American Journal of
Preventive Medicine

RESEARCH ARTICLE

A 2-Year Holistic Health and Stress Intervention: Results of an RCT in Clergy

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Introduction: This study sought to determine the effect of a 2-year, multicomponent health intervention (Spirited Life) targeting metabolic syndrome and stress simultaneously.

Design: An RCT using a three-cohort multiple baseline design was conducted in 2010–2014.

Setting/participants: Participants were United Methodist clergy in North Carolina, U.S., in 2010, invited based on occupational status. Of invited 1,745 clergy, 1,114 consented, provided baseline data, and were randomly assigned to immediate intervention (n=395), 1-year waitlist (n=283), or 2-year waitlist (n=436) cohorts for a 48-month trial duration.

Intervention: The 2-year intervention consisted of personal goal setting and encouragement to engage in monthly health coaching, an online weight loss intervention, a small grant, and three workshops delivering stress management and theological content supporting healthy behaviors. Participants were not blinded to intervention.

Main outcome measures: Trial outcomes were metabolic syndrome (primary) and self-reported stress and depressive symptoms (secondary). Intervention effects were estimated in 2016 in an intention-to-treat framework using generalized estimating equations with adjustment for baseline level of the outcome and follow-up time points. Log-link Poisson generalized estimating equations with robust SEs was used to estimate prevalence ratios (PRs) for binary outcomes; mean differences were used for continuous/score outcomes.

Results: Baseline prevalence of metabolic syndrome was 50.9% and depression was 11.4%. The 12-month intervention effect showed a benefit for metabolic syndrome (PR=0.86, 95% CI=0.79, 0.94, $p<0.001$). This benefit was sustained at 24 months of intervention (PR=0.88; 95% CI=0.78, 1.00, p=0.04). There was no significant effect on depression or stress scores.

Conclusions: The Spirited Life intervention improved metabolic syndrome prevalence in a population of U.S. Christian clergy and sustained improvements during 24 months of intervention. These findings offer support for long-duration behavior change interventions and population-level interventions that allow participants to set their own health goals.

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0749-3797/$36.00
https://doi.org/10.1016/j.amepre.2017.04.009

Trial registration: This study is registered at www.clinicaltrials.gov NCT01564719.
Am J Prev Med 2017;53(3):290–299.

INTRODUCTION

Metabolic syndrome (MetS), defined by the International Diabetes Federation as central obesity plus any two of the following: elevated triglycerides, low high-density lipoprotein (HDL), hypertension, and abnormal glucose regulation,[1] is associated with increased risk for type 2 diabetes, cardiovascular disease, stroke, and mortality.[1–3] Weight loss is one approach to reverse MetS. Although weight loss trials have demonstrated decreases in weight, improvements are rarely maintained at 12 and 24 months post-intervention.[4,5] One hypothesis as to why weight improvements are temporary is that chronic stress might, via elevation in glucocorticoid secretion, drive a desire to consume caloric, energy-dense food. Consumption of comfort foods may stimulate pleasure centers in the brain, thus regulating stress-induced systemic arousal.[6] Longer interventions may allow participants to practice dietary behaviors during both high- and low-stress periods. Such long-term practice under diverse conditions may be critically important to sustaining weight loss.

Potentially, jointly targeting MetS and stress management for 2 years may reduce MetS and decrease weight through stress management and long-term practice of healthy dietary behaviors. Few studies have examined interventions with dual primary aims of weight loss and stress management, and they have been relatively small, short-term pilot studies with highly selective, mostly female samples.[7,8] Outcomes generally have been positive, but owing to short follow-up periods, have not addressed the challenge of long-term behavior change.

One population that suffers chronic stress and high rates of obesity is clergy. Clergy experience a number of work-related stressors, including work overload, unpredictable schedules, intrusiveness, and criticism from parishioners.[9] Clergy exhibit above-average rates of depression and obesity.[10,11] Obesity prevalence in United Methodist Church (UMC) clergy was 41% in a national U.S. study and also in a North Carolina (NC) study.[12,13]

There are several benefits to studying obesity, stress, and MetS in clergy. First, clergy have high rates of obesity and chronic stress. Second, a large percentage of clergy are male; among UMC clergy, approximately 71% are male.[14] In spite of the fact that male obesity rates appear to be climbing,[15] men have been under-represented in weight loss interventions to date.[16] Third, successful interventions tailored to Christian clergy, estimated at 244,200 in the U.S.,[17] may be adapted and offered to the large number of Christian churchgoers in the U.S.

The Spirited Life trial was a pragmatic trial (estimated pragmatic–explanatory continuum indicator summary [PRECIS] score of 84% with 100% being extremely pragmatic[18,19]; Appendix, available online) of a combined weight reduction and stress management intervention among an employee population of clergy. It was designed to assess changes in the prevalence of MetS (primary outcome), weight, depression, and stress symptoms (secondary outcomes). Details of the trial rationale, intervention, and implementation are available elsewhere.[20] The trial used a multiple baseline trial design with three cohorts randomly assigned to intervention start dates spaced 1 year apart (immediate intervention, 1-year waitlist, and 2-year waitlist cohorts). The primary hypothesis was that the intervention would lead to a lower prevalence (or mean level) of MetS, weight, stress symptoms, and depression at 12, 18, and 24 months of intervention. The 12-, 18-, and 24-month intervention effects were estimated using standard modeling approaches for data from a multiple baseline RCT. This article reports outcomes during the three cohorts' intervention and waiting periods.

METHODS

The original protocol for the trial has been published.[20] The CONSORT checklist is provided as supporting information (Appendix Tables 2, 3, available online).

Study Population

Eligible participants were all clergy members in July 2010 of the NC Annual Conference and the Western NC Annual Conference of the UMC; these two governing bodies employ approximately 1,800 UMC clergy. All individuals were invited based on clergy occupation status rather than health status. There were no health status inclusion criteria, and clergy with and without MetS, depression, and stress symptoms were recruited. Exclusion criteria were intentionally few; pastors on leave and most extension ministers (e.g., seminary professors, hospital chaplains) were excluded.

An extensive communication campaign was conducted in September–October 2010 to inform all NC UMC clergy, regardless of health status, about the trial. A total of 1,745 eligible clergy were invited to participate, beginning with online consent. Consenting participants had to complete both an in-person cardiometabolic screening and online survey to enroll. A total of 1,114 clergy (64%)

met these criteria. Using a randomized multiple baseline design, participants were randomly assigned to one of three intervention start dates: January 2011 (Cohort 1, "immediate intervention cohort"), January 2012 (Cohort 2, "1-year waitlist cohort"), and January 2013 (Cohort 3, "2-year waitlist cohort"). Start dates were spaced 1 year apart so that all three cohorts began the 2-year intervention during the same season. More participants (40%) were randomized to the 2-year waitlist cohort to guard against attrition. More participants were randomized to the immediate intervention cohort (35%) than the 1-year waitlist cohort (25%) to intervene with more clergy sooner. Randomization was stratified by geographic district (sub-administrative units in Conferences: 27 levels). Using the list of 1,114 enrolled participants, an independent statistician generated random allocation sequences for each district, ensuring the overall 40%:35%:25% split. Random allocations were implemented by study personnel. Given the pragmatic nature of the trial, blinding of participants and intervention personnel was not possible. Personnel who measured physical outcomes were blinded to trial cohort.

The 2-year Spirited Life intervention began with a required 3-day workshop. Figure 1 shows the flow of participants through randomization and data collection. Cardiometabolic and survey

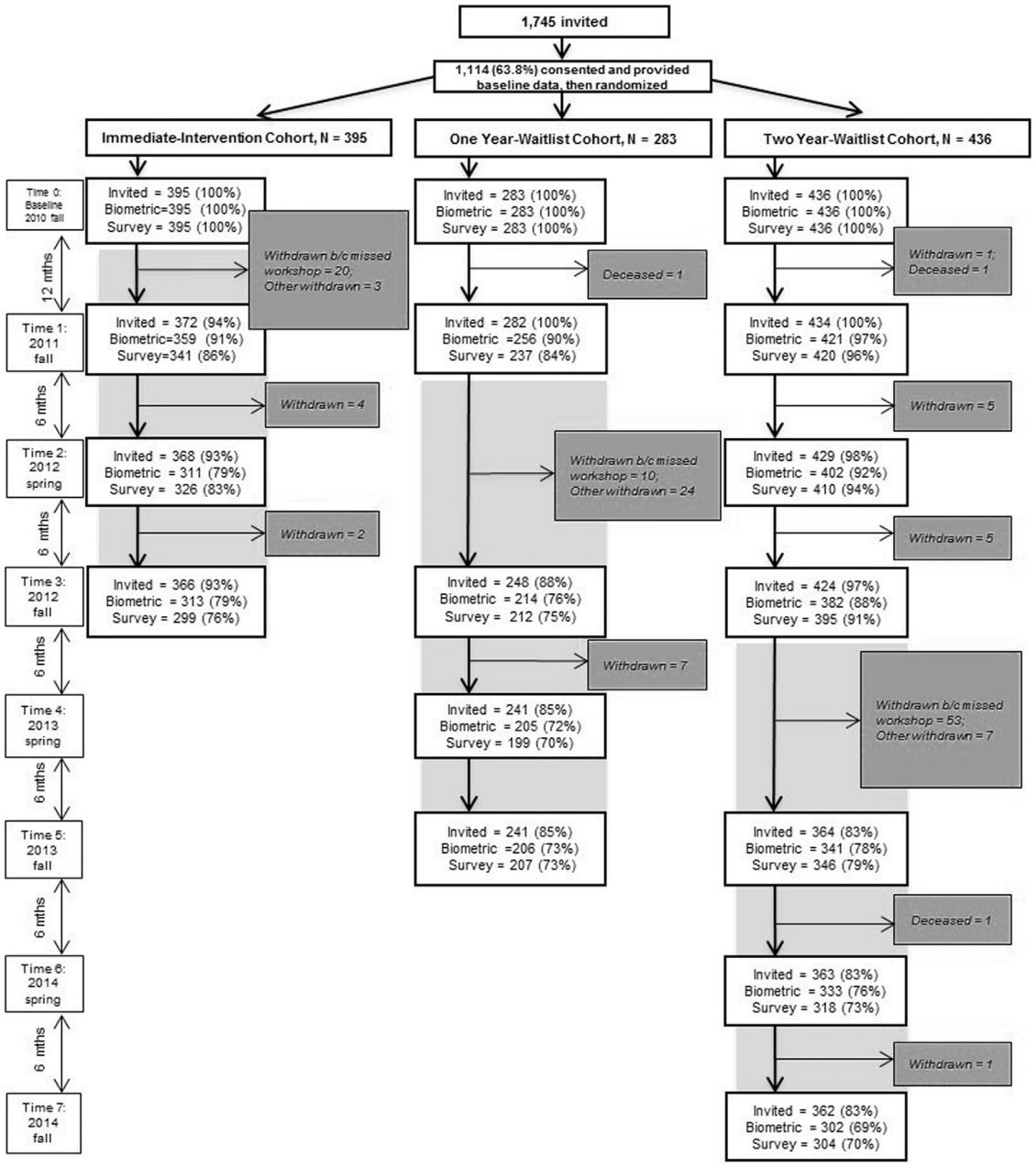

Figure 1. Trial profile: Cardiometabolic (biometric) and survey data collection at each assessment point during the 48-month study.

Note: Shading indicates when the Spirited Life intervention was delivered to each cohort (with start dates each January, spaced 1 year apart). Percentages of cardiometabolic assessment participants and of survey participants were calculated with the number of subjects randomized as denominator.

data were collected for the entire sample at the trial baseline (fall 2010) and repeatedly through fall 2014. Each cohort was assessed just prior to intervention and at 12, 18, and 24 months into the intervention. In addition, the 2-year waitlist cohort was assessed at every time point that the immediate intervention cohort was assessed to provide control comparison measurements for the full 2-year intervention duration of the immediate intervention cohort (Figure 1). Duke University's Arts and Sciences IRB approved all procedures and participants gave free and informed consent.

The intervention consisted of four components, described here briefly and elsewhere in detail.[20] Only the initial workshop was required. It delivered the Williams LifeSkills (WLS) stress management program plus theological content supporting healthy behaviors (e.g., God's becoming flesh in Jesus urges Christians to be good stewards of their bodies). WLS is a protocol-driven, manualized training program shown to improve stress coping and interpersonal relationship skills.[21] Two additional 2-day workshops were spaced midway and at the end of the intervention. They included opportunities for clergy to articulate core values, recommit to behavior change, and plan for sustaining their accomplishments. Intervention health coaches contacted participants after their initial workshop to schedule health coaching calls. Participants were encouraged to have monthly calls but were allowed to space them less frequently. During calls, health coaches utilized motivational interviewing with a focus on goal setting and support (Appendix, available online). Regardless of weight status, participants were encouraged to register for a 10-week online weight loss program called Naturally Slim®. Naturally Slim® emphasized eating only when hungry; decreasing sugar intake; eating smaller portions; and balancing fats, proteins, and carbohydrates. In January of the second year, participants were encouraged to apply for $500 grants to assist in achieving their health goals. The intervention content was the same for each cohort, except the 2-year waitlist cohort was offered the online stress management program meQuilibrium (www.mequilibrium.com/) rather than WLS, based on participant feedback that clergy training includes much of the WLS content. Both WLS and meQuilibrium have cognitive behavioral underpinnings. WLS focused on deciding between action and deflection, problem solving, assertion, listening, and empathy with many role plays, whereas meQuilibrium offered self-assessments of one's environment, interpersonal relationships, and the thoughts that precede emotions, paired with online journaling and exercises.

Measures

Cardiometabolic data collection, performed by staff trained using detailed protocols (Appendix, available online), assessed the five MetS components. MetS indicators were derived for each participant at each measurement time point using the International Diabetes Federation definition[1] (Appendix, available online). BMI categories were created using the National Heart, Lung, and Blood Institute definition.[22]

A 45-minute online survey included the secondary outcome measures of stress symptoms and depression. Stress symptoms were measured using the 10-item Perceived Stress Scale, with scores ranging from 0 to 40. Depressive symptoms were measured using the Patient Health Questionnaire-8,[23] consisting of eight items on the frequency of depression symptoms during the past 2 weeks, with scores ranging from 0 to 24. Based on previous validation studies, scores of $\geq$10 were used to indicate moderate or severe depression[24] (referred to as "depression").

The prespecified primary outcome measure was prevalence of MetS and secondary outcome measures were the prevalence of depression (Patient Health Questionnaire-8 score $\geq$10), mean stress scores, and mean weight, comparing the immediate intervention and the 2-year waitlist cohort 24 months after trial baseline. Additional prespecified comparisons included the same comparisons at 12 months after trial baseline (Appendix, available online). Data from all three cohorts (waitlist and intervention periods) were combined in a single statistical model. Combining all information available in the intervention periods of both waitlist cohorts maximized statistical power to estimate the 12-, 18-, and 24-month intervention effect for each outcome (Appendix, available online).

Statistical Analysis

The trial was powered at 83% to detect a difference of 10 percentage points for MetS prevalence, and powered at 78% for a 5.6 percentage point difference for depression prevalence, between immediate intervention and 2-year waitlist cohorts at 24 months using a two-tailed t-test at the 5% significance level. The Appendix (available online) provides additional power analyses.

Baseline and follow-up data were summarized by randomized cohort as appropriate: cases (proportions) for categorical outcomes and means (SD) for continuous outcomes. The intention-to-treat principle was used for all follow-up analyses, whereby all participants were analyzed in the cohort to which they were randomized even if they later changed cohorts or did not participate in intervention activities at any time. All reported p-values are two-sided. Analyses were based on a prespecified analysis plan and performed using SAS, version 9.4 and Stata, version 14.1 in 2016.

Data from the three cohorts at all follow-up time points and from all participants were modeled together, including data from participants who were later lost to follow-up. To account for within-person correlation of outcomes due to multiple follow-up measures on each participant, generalized estimating equations were used to estimate population-averaged effect estimates.[25] An unstructured correlation matrix with robust SEs was used to account for the correlation between multiple responses for the same participants. To estimate prevalence ratios (PR) for binary outcomes (MetS, MetS components, depression, and attained target proportion of weight loss), a Poisson distribution with log-link—a valid approach for binary outcomes when used in the generalized estimating equation framework with robust SEs—was used.[26] A Gaussian regression with an identity link for continuous outcomes (weight) and score outcomes (perceived stress) was used to estimate mean differences. Robust SEs were used to account for possible model misspecification (e.g., due to slight skewness). All models treated intervention level (four levels: waiting, 12 months, 18 months, and 24 months of intervention) and post-baseline follow-up time point (seven levels: 6-month intervals from 12 months to 48 months post-baseline, Figure 2) as categorical factors. Post-baseline follow-up time point was included to account for the possible confounding effect of time that is due to naturally occurring health changes across such a lengthy (48-month) trial.[27] All models adjusted for the baseline level of the

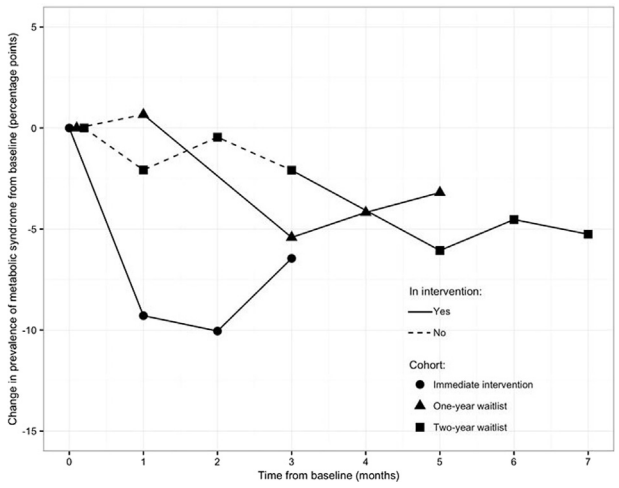

Figure 2. Change in the prevalence of metabolic syndrome over time by intervention cohort.

Note: The estimated prevalence changes are based on imputed data (Appendix, available online). Each change score is calculated as the cohort's estimated prevalence of metabolic syndrome (MetS) at a given follow-up time, minus the prevalence of MetS at time 0. For image clarity, the baseline prevalence scores are slightly shifted on the time axis, but all were measured at time 0.

outcome and district as a categorical factor (27 levels) to account for the stratified randomization.[28]

Stratified analyses were conducted to examine weight separately for participants who were obese and overweight at baseline. To assess clinical benefit, individual weight loss of 3% and 5% of the starting weight for all participants was examined, as even modest weight loss may improve blood pressure, cholesterol, and blood sugar levels.[29–32] Generalized estimating equation analysis of all available data provides unbiased estimated intervention effects when the outcome missing data pattern is either missing completely at random or a covariate-dependent missing pattern,[33] and the predictors of missing outcomes are included as covariates. Doubly robust multiple imputation was performed to test whether the results were robust to missing data.[34] The use of this procedure did not substantively alter the results (Appendix Table 1, available online).

RESULTS

Participants were predominantly male (69.3%), white (89.0%), married (89.0%), and obese or overweight (82.8%), with a mean age of 51.9 (SD=10.0) years (Table 1). The three cohorts were comparable at baseline for MetS, with an overall prevalence of 50.9%. A higher proportion (15.1%) of participants in the immediate intervention cohort were classified as having depression compared with the 1-year (11.0%) and 2-year waitlist (8.4%) cohorts. Figure 1 shows that 26 participants withdrew or died before the first follow-up (12 months). Overall, 1,054 (94.6%) participants provided at least one follow-up measurement. Baseline outcomes indicated that, compared with the 1,054 who provided at least one follow-up measurement, the 60 (5.4%) participants with no follow-up data were more likely at baseline to have depression (15.0% vs 11.2%), MetS (60.0% vs 50.3%), and hypertension (66.7% vs 51.8%), but not central obesity, elevated triglycerides, elevated hemoglobin A1c, or reduced HDL. The 60 participants with no follow-up data were spread across cohorts (n=28, 24, and 8 for the three respective cohorts). Sensitivity analyses including the lost cases with imputed values for MetS indicated the results were robust to missing values (Appendix, available online).

For all cohorts, response rates exceeded 75% in the first 24 months of the trial (Figure 1). The lowest response rate was 69% for the 2-year waitlist cohort's 48-month cardiometabolic measurement.

Baseline prevalence of MetS was 50.9% for the whole trial sample (Table 1). Changes in observed and model-based estimates of MetS prevalence by cohort over time are shown in Appendix Table 3 (available online) and Figure 2, respectively. For those with at least one follow-up measurement, there were decreases in MetS prevalence in each cohort (ranging from 3.7 to 6.6 percentage points) from immediately pre-intervention to 24 months of intervention (Appendix Table 4, available online). These changes were 49.5% to 42.9% for immediate intervention, 49.8% to 46.1% for 1-year waitlist, and 49.6% to 45.1% for 2-year waitlist cohorts. Using all intervention and control period data from all cohorts, and adjusting for follow-up time points, the 12-month intervention effect on the primary outcome of MetS (Table 2) was estimated to have 14% lower prevalence (PR=0.86, 95% CI=0.79, 0.94, $p<0.001$). This effect was sustained over 2 years with a 24-month intervention effect estimated at a lower prevalence of 12% (PR=0.88, 95% CI=0.78, 1.00, p=0.04).

Baseline prevalence of the five MetS components in the whole sample are shown in Table 1. The most prevalent components at baseline were central obesity (81.2%), low HDL (57.4%), and hypertension (52.6%), and the less prevalent components were elevated triglycerides (50.9%) and abnormal glucose regulation (13.7%). Prevalence of the five components by cohort over time are shown in Appendix Table 4 (available online). Using all intervention and control period data from all cohorts and adjusting for follow-up time points, there was a beneficial 24-month intervention effect for the three most prevalent components with a PR for central obesity of 0.91 (95% CI=0.86, 0.96, $p<0.001$), for low HDL of 0.90 (95% CI=0.81, 1.00, p=0.04), and for hypertension of 0.81 (95% CI=0.72, 0.91, $p<0.001$) (Table 2). Comparable benefits were estimated at 12 months for all three outcomes, together with a benefit for elevated

Table 1. Baseline Characteristics of the Spirited Life Study Participants by Randomized Cohort (N=1,114)

Characteristics	Immediate intervention cohort (*n*=395)	1-year waitlist cohort (*n*=283)	2-year waitlist cohort (*n*=436)	Total (N=1,114)	Sample size
Male gender	271 (68.6)	199 (70.3)	302 (69.3)	772 (69.3)	1,114
Race					1,114
White	352 (89.1)	250 (88.3)	389 (89.2)	991 (89.0)	
African American	25 (6.3)	18 (6.4)	25 (5.7)	68 (6.1)	
Other	18 (4.6)	15 (5.3)	22 (5.0)	55 (4.9)	
Highest level of education achieved					1,112
College and below	61 (15.5)	47 (16.6)	85 (19.5)	193 (17.4)	
Master's	285 (72.5)	201 (71.0)	302 (69.3)	788 (70.9)	
Doctorate	47 (12.0)	35 (12.4)	49 (11.2)	131 (11.8)	
Married	353 (89.6)	252 (89.0)	386 (88.5)	991 (89.0)	1,113
Appointed to rural (versus urban) church	119 (30.3)	97 (34.3)	148 (34.3)	364 (32.8)	1,108
BMI categories					1,104
Obese	198 (50.4)	133 (47.2)	207 (48.3)	538 (48.7)	
Overweight	131 (33.3)	97 (34.4)	148 (34.5)	376 (34.1)	
Normal/underweight	64 (16.3)	52 (18.4)	74 (17.2)	190 (17.2)	
Metabolic syndrome	193 (49.2)	142 (50.9)	225 (52.3)	560 (50.9)	1,101
Central obesity	321 (82.1)	234 (83.3)	339 (79.0)	894 (81.2)	1,101
Elevated triglycerides	186 (47.4)	140 (50.4)	232 (54.3)	558 (50.9)	1,097
Low HDL	209 (53.5)	157 (56.5)	263 (61.7)	629 (57.4)	1,095
Hypertension	209 (53.2)	147 (52.1)	226 (52.4)	582 (52.6)	1,106
Abnormal glucose regulation	42 (10.8)	46 (16.9)	60 (14.3)	148 (13.7)	1,083
PHQ-8 depression	59 (15.1)	31 (11.0)	36 (8.4)	126 (11.4)	1,104
Age, years, M (SD)	51.6 (10.0)	51.7 (10.1)	52.3 (9.9)	51.9 (10.0)	1,107
Weight, kg, M (SD)	95.3 (23.7)	93.6 (23.4)	94.6 (23.4)	94.6 (23.5)	1,103
BMI, kg/m^2, M (SD)	31.6 (7.4)	30.9 (7.2)	31.0 (7.1)	31.2 (7.3)	1,103
PHQ-8 depressive symptoms, M (SD)	4.6 (4.5)	4.1 (4.1)	3.9 (3.7)	4.2 (4.1)	1,104
Perceived stress, M (SD)	13.0 (6.3)	12.5 (6.1)	12.4 (6.1)	12.6 (6.2)	1,100

Note: Data are presented as *n* (%) unless otherwise noted. Eight Spirited Life participants were pregnant or within 6 months postpartum at baseline. Therefore, they were excluded for the metrics of weight, BMI, metabolic syndrome, central obesity, elevated triglycerides, low high-density lipoprotein, hypertension, abnormal glucose regulation, and depression.
HDL, high-density lipoprotein; PHQ-8, Patient Health Questionnaire-8

triglycerides (PR=0.87, 95% CI=0.79, 0.96, p=0.005), which was not sustained at 24 months of intervention (PR=0.96, 95% CI=0.84, 1.09, p=0.53).

Beneficial weight outcomes were found for each cohort and time point. From immediately pre-intervention to 24 months of intervention, weight change was –3.4 kg for immediate intervention, –4.4 kg for 1-year waitlist, and –1.7 kg for 2-year waitlist cohorts (Appendix Table 5, available online). The overall 24-month intervention effect was estimated as a mean weight of 1.75 kg (95% CI=0.74, 2.76, $p<0.001$) less than control, and, for participants who were obese at baseline, was 1.81 kg (95% CI=0.01, 3.62, p=0.048) less (Appendix Table 7, available online). The Appendix and Appendix Table 6 (both available online) report more weight outcomes, including loss of 3% and 5% of baseline body weight.

Baseline prevalence of depression was 11.4% across the whole trial sample (Table 1). Changes in prevalence of depression by cohort over time are shown in Appendix Table 4 (available online). There was no evidence of an intervention benefit on depression, with a 12-month PR of 1.03 (95% CI=0.78, 1.38, p=0.82) and 24-month PR of 0.83 (95% CI=0.53, 1.28, p=0.39) (Table 2).

The baseline mean perceived stress score was 12.6 (Table 1). Changes in mean stress scores, which slightly decreased for each cohort over time, are depicted in Appendix Table 4 (available online). There was no evidence of an intervention benefit on mean stress scores. The 12-month mean difference was 0.10 (95% CI= –0.38,

Table 2. Effectiveness of the Spirited Life Intervention on Main Health Outcomes by Intervention Duration (N=1,054)

Outcome variable	12-month intervention effect	18-month intervention effect	24-month intervention effect
Metabolic syndrome[a]	**0.86 (0.79, 0.94)***; $p<0.001$**	**0.78 (0.69, 0.90)***; $p<0.001$**	**0.88 (0.78, 1.00)*; $p=0.042$**
Central obesity[a]	**0.93 (0.89, 0.97)***; $p<0.001$**	**0.92 (0.87, 0.97)**; $p=0.003$**	**0.91 (0.86, 0.96)***; $p<0.001$**
Elevated triglycerides[a]	**0.87 (0.79, 0.96)**; $p=0.005$**	**0.83 (0.71, 0.97)*; $p=0.020$**	0.96 (0.84, 1.09); $p=0.532$
Low HDL[a]	**0.92 (0.86, 0.98)*; $p=0.016$**	**0.86 (0.78, 0.95)**; $p=0.003$**	**0.90 (0.81, 1.00)*; $p=0.041$**
Hypertension[a]	**0.80 (0.74, 0.87)***; $p<0.001$**	**0.85 (0.75, 0.96)*; $p=0.010$**	**0.81 (0.72, 0.91)***; $p<0.001$**
Abnormal glucose regulation[a]	1.00 (0.88, 1.14); $p=0.961$	1.10 (0.91, 1.32); $p=0.347$	0.98 (0.81, 1.20); $p=0.876$
PHQ-8 depression[a]	1.03 (0.78, 1.38); $p=0.818$	0.94 (0.62, 1.44); $p=0.790$	0.83 (0.53, 1.28); $p=0.389$
Perceived stress[b]	0.10 (−0.38, 0.58); $p=0.67$	0.44 (−0.22, 1.11); $p=0.19$	−0.28 (−0.98, 0.42); $p=0.44$

Note: For each intervention level (12 months, 18 months, or 24 months in intervention vs no intervention), prevalence ratios are estimated for binary outcomes (metabolic syndrome, components of metabolic syndrome, and depression) using Poisson GEE and mean differences are estimated for the score outcome (stress), using Gaussian GEE regression modeling. All models adjust for time, district, and the baseline measure of the respective outcome and use an unstructured working correlation matrix and robust SEs (to account for outcome misspecification). Boldface indicates statistical significance (*$p<0.05$; **$p<0.01$; ***$p<0.001$). For abnormal glucose regulation and depression, the correlation structure of the model is specified as exchangeable to avoid convergence problems. For all outcomes except perceived stress, data were collected and analyzed through 48 months from baseline. For perceived stress only, data were not collected at 42 and 48 months and therefore those time points were not included in the perceived stress analysis.

[a]Data are presented as prevalence ratio (95% CI); *p*-value for all categorical variables.

[b]Data are presented as mean difference (95% CI); *p*-value for perceived stress.

HDL, high-density lipoprotein; PHQ-8, Patient Health Questionnaire-8.

0.58, $p=0.67$); the 24-month mean difference was –0.28 (95% CI= –0.98, 0.42, $p=0.44$) (Table 2).

DISCUSSION

The Spirited Life trial demonstrates that a 2-year intervention providing culturally tailored content supporting healthy behaviors and training in stress management and weight loss can improve and, importantly, sustain changes during 24 months of intervention in MetS, central obesity, HDL, and hypertension at a population level. Although few interventions have such a long duration, participants were willing to engage in a 2-year intervention. The long duration may have allowed participants to practice healthy behaviors and still have support in place to minimize any lapses in those behaviors. The inclusion of a small grant at the intervention midpoint may have encouraged continued participation and assisted with maintaining newly established healthy behaviors.

The primary aim was to decrease MetS prevalence in this high-risk population, and at 12 months of intervention, there was a 14% lower prevalence of MetS. Improvements in MetS prevalence were maintained over time with a 22% lower prevalence at 18 months and 12% lower prevalence at 24 months of intervention. Of the five components of MetS, the beneficial effects of the intervention at 24 months were mainly driven by prevalence improvements in central obesity, HDL, and blood pressure. Benefits to the prevalence of elevated triglycerides were observed at 12 and 18 months only, despite prevalence improvements in central obesity. Benefits were not observed for abnormal glucose regulation (hemoglobin A1c), which was the least prevalent MetS component in the sample and did not show a trend toward improvement. Future interventionists targeting MetS should consider including a specific diabetes program component.

Because Spirited Life took a population-level approach and invited all UMC clergy in NC regardless of health status or readiness for behavioral change, enrollment was likely de-stigmatized. Sixty-four percent of invited clergy enrolled. Many participants reported they enrolled to be supportive of other clergy in their Conference, rather than wanting to change their own behavior. Participants were not required to engage in any specific intervention activity other than the initial 3-day workshop, nor did they have to focus their energy on a metabolic outcome if they preferred to pursue other goals (e.g., spiritual well-being). However, after enrollment, many participants engaged in multiple intervention activities (Appendix, available online), suggesting that interventionists should focus efforts on initial enrollment and culturally tailoring programming for maximum acceptability. Another advantage of this population-level approach was the possibility of broadly and positively influencing social norms.

The disadvantages of this population approach included spending intervention resources on participants

without current health needs and likely attenuation of key outcomes. For example, not every participant was obese or motivated to lose weight. With an estimated 24-month intervention effect of −1.75 kg compared with control participants, the weight change observed in this trial was less than those that employ obesity inclusion criteria and participant interest in losing weight.[35,36] Nevertheless, at 24 months, 47.3% of the immediate intervention cohort lost 3% or more of their baseline body weight, a percentage that obesity treatment guidelines indicate can produce clinically meaningful reductions in triglycerides and blood glucose.[29] By comparison, in a YMCA effectiveness study of the 6-month Diabetes Prevention Program (DPP) plus an 8-month maintenance intervention, participants sustained an average loss of 4.8% of their baseline weight at 28 months.[37] DPP is a much more intensive lifestyle intervention than Spirited Life, making the current study's findings notable.[38] To scale Spirited Life in the future, it may be possible to exchange its health coaching for the recent DPP scaling work that uses online health coaching and peer groups (www.omadahealth.com/solution), especially if peer groups of clergy could be formed. The long intervention periods of Spirited Life and DPP may be key to sustaining weight loss; weight gain is common in the absence of weight maintenance programming.[39]

Random imbalance in depression was observed at baseline; the immediate intervention cohort started with a higher prevalence than the other cohorts, which was accounted for in modeling by baseline adjustment. The intervention did not have a significant effect on depression at 12, 18, or 24 months of intervention. The lack of impact on depression prevalence could be due to the intervention's focus on stress rather than depression, although clinical trials of WLS demonstrated reductions in depression levels among patients post–coronary bypass surgery and caregivers for relatives with Alzheimer's disease.[40,41] Null findings could also be due to an ineffectual intervention for depression, the difficulty of reducing prevalence in low-prevalent disorders, or less severe depression in this sample.

A study hypothesis was that weight loss would be better sustained in the presence of improvements in stress symptoms. However, baseline mean stress scores were lower than the literature indicating a large number of stressors for clergy would suggest.[9,42,43] Study authors investigated this discrepancy by conducting a cognitive interviewing study with 12 clergy for each item on the 10-item Perceived Stress Scale and found that at least half had theological concerns with all but three items.[44] Clergy indicated that items such as "things are going your way" and "you could not overcome" directly conflict with seeking God's way and being faithful. Because of these concerns, this study's changes in stress scores cannot be interpreted. It is difficult to know whether: this measure is invalid for clergy; floor effects limited the possibility of finding a change in scores; or there was no true impact of this individual-level intervention on perceived stress, given the systems-level stressors experienced by UMC clergy (e.g., complex church dynamics, a shrinking denomination). Researchers should explore other ways to measure perceived stress in clergy, such as the Clergy Occupational Distress Index.[45] They should continue to seek interventions that decrease stress and depressive symptoms among clergy, which may affect weight loss and are important in their own right. Given the modest (e.g., 1.7 kg) weight loss findings, it does not appear that the combined stress management–weight loss intervention resulted in greater weight loss than weight loss interventions alone. However, as noted earlier, this could be because participants were recruited based on clergy rather than obese status.

Limitations

Trial limitations include the use of self-report measures for stress and depression and power to detect only large effect sizes in those outcomes. Using waitlist control groups with clergy who regularly interact may have resulted in spillover effects; if so, outcomes may be underestimated. One study strength was its attention to religious culture through including theological reasons to attend to health. However, this may confine the generalizability of study findings primarily to U.S. Christian clergy, although with minor adaptations, Spirited Life may be extended to the large church-affiliated population in the U.S. Other study strengths include the collection of cardiometabolic data, a large sample size, a long intervention duration, and use of a randomized multiple baseline design.

CONCLUSIONS

This trial demonstrates that the Spirited Life intervention is beneficial to U.S. Christian clergy in improving MetS, central obesity, HDL, and hypertension, as well as sustaining these improvements during 24 months of intervention. These findings offer support for long-duration behavior change interventions and population-level interventions that allow participants to set their own health goals. Future studies should continue to test interventions aimed at the dual goals of MetS and stress symptom reduction powered to detect meaningful but smaller stress and depression reductions than targeted here, and should consider testing multiyear weight loss programs with an eye toward enhanced scalability.

ACKNOWLEDGMENTS

The United Methodist clergy of North Carolina, along with support from their bishops and leaders, made this trial possible. Data were collected and organized by Crystal MacAllum, Gail Thomas, Ed Mann, and their team at Westat, as well as Amanda Wallace and Alana Bennett. Thirteen Wellness Advocates implemented the intervention with great care. Amanda Wallace and Adeola Awodele helped prepare the manuscript. This trial was funded by the Rural Church Area of The Duke Endowment, http://dukeendowment.org/. The Duke University Arts and Sciences IRB protocol number is A0208.

The tasks completed by each author are as follows. Conceived and designed the trial: RJPB, GGB, RW, DT, HEM, RS. Performed the trial (acquired the data): RJPB, RS, HEM, MK, RM, CW, KR, HH, DT. Analyzed the data: ELT, XFL, JY, DE. Interpreted the data: RJPB, ELT, GGB, XFL, JY, RW, VW, DT, KR, RM, CW, HEM, RS, DE. Wrote the first draft of the manuscript: RJPB, ELT, GGB, RW. Provided critical revision of the manuscript for important intellectual content: RJPB, ELT, GGB, XFL, JY, RW, RS, HEM, MK, RM, CW, KR, VW, DT, DE. Obtained funding: DT. Administrative, technical, or material support: GGB, XFL, JY, RW, RS, HEM, MK, RM, CW, KR, VW. Supervision: RJPB, ELT, CW, DT, RS.

The trial registration number in www.ClinicalTrials.gov is NCT01564719. Trial rationale but not outcomes were presented at the 34th Annual Meeting and Scientific Sessions of the Society of Behavioral Medicine, the APA Division 27 2013 Biennial Conference, and the Society for the Scientific Study of Religion 2011 Annual Meeting.

Gary G. Bennett holds equity in Scale Down and Coeus Health, which produce digital health interventions for obesity. He also serves on the science advisory board at Nutrisystem and the board of directors at Girl Trek. Redford B. Williams is a founder of and major stockholder in Williams LifeSkills, Inc. Virginia P. Williams is a founder of and major stockholder in Williams LifeSkills, Inc. No other financial disclosures were reported by the authors of this paper.

SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at https://doi.org/10.1016/j.amepre.2017.04.009.

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