow-up time.

RESULTS

Study Participants

Of the 481 participants who enrolled in the initial 12-month program, 332 consented to participate in the 24-month follow-up. These individuals ($N = 332$) tended to be older than those who did not continue into the second year (n = 149; Table 1), but were otherwise comparable. Individuals participating in the second year were predominately middle-aged (mean age = 55.98) men (85.5%) with moderate obesity (mean BMI = 36.2). They were ethnically diverse, with 42% non-white and 44% reporting less than $20,000 annual income, and based on electronic medical health record data, most had multiple physical and mental health diagnoses (Table 1). Table 2 shows baseline characteristics by arm for the 332 participants who consented to the second year.

Table 1 Baseline Characteristics of the ASPIRE-VA Participants in Initial and Follow-Up Treatment

Characteristics	Total ($n = 481$)	Follow-up Yes ($n = 332$)	Follow-up No (n = 149)	p values
Age, M (SD)	55.0 (10.0)	55.98 (9.5)	52.69 (10.7)	<0.001
BMI (kg/m^2)	36.5 (6.2)	36.2 (6.0)	37.1 (6.7)	0.12
Male	409 (85.0)	284 (85.5)	125 (83.9)	0.64
Race/ethnicity				
Black	196 (40.7)	135 (40.7)	61 (40.9)	
White	276 (57.4)	194 (58.43)	82 (55.03)	0.06
Other	9 (1.9)	3 (0.90)	6 (4.027)	
Education, years				
< 13	108 (22.5)	73 (22.0)	35 (23.5)	
13–16	254 (52.8)	174 (52.4)	80 (53.7)	0.46
≥ 16	108 (22.5)	75 (22.6)	33 (22.2)	
Missing	11 (2.3)	10 (3.0)	1 (0.7)	
Income < $20,000	196 (42.9)	137 (43.9)	59 (40.7)	0.52
Health-related disability	249 (55.2)	166 (54.1)	83 (57.6)	0.48
Charlson Comorbidity Index, M (SD)	1.1 (1.5)	1.2 (1.5)	0.98 (1.4)	0.16
Depression	156 (32.5)	105 (31.7)	51 (34.2)	0.59
PTSD	76 (15.8)	57 (17.2)	19 (12.8)	0.22
Serious mental illness	31 (6.5)	18 (5.4)	13 (8.7)	0.18
Substance use disorder	82 (17.0)	57 (17.17)	25 (16.78)	0.90
Diabetes	177 (36.8)	122 (36.8)	55 (36.9)	0.97
Hypertension	319 (66.3)	226 (68.1)	93 (62.4)	0.23
Hypercholesterolemia	244 (50.8)	171 (51.51)	73 (48.99)	0.61
EQ-5D pain				
None	89 (18.8)	64 (19.6)	25 (17.0)	
Moderate	323 (68.3)	218 (66.9)	105 (71.4)	0.62
Severe	61 (12.9)	44 (13. 5)	17 (11. 6)	
Site				
Site 1	239 (49.7)	167 (50.3)	72 (48.3)	0.69
Site 2	242 (50.3)	165 (49.7)	77 (51.7)	

Weight Change Over 24 Months

We examined weight change using age-adjusted and unadjusted models, which yielded similar results. The findings from unadjusted models are presented. All three intervention groups showed significant weight loss 24 months after baseline; weight change for this period was comparable across the three programs, with mean change of −1.40 kg in ASPIRE-Group, −2.13 kg in ASPIRE-Phone, and −1.78 kg in MOVE!

Table 2 Baseline Characteristics of the ASPIRE-VA Participants in Extended 2nd Year of Treatment by Arm

Characteristics	ASPIRE-Phone ($n = 105$)	ASPIRE-Group ($n = 115$)	MOVE! ($n = 112$)	p values
Age, M (SD)	56.9 (9.0)	55.8 (9.4)	55.3 (10.1)	0.45
BMI (kg/m^2), M (SD)	35.5 (5.6)	36.4 (6.0)	36.5 (6.4)	0.38
Male (%)	87 (83.0)	98 (85.2)	99 (88.4)	0.51
Race/ethnicity (%)				
Black	43 (41.0)	50 (43.4)	42 (37.5)	
White	61 (58.0)	64 (55.7)	69 (61.6)	0.93
Other	1 (1.0)	1 (0.9)	1 (0.9)	
Education, years (%)				
< 13	24 (22.9)	25 (21.7)	24 (21.4)	
13–16	49 (46.7)	59 (51.3)	66 (58.9)	0.29
≥ 16	29 (27.6)	29 (25.2)	17 (15.2)	
Missing	3 (2.9)	2 (1.7)	5 (4.5)	
Income < $20,000 (%)*	36 (34.3)	52 (45.2)	49 (43.8)	0.10
Health-related disability (%)	41 (39.0)	60 (52.2)	65 (58.0)	0.01
Charlson Comorbidity Index, M (SD)	1.1 (1.3)	1.2 (1.5)	1.2 (1.6)	0.11
Depression (%)	20 (19.0)	41 (35.7)	44 (39.3)	0.003
PTSD (%)	12 (11.4)	25 (21.7)	20 (17.9)	0.12
Serious mental illness (%)	6 (5.7)	4 (3.5)	8 (7.1)	0.46
Substance use disorder (%)	6 (5.7)	13 (11.3)	38 (33.9)	<0.001
Diabetes (%)	34 (32.4)	48 (41.7)	40 (35.7)	0.34
Hypertension (%)	70 (66.7)	79 (68.7)	77 (68.8)	0.93
Hypercholesterolemia (%)	48 (45.7)	68 (59.1)	55 (49.1)	0.11
EQ-5D pain (%)†				
None	23 (21.9)	26 (22.6)	15 (13.4)	
Moderate	67 (63.8)	73 (63.5)	78 (69.6)	0.40
Severe	12 (11.4)	15 (13.0)	17 (15.2)	
Site (%)				
Site 1	54 (51.4)	51 (44.3)	62 (55.4)	0.24
Site 2	51 (48.6)	64 (55.7)	50 (44.6)	

**20 Patients with missing values*
†6 Patients with missing values

(Table 3). Results from secondary analyses, taking an intention-to-treat approach that included all 481 participants from the ASPIRE-VA trial (data not shown), were consistent with the findings based on the primary analytic cohort ($n = 332$).

Post hoc analyses exploring weight change patterns over the 2-year intervention period revealed that between 12 and 24 months, participants in the ASPIRE-Phone and MOVE! groups maintained or continued their weight loss, but participants in the ASPIRE-Group experienced significant weight regain (Fig. 2). Further exploratory analyses revealed that participants with diabetes had a different weight trajectory in the second year across the three arms (chi-square = 24.37, $p < 0.001$). Specifically, participants with diabetes who were in the ASPIRE-Group arm had significant weight loss during the first year of treatment (−2.6 kg; 95% CI: −4.37, −0.83), adjusting for age, but in the second year they had significant weight gain (+2.8 kg, 95% CI: 0.92, 4.69; Fig. 3).

Engagement

Over 24 months, participants in the two ASPIRE SC programs completed more sessions than MOVE! participants: 18.9 sessions (95% CI: 17.0–20.9) for ASPIRE-Group, 20.8 (95% CI: 18.8–22.8) for ASPIRE-Phone, and 8.6 (95% CI: 6.9–10.3) for MOVE!. In the second year, participants in ASPIRE-Group (2.6; 95% CI: 2.2–3.0), ASPIRE-Phone (2.4; 95% CI: 2.0–2.9), and MOVE! (2.3; 95% CI: 1.4–3.3) completed a comparable number of sessions, indicating that engagement differences were accrued during the first year.

DISCUSSION

To our knowledge, this is the first study to examine longer-term weight loss treatment in the VA and in a sample of predominantly middle-aged and ethnically diverse male veterans with multiple chronic behavioral and health conditions. Results from the present study show that, while all three groups experienced weight loss 2 years after baseline, the ASPIRE treatment was insufficient to maintain the higher weight loss seen at 12 months in the ASPIRE-Group arm compared to the other two programs: by 24 months, all three programs had comparable weight loss.

These findings have implications for the design of VA population-based services to support the long-term healthy weight management of their veterans. Perhaps the most provocative questions raised by these findings concern the level and type of continuous-care obesity treatments that are needed to better serve this medically complex population. Little is known about which treatment approaches and intensities are optimal for continued weight loss.[8,30–32] One trial that tested three approaches, one of which was in-person monthly contact, found that on average, all participants in all three approaches gained weight after having lost at least 4 kg in the prior 6 months; however, participants in the in-person group gained the least weight.[33] We believed a priori that participants in the ASPIRE-Group arm, who initially experienced twice the weight loss in the first year compared to either ASPIRE-Phone or MOVE!, would have continued to experience greater weight loss than those in the other two programs in the second year—after all, the program components, including the coaches, remained the same.

One possible reason for the higher weight loss in the ASPIRE-Group in the first year is the group cohesion that leveraged social support from peer veterans within the groups.[26] Although anecdotal, ASPIRE-Group participants expressed concerns to their coaches about reducing the frequency of coaching sessions; based on coaches' feedback, less frequent sessions appeared to impact group cohesion and commitment over time. During the first 3 months, participants had weekly sessions, which then decreased to biweekly and then monthly in the first year; in the second year, sessions were further reduced to every 2 months.

It appears that much of the weight regain seen in the second year was driven by participants with diabetes (Fig. 3) who lost weight in the first 3 months but then started regaining it as sessions became increasingly less frequent. Evidence is emerging of specific regimen-related distress among patients with diabetes, and how this emotional distress has been associated with negative behavioral and health outcomes.[34–36]

Table 3 Weight Change by Time Point and Program

	Month	Weight change from baseline	Lower CI	Upper CI	*p* values:		
					vs. baseline	vs. phone	vs. MOVE!
ASPIRE-Phone $n = 105$	3	–1.66	–2.88	–0.44	0.007		0.40
	12	–1.93	–3.13	–0.74	0.001		0.47
	18	–1.78	–3.02	–0.54	0.005		0.92
	24	–2.13	–3.43	–0.83	0.001		0.92
ASPIRE-Group $n = 115$	3	–2.38	–3.55	–1.21	<0.001	0.40	0.09
	12	–3.00	–4.14	–1.86	<0.001	0.21	0.04
	18	–1.62	–2.82	–0.42	0.008	0.77	0.85
	24	–1.40	–2.61	–0.18	0.024	0.56	0.63
MOVE! $n = 112$	3	–0.91	–2.14	0.32	0.147	0.40	
	12	–1.32	–2.48	–0.16	0.025	0.47	
	18	–1.71	–2.95	–0.46	0.007	0.92	
	24	–1.78	–3.07	–0.49	0.007	0.92	

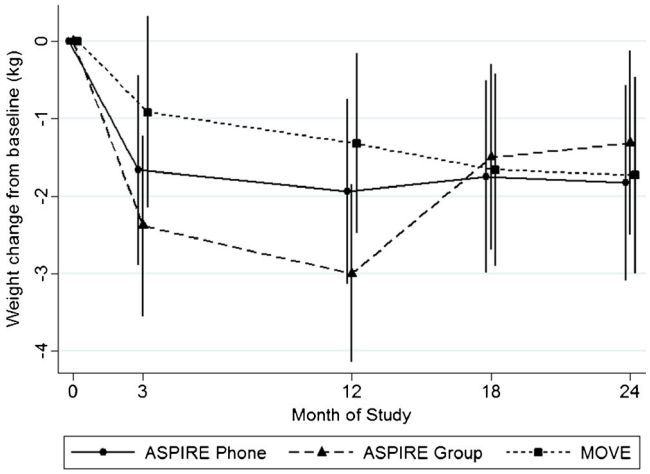

Figure 2 Weight loss across initial treatment and long-term follow-up by group ($n = 332$).

These participants who might have benefited from the social support provided by their groups may have been especially affected by the loss of more frequent group sessions. These findings point to the possibility that participants with diabetes may need longer-term and more intensive treatment, with at least biweekly contact,[37] in order to maintain weight loss. Because one-third of the patients in the present study had diabetes, and prevalence of the disease is high among VA users overall,[38] these individuals are an important subgroup in which to address obesity.

Participants in the two SC groups engaged in an almost threefold higher number of sessions across the 24 months, but overall, that difference was attributed to higher participation in the first year. By the second year, all three groups completed fewer than three visits on average. Further research is needed to explore whether offering more sessions over a longer period would help keep participants engaged without breaking connections among peer participants and with interventionists. Additional components, such as refresher groups or focused weight campaigns[19], more frequent sessions with individual check-ins, and/or a combination of these elements have the potential to enhance long-term weight loss maintenance

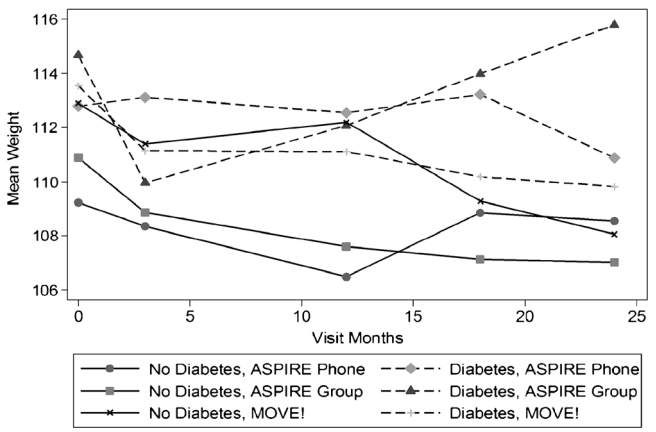

Figure 3 Weight loss and maintenance over time by diabetes status and group.

outcomes, especially for individuals with diabetes. These recommendations are offered despite recognition of constrained program resources and capacity limits, in the hope that alternative innovative evidence-based approaches[39] for engaging veterans in longer-term obesity treatment may be prioritized moving forward. Findings from other published secondary analyses of the ASPIRE-VA trial results suggest that other subgroups of patients, including individuals with pain[11] or binge eating,[40] may also benefit from tailored or more intensive weight loss support.

Despite the issues highlighted above, it is important to note that minimal maintenance support (i.e., one contact every other month) appeared to be sufficient to help maintain continued gradual and modest weight loss for participants in the ASPIRE-Phone and MOVE! programs over 2 years (and perhaps for individuals without diabetes within ASPIRE-Group). In the VA, nearly 75% of MOVE! services are delivered via in-person groups.[9] Although some VA providers and staff believe telephone-based programs are not effective,[41] our findings and those of previous studies[37] show that phone-based treatment can promote gradual long-term weight loss and maintenance over 2 years.[37] Offering this option may improve access for veterans with significant transportation or scheduling issues that limit their ability to come to the VA for treatment. Promising new automated technologies and programs such as TeleMOVE[29] and online-adapted versions of the Diabetes Prevention Program (DPP) have been piloted[42] and offer the potential for further expanding treatment delivery options.

Several limitations apply. First, not all participants in the initial ASPIRE-VA trial consented to participate in the second year. Thus, we must be cautious in interpreting our results. However, other than age, results showed that there were no differences, including initial weight loss, between those who consented and those who did not consent to the second year of treatment. Second, there were significant program differences between the two SC programs and the MOVE! program, which varied in its offerings across the two study sites. However, there is wide variability across sites nationally in weight management offerings in usual care. Third, unlike other long-term weight loss trials,[37,43] we had pragmatic eligibility criteria (e.g., participants were not required to lose 5–10% of their baseline weight to be eligible to participate in the second year),[44] thus limiting our ability to assess maintenance of prior clinically significant weight loss. Fourth, we did not randomize patients to programs in the second year. Therefore, this was not a weight-maintenance randomized controlled trial. Fifth, the exploratory analyses that highlight the potential impact of diabetes leading to longer-term weight gain are speculative, because medications used to treat diabetes may facilitate or impede weight loss depending on the regime. Controlling for medication regime is a complex undertaking and is outside the scope of this study. We acknowledge that it may be fruitful to target weight loss treatment to individuals with prediabetes to reduce the incidence of diabetes,[45] and ultimately to lower the

currently high prevalence of diabetes; however, we were not able to ascertain prediabetes status among our participants. Lastly, participants in the ASPIRE-VA were on average over 50 years old. With recent deployments to Iraq and Afghanistan winding down, younger veterans comprise an increasing share of the population. Future research is needed to design programs to engage younger veterans in healthy weight loss.[9]

Overall, these findings highlight the need for the VA to provide not only ongoing/continuous care for obesity,[24] but to have sufficiently frequent contact (at least monthly, or even more frequently for special subgroups including individuals with diabetes) to promote long-term weight loss maintenance. Finally, these findings highlight that phone-based coaching is a viable treatment modality for increasing access. Moving forward, combining evidence from this and other evaluations to date,[46–50] the VA can continue their leadership in developing effective and cutting-edge population-based initial treatment and long-term continuous-care weight management programs for US veterans.

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Compliance with Ethical Standards:

Conflict of Interest: *The authors declare no conflicts of interest.*

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