Use of a Randomized Multiple Baseline Design

Rationale and Design of the Spirited Life Holistic Health Intervention Study

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Abstract

Clergy suffer from high rates of obesity, chronic disease, and depression, and simultaneously underestimate the toll these take on their daily functioning. Health interventions are needed for clergy and may be tailored to their occupational context and theological beliefs. Few studies have sought to improve clergy health. No prior studies have utilized a randomized design. Spirited Life is a randomized, multiple baseline study that offered enrollment to nearly all United Methodist Church clergy in North Carolina in fall 2010. A total of 1,114 clergy (response rate=64%) enrolled. Using a multiple baseline design, we randomized participants to three cohorts. Each cohort began the health intervention in one of three consecutive years. The third cohort served as a randomized waitlist control cohort, allowing comparisons between the first and third cohorts. The two-year Spirited Life intervention consists of: 1) a theological underpinning for health stewardship based on incarnation, grace, and response and delivered during workshops; 2) the stress management program Williams LifeSkills; 3) Naturally Slim, an online weight loss program; 4) phone contact with a Wellness Advocate; and 5) $500 small grants for health goals. Metabolic syndrome is the primary endpoint. Stress and depressive severity are secondary endpoints. We measured each construct before, twice during, and at the end of the two-year intervention. Study outcomes, to be published after follow-up data are gathered, will provide evidence of the effectiveness of the combined intervention components of Spirited Life. If successful, the intervention may be considered for use with other clergy and faith populations.

Keywords: Randomized controlled trial, multiple baseline design, clergy, metabolic syndrome, depression

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1. Introduction

The number of clergy in the United States (US) is substantial. The US Department of Labor estimated that in 2010 there were 230,800 clergy of all faiths, with a predicted growth rate of 18% by 2020 [1]. Clergy occupy a unique role in our society; they engage in worship, preaching, and counseling, and serve as community liaisons and role models [2] and [3]. Extensive evidence, reviewed below, indicates that mental and physical health are worse for clergy than in the population at large.

Obesity rates in the US are high. In 2009-2010, 35.5% of men and 33.4% of women were obese. Although the obesity rate for women in 2009-2010 did not differ significantly from the rate a decade earlier, the obesity rate for men rose from 27.5% in 1999-2000 [4]. Corresponding with these high rates of obesity are high rates of type 2 diabetes [5], hypertension [6], and cardiovascular disease [7] , resulting in a large number of US adults who are burdened by multiple diagnoses. Metabolic syndrome, defined as central obesity (i.e., a large abdominal circumference) plus any two of the following: hypertension, type 2 diabetes, elevated triglycerides, and diminished HDL--indicates heightened risk for cardiovascular disease, stroke, and death [8].

Recent studies indicate that clergy are experiencing higher than national rates of obesity, type 2 diabetes, and hypertension, even when making demographic adjustments [9] and [10]. Clergy also report multiple stressors [11], [12], and [13] and high rates of depression [14], [15], and [16]. Numerous Christian denominations across the US are experiencing the cost of clergy's high disease burden. The health benefits boards of the Evangelical Lutheran Church in America, the Reform Church of America, the United Methodist Church, and others are seeking ways to improve clergy health as a means to preserve funds to keep churches open.

In this paper, we present the rationale and design of the Spirited Life randomized multiple baseline study. This study's primary endpoint is metabolic syndrome, with secondary endpoints of stress and depression severity. The study tests whether a combination of stress management and weight loss activities, paired with a theological underpinning and regular support from Wellness Advocates, affects these outcomes. Spirited Life attempts to motivate behavior change specifically in clergy by 1) providing theological reasons to attend to one's health and 2) grounding the intervention in a larger holistic health framework in which participants are encouraged to tailor aspects of the intervention to the areas of health most interesting to them. Qualitative research indicates that a holistic health orientation is integral to clergy health beliefs [17].

2. Background and Rationale

In this section, in order to state clearly the rationale for the Spirited Life study, we provide background information on: obesity and chronic disease in clergy; mental health disorders in clergy; the importance of spiritual well-being in clergy; existing health interventions for clergy; holistic health interventions; and the relationship between weight and stress. In the subsequent sections, we describe in detail the Spirited Life study.

2.1. Prevalence of obesity and chronic disease in clergy

There are few studies on the physical health of clergy, but those that exist indicate a looming health crisis. A 2001 US study of Evangelical Lutheran Church clergy reported an obesity rate (BMI > 30) of 34%, compared to a national general population obesity rate at the time of 22% [10]. A 2012 US study of United Methodist Church clergy reported an obesity rate of 41% [9], which is higher than the 2010 national average of 35.7% [4]. Neither of these studies accounted for age or gender, which could explain the high obesity rates, since the mean age of clergy in these studies were 51 and 53 and both studies over-represented males. However, a 2008 survey of all United Methodist Church clergy serving in North Carolina adjusted for age, gender, insurance status, employment status, and race and found that 39.7% of clergy, compared to 29.4% of North Carolinians, were obese [18]. The study further indicated discrepantly high rates for clergy in self-reported diagnoses of diabetes (9.8% versus 6.5% among all North Carolinians), arthritis (29.2% versus 26.7%), hypertension (29.0% versus 24.7%), and asthma (13.8% versus 9.7%).

Interestingly, participants in the same study perceived their overall physical health functioning to be *better* than the national norm [19]. The authors speculated that clergy did not perceive the negative impacts of their poor health on their work and social activities because of the sedentary nature of their occupation paired with their strong personal call to the ministry. Data from multiple studies suggest that interventions to improve the health of clergy are needed, but because clergy may not perceive themselves to be unhealthy, program developers should attend to the fact that clergy may need convincing.

2.2. Prevalence of mental health disorders in clergy

Researchers have conducted only a handful of studies on depression in clergy using validated depression measures. Most of these studies utilize the Center for Epidemiological Studies Depression (CES-D) scale [20] and report depression rates ranging from 17% for Church of Nazarene pastors [21], to 18% and 20% of Roman Catholic clergy in separate studies [14] and [16]. In our study of United Methodist clergy, we found a depression rate of 8.7% using the Patient Health Questionnaire-9 [22] , compared to 5.5% in a nationally representative sample using the same measure (author citation). Overall, rates of clergy depression appear high from these studies, but more research is needed with larger sample sizes and additional denominations.

2.3 Stress and effort-reward imbalance theory in clergy

Stress may be an important contributor to clergy depression and overeating. Researchers have found that work-related stressors are associated with worse emotional well-being among clergy [23], and also that difficult parishioners, work overload, and excessive schedule demands are associated with clergy burnout [24]. There is a rich literature that has identified common sources of clergy stress and categorized them as vocational stressors (inadequate pay, low work satisfaction, unrealistic time demands, relocation), intrapersonal stressors (emotional exhaustion, burnout, low personal satisfaction, sense of personal failure), family stressors (low family satisfaction, lack of family time, lack of privacy), and social stressors (high expectations regarding behavior, criticism, intrusiveness, lack of social support) [13]. Lee and Iverson-Gilbert (2003) summarize these stressors as personal criticism, boundary ambiguity, presumptive expectations, and family criticism [12]. In addition, family stressors and life transitions, such as the frequent moves some clergy make, can exacerbate the stressors of ministry and disrupt relationships with health care providers [25].

In the face of this long list of stressors, clergy can respond with adaptive or maladaptive stress responses [26]. An adaptive stress response occurs when clergy leverage their knowledge, skills, and characteristics to cope

successfully with a stressor, even growing stronger through the process. For example, seeking emotional support from friends and family is adaptive and may ultimately strengthen those social bonds. A maladaptive stress response occurs when a clergyperson either does not have adequate resources to cope with a stressor, or when a stressor becomes long-term and a clergyperson has no opportunity for rest or rejuvenation. When individuals' responses to stressors are maladaptive, the result is evident in physiological indicators such as poor sleep, cognitive indicators such as rumination, behavioral indicators such as overeating, and emotional indicators such as depression and anxiety. With our dual interests in clergy obesity and depression, we are keenly interested in stressors and stress responses.

The occupational health theory, effort-reward imbalance theory, readily applies to clergy. Effort-reward imbalance theory postulates that high effort paired with low reward leads to emotional distress and poor health outcomes [27]. The specific stressors defined by Siegrist are extrinsic demands, intrinsic demands, and the absence of rewards. Examples of extrinsic demands among clergy include unpredictable schedules due to congregant deaths and crises, high-conflict committee meetings, rapid switching between tasks throughout the day, and seasonal periods of increased time demands [3]. Examples of intrinsic demands for clergy include an intense commitment to work, driven in part by feeling a sacred call to their work; and feeling guilty for not doing enough in a set of responsibilities that are ongoing [28].

Examples of rewards include money, approval, and work satisfaction. Of these rewards, work satisfaction is often high for clergy [29]. However, clergy earn relatively low wages for their education level; the median 2010 salary for clergy in the US was just under $44,000 [30] , which is lower than the average $67,000 annual salary that someone with a master's degree in the US earns [31]. In terms of approval, a pastor's work is judged by multiple sources, including denomination officials, church members, and the pastor's own judgment as to whether their actions are consistent with their beliefs and commitments. Effort-reward imbalance theory emphasizes the reward of status control, which is maintaining one's job stability and social role at work [27] and [28]. Clergy have varying but often low status control, because church leaders can force clergy out. Thus, even the rewards that clergy may experience vary and bring with them a degree of stress. The picture painted for clergy is one in which rewards and demands are unbalanced. Effort-reward imbalance theory would therefore predict higher emotional distress and poorer physical health among clergy.

2.4 Importance of spiritual well-being to clergy

Health interventions often seek to promote physical or mental health, or both. However, our population of interest is clergy, who place a strong value on spiritual well-being. In a qualitative study that asked clergy to define health, clergy gave responses such as, "wholeness of the spirit. Mind, body, and spirit"; "a general sense of well-being"; and "spiritual, emotional, physical, mental well-being" [32]. In addition, clergy rely on spiritual practices as sources of strength when coping with stress. For example, Bible study, prayer, meditation, releasing control of worries to God, and reminding oneself of God's long-range vision have all been described as successful stress management strategies [33] and [34]. For these reasons, we considered it essential to create a health intervention that potentially impacts spiritual well-being and does not isolate it from other aspects of health.

Spiritual practices may be sources of strength, but one's calling to serve God can make decisions about spending time on one's own health and well-being complicated. Clergy can decide that time spent on their own needs detracts from the larger mission of caring for others [32]. Thus, clergy may neglect their health for

theological reasons. In Spirited Life, we sought to help clergy think through the theological underpinnings of health and of reasons to care for themselves.

2.5 Existing health interventions for clergy

A recent review of clergy health programming identified 56 Protestant clergy health programs in the US. Relatively few (13) were engaged in impact evaluation, and even then evaluation findings were not yet available [35]. A large number of the programs utilized a retreat format in which clergy took 2 to 14 days away from work to join with other clergy and health experts to focus on their health [36] and [37]. The benefit of this retreat format is that it allows clergy to clear their schedule and temporarily attend to their health. The downsides are that this format does not enable clergy to learn how to integrate health behaviors into their daily lives, and it can be difficult for pastors to take time away from their responsibilities at their parishes. Several of the identified clergy health programs utilized a blended format in which, for example, they had five weekend retreats spread over 18 months. It is notable that many clergy health programs lasted 12 months or more, which is considerably longer than most health programs.

2.6 Holistic health interventions

Based on epidemiological and other studies of clergy health, we selected metabolic syndrome to be our primary intervention endpoint, with stress and depressive severity as secondary endpoints. To maximally engage clergy, we designed a holistic health program. By broadening the program to include multiple aspects of physical health, mental health, and spiritual well-being, we achieved three advantages. First, a holistic health program is attractive to clergy, who generally define health holistically and see the relationships between mental, physical, and spiritual health [32]. For clergy, a focus on a single health condition or only physical health would be unattractive because it would be at odds with their own conception of health as holistic. Second, a holistic health stance removes stigma from Spirited Life that may otherwise exist if we focused only on obesity or depression. Mental health in particular is stigmatized for clergy [32], [38], and [39], despite the high depression rates clergy experience; a holistic health program allows participation without stigma. Third, holistic health content allows participants to enter the program with a focus on the personal health issues they most care about, even as they also receive intervention content aimed at our desired outcomes.

In addition, we sought to create a population-level rather than an individual-level intervention, partly because of the wishes of our funder and partly to respect the culture of the United Methodist Church, which is connectional in nature and focuses on the ministerial body as a whole rather than on individual pastors. These priorities on holistic health and a population-based program led us to create a program for all members of our population, regardless of health status. It also led us to create a program in which participants identify and set their own health goals. Although Spirited Life provides some uniform educational content and health behavior change strategies to all participants, it also allows participants to tailor the program to their individual needs, for example, through small grants and work with Wellness Advocates. Tailored interventions have been demonstrated to be more efficacious than unspecified interventions [40].

2.7 Relationship between weight and stress

Clergy have nearly ubiquitous exposure to chronic psychosocial stressors. The workplace is a primary source of stress exposure for nearly all individuals [41] and [42], because of the extended amount of time and

effort expended there [43]. However, the usual set of occupational stressors is magnified for many clergy, due to the highly interpersonal nature of their work paired with their status as moral leaders. This combination opens clergy up to personal criticism, family criticism, and presumptive expectations, and also leads to exceptional challenges of work-life balance and boundary ambiguity [12] and [44]. Moreover, clergy frequently work in situations that discourage taking breaks, and parishioners expect them to be available 24 hours a day [45] and [13]. Chronic stress has long been posited to influence dietary behaviors and weight gain. Exposure to chronic stressors alters hypothalamic-pituitary-adrenal (HPA) axis functioning, causing dysregulation in the secretion of the glucocorticoid hormone cortisol. A number of observational studies have demonstrated associations of cortisol dysregulation with visceral adiposity and obesity [46], [47], [48], and [49].

Chronic stress might also drive, via elevation in glucocorticoid secretion [50], the excess consumption of highly caloric, energy-dense "comfort foods" [51], increased consumption of which might be used as a behavioral coping strategy among those with excess stress exposure [52] and [53]. Such dietary behaviors may be functional; recent evidence suggests that comfort food consumption stimulates pleasure centers in the brain, thus regulating stress-induced systemic arousal [50]. Several prospective investigations have demonstrated positive associations between psychosocial stress and weight gain, in a range of populations and with up to 15 years of follow-up [54], [55], and [56].

Because of the possible relationships between stress and obesity via cortisol dysregulation, and stress and dietary behaviors, we hypothesized that targeting stress management and weight loss together would enhance weight loss, which in turn would contribute to a decrease in rates of metabolic syndrome. Relatively few studies have examined interventions with the dual primary aims of weight loss and stress management. In the best example we could find of an intervention focusing on both, Cox and colleagues compared a behavioral weight loss intervention to one with an additional emphasis on stress management [57]. They enrolled only women who had elevated stress levels. They found significant weight loss in both groups at 3 months, with significantly greater weight loss in the combination treatment arm. Interestingly, despite greater weight loss among participants who received stress management content, stress levels decreased equally in the two groups.

Other studies have examined weight change as a secondary outcome. Katzer and colleagues investigated the effects of a 10-week program focused on healthy eating and physical activity, versus the same program with additional relaxation response training that included meditation, mindfulness, and progressive muscle relaxation [58]. The group that received the additional relaxation response training lost more weight at 12 months than the group that received the healthy eating and physical activity training only. However, neither group experienced a significant pre-post change in weight at 12 months, which the authors attribute to their focus on overall health rather than weight loss per se. The combination group also experienced a greater reduction in depression. Daubenmier and colleagues created a 4-month intervention of mindfulness-based stress reduction and mindfulness-based eating awareness training to target stress eating [59]. The intervention group improved in anxiety and mindfulness compared to the control group, although there were no overall between-group differences in weight, abdominal fat, perceived stress, chronic stress, or cortisol awakening response. Nevertheless, in subgroup analysis, obese intervention participants maintained their body weight, in contrast with obese control participants who gained weight. Participants who improved in mindfulness and chronic stress reduced abdominal fat over time. Finally, Dalen and colleagues tested a 6-week group intervention on mindfulness stress reduction training [60]. There was no comparison group. Significant decreases were found three months later in weight, depression, perceived stress, and negative affect.

Overall, the studies that have attempted to promote change in both stress and weight outcomes have been relatively small, short-term pilot studies with highly selective, mostly female samples. Outcomes have been generally positive, but because of their limited follow-up, they do not address the challenge of promoting long-term behavior change. In some studies, participants in both intervention and comparison conditions lost weight, making it especially important to conduct studies with comparison groups. On a more hopeful note, the one study with weight loss as a primary outcome found greater weight loss among participants receiving the combined stress management and weight loss intervention. More evidence is necessary to determine whether interventions that combine stress management techniques with behavioral weight loss strategies can promote and sustain beneficial change in both outcomes.

The length of intervention may also play a critical role within the cycle of stress and sustained weight loss. It is possible that people who lose weight through an intervention are unable to sustain their weight loss partly because they are not adaptively responding to stress. With a maladaptive response to stress, they may experience elevated glucocorticoid secretion, and regulate it through consuming energy-dense foods. An intervention that successfully sustains weight loss may need to be long enough for participants to cycle through high- and low-stress periods and practice adaptive stress responses.

2.8 Background Summary

Clergy experience above average prevalence rates of obesity and chronic disease. They also experience high rates of depression and anxiety. Although physical and mental health are important to clergy, clergy also value spiritual well-being. Even though a number of programs exist that seek to bolster clergy health, few are being studied and none has been tested in a randomized controlled trial. For these reasons, we initiated the Spirited Life study.

3. Manuscript Outline

We spend the remainder of this manuscript detailing the Spirited Life study. We begin by describing its purpose, design, inclusion and exclusion criteria, recruitment and enrollment activities, research procedures, endpoints, and schedule of events from a participant's perspective. We then describe the Spirited Life intervention components, reflect on the strengths and limitations of our study and on program design choices, and connect the Spirited Life components to the Theory of Reasoned Action and Planned Behavior. Finally, we provide human subjects and clinical registry information and describe the current status of the study.

4. Purpose

To address the lack of rigorously tested clergy health interventions, we designed and are implementing the Spirited Life study to test whether a two-year holistic health program decreases rates of metabolic syndrome, depressive symptoms, and maladaptive stress responses among United Methodist clergy throughout North Carolina. The two-year program begins with an in-person, three-day workshop focused primarily on three things: 1) stress management, 2) a theological understanding of health, and 3) a theological rationale for why clergy ought to care for themselves. It continues with an online weight-loss program and monthly contacts with Wellness Advocates who utilize motivational interviewing to help participants set and progress on holistic health goals. Spirited Life includes two additional two-day workshops that reinforce the theological rationale; provide

additional content on stress management, weight-loss strategies, and health behavior change; and create opportunities for Spirited Life participants to interact with one another. In addition, all participants are screened for metabolic syndrome before, twice during, and at the end of the two years of intervention. At these screenings, participants from all study arms are provided verbal and written feedback on their health screening results.

5. Design

Spirited Life is an effectiveness study that uses a randomized, multiple baseline design to determine when participants will receive the intervention. Multiple baseline design studies are time-series studies for multiple cohorts; each cohort intentionally receives the intervention at a different time point [61] and [62]. Data are collected for each cohort, even when the cohort is not actively receiving the intervention. The combination of staggering the intervention timing and ongoing data collection allows researchers to examine differences in variables of interest between a cohort receiving the intervention and a cohort waiting to receive the intervention. Researchers can also examine trends in variables before and after receipt of the intervention. In particular, the trends observed in cohorts that have not yet received the intervention can be useful in understanding the patterns of extraneous variables [63] and [62]. The multiple baseline design has additional strengths, including increased confidence that changes in outcomes are a result of the intervention, if those outcomes are found for each cohort and occur across cohorts with consistent amounts of time elapsed [63]. For multiple baseline designs, it is highly recommended that individuals (or population groups) be randomly assigned to different starting points for the intervention [62] and [63], and we followed this recommendation. When random assignment is used, the multiple baseline design offers strong internal validity [62]. Nevertheless, there are a number of issues to consider, including the representativeness of the initial cohorts, the stability of measures at baseline, and autocorrelation in analyzing repeated measures [63].

In the Spirited Life study, we enrolled all possible participants and then randomly assigned them to one of three cohorts, whose intervention timing is staggered by one year each. Fig. 1 provides a simple initial illustration of these three cohorts, the timing of the start of their two-year intervention period, and our data collection schedule.

5.1. Inclusion and exclusion criteria

Our inclusion criteria were intentionally broad, given our goal to design a population-based intervention. We included pastors from the North Carolina United Methodist Church (UMC) Annual Conference and the Western North Carolina UMC Annual Conference who were elders, probationary elders, deacons, interim supply pastors, or local pastors in July 2010. We also included bishops, district superintendents, campus ministers, and clergy on Conference staff. Clergy could participate if they were full or part-time pastors, student pastors, non-United Methodist if they were serving a UMC church in one of the two NC Conferences, or if they were formerly retired pastors who were serving a church in July 2010. We excluded pastors on leave and extension ministers other than Conference staff and campus ministers. Clergy of any health status were allowed to participate.

5.2. Recruitment and enrollment activities

In September 2010, we conducted an extensive communication effort to inform all UMC clergy in the two NC Conferences about Spirited Life. We used the public UMC Conference directories to obtain names and contact information for all clergy who met inclusion criteria. We mailed each potential participant a colorful booklet describing the Spirited Life study. We also posted materials on our website and sent emails with the web link to all potential participants. We met with the clergy leadership, including the two bishops and the 27 district superintendents, to explain the study and encourage them to promote participation among clergy in their district. In addition, we held five webinars in which clergy could learn more and ask questions.

Interested clergy were prompted to enroll online. Enrollment consisted of a first step in which they entered their name and basic contact information, and a second step in which they were directed to an online consent form. Provisions were made to accommodate clergy without internet access. The enrollment window was limited to October 2010.

A total of 1,745 clergy were invited to participate in the Spirited Life study. Of these, 1,114 consented to the study and completed baseline data collection, resulting in a 64% response rate.

5.3. Research procedures

All participants, regardless of randomized cohort assignment, participate in biometric and survey data collection. The biometric data collection mimics a health screening and therefore can be considered an intervention in its own right. We measure participants' height, weight, and abdominal circumference; stick their finger for a cholesterol panel and HbA1c (a diabetes indicator test); and take their blood pressure three times, with a five-minute rest period in between each measure. We have established written protocols for this biometric data collection that staff adhere to strictly, and we routinely assess data collection procedures for quality assurance. The results of these biometric tests are written on a form that we give to the participant. This form includes a box showing the five indicators of metabolic syndrome and the gender-specific value that would signify risk for each indicator, using the International Diabetes Federation guidelines [8]. Staff write the participant's values for each of the metabolic syndrome indicators and make a check mark under one of two columns: "Normal?" or "Increased risk?". We then explain to each participant how his or her results relate to each of the five indicators of metabolic syndrome. This protocol is followed for participants in both the intervention and waiting cohorts. Thus, our control cohort can be conceptualized as a 'health screening only' cohort more than a no-intervention control cohort.

The survey is self-administered online. At each data collection time point, participants receive an email notification with their username and password and web link. During data collection windows of approximately two months, participants who have not yet taken the survey are reminded to do so via email several times and a final time by phone. We do not provide any feedback on participants' survey responses, but the act of taking the survey may raise their awareness of life aspects such as depression, anxiety, and stress.

5.4. Endpoints

This study's primary endpoint is a comparison of metabolic syndrome diagnosis rates between Cohort 1 and Cohort 3 at 23 months. Metabolic syndrome is measured through biometric data collection. Secondary endpoints are assessed in the survey taken at 23 months and include depressive severity measured by the Patient Health Questionnaire-9 (PHQ-9) [64], and stress severity measured by the Perceived Stress Scale [65]. The PHQ-9

consists of nine items on the frequency of depression symptoms during the past two weeks. Example items include: “Over the last two weeks, how often have you been bothered by”… “little interest or pleasure in doing things” and “feeling tired or having little energy.” We chose this measure because its items closely track the symptoms of depression identified in the *Diagnostic Statistical Manual of Mental Disorders* published by the American Psychiatric Association to diagnose depression [66]. The PHQ-9 has also been rigorously validated psychologists independently assessing patient depression through interviews and the researchers comparing those assessments to patient responses to the PHQ-9 instrument [22] and [64]. Based on these validation studies, it is possible to define depression using the PHQ-9 as a score of 10 or higher [22] and [64]. The Perceived Stress Scale is a ten-item measure designed to measure subjectively perceived stress [65] and [67]. An example item is, “In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?” The Perceived Stress Scale has been tested among large psychiatric and community samples and offers national norms [67] and [68].

5.5. Schedule of events

The flow of study activities is described in Fig. 2, and Fig. 3 summarizes the schedule of study activities from a participant’s perspective.

5.6. Intervention

5.6.1. Conceptual model

We utilized the Theory of Reasoned Action and Planned Behavior [69], drawing on the Integrated Behavioral Model [70], to conceptualize how Spirited Life would lead to changes in outcomes. The Theory of Reasoned Action and Planned Behavior proposes that behavior is influenced most importantly by intentions to behave a certain way. It further proposes that one’s behavioral intentions are influenced by three constructs, each of which has its own set of influencing constructs. First, intentions are influenced by attitudes toward the behavior. Those attitudes are, in turn, influenced by whether one expects that performing the behavior will lead to positive or negative outcomes and how strongly they believe it. Second, intentions are influenced by subjective norms, which are beliefs about whether most people approve or disapprove of the behavior. Subjective norms are influenced by whether one thinks that people who are important to them will approve or disapprove of the behavior, and how motivated one is to get approval from those people. Finally, intentions are influenced by perceived control, which is how sure one is that he or she can enact the behavior. Perceived control is influenced by one’s assessment of barriers and facilitators to enacting the behavior, paired with one’s perceived power over barriers. To this theory, we added some concepts from the Integrated Behavioral Model, namely, that behaviors are also affected by knowledge and skills, environmental constraints, and habit [70].

Our conceptual model for Spirited Life is depicted in Fig. 4. We hypothesize that our intervention programming will lead to improvements in metabolic syndrome, depressive severity, and stress levels by enhancing participants’ intentions to change behavior through the paths of changing their attitudes, subjective norms, and perceived control. We further hypothesize that increased knowledge, new or improved skills, environmental changes, and adopting new habits will lead to improvements in our three key outcomes. Detailed conceptual models for the specific outcomes of metabolic syndrome, depressive severity, and stress are available upon request.

During the intervention time period, participants assigned to each cohort receive approximately two years of intervention services. These intervention services consist of theological content delivered in workshops, Williams LifeSkills, Naturally Slim, Wellness Advocates, and small grants.

5.6.2. Theological Content Delivered in Workshops

We hypothesize that the health of clergy is worse than that of their non-clergy peers, because, in part, many clergy interpret their call to ministry to be all-encompassing and intertwined with self-sacrifice in such a way as to permit sacrificing their own health, if they believe that doing so is in the service of God. In Spirited Life, we sought to counter this theological reason for sacrificing one's health with a theological reason for caring for one's health. The theological aspect we emphasize is Incarnation. From the Christian perspective, the Incarnation (God's having become flesh in Jesus of Nazareth) has profound anthropological implications. In taking on human flesh, God declared our bodies good, honorable, and worthy of care. When health practices are inappropriate – leading to, for example, obesity – the problem is not only one of poor self-care, but also one of misremembering the depth of Incarnation.

We believe that clergy, in their busyness and role overload, may become removed from the theological lessons of the Sacred Text they once explored in-depth. Because they generally preach on some portion of the Sacred Text weekly, it remains an important aspect of their work, but we surmise that the demands of their work often prevent them from taking the lessons of Scripture to heart for their own lives. We designed the theological content of Spirited Life to enable pastors to reconnect with Scripture and theology. We urge them to consider their own well-being – physical, mental, and spiritual – in the context of the original formative immersion in Scripture and theology that once inspired their choice of the ministry as a vocation.

In addition, because the pastors in Spirited Life are United Methodists, we remind them of the founder of Methodism, John Wesley, whose understanding of health was, especially in its 18th century context, amazingly broad and practical. Wesley's book *Primitive Physick* took into account the best medical thinking of the time and was broadly distributed in Great Britain and America [71]. Wesley's book instructed the earliest Methodists on habits of diet and exercise that are still widely counseled today [72]. Following Wesley, Spirited Life offers pastors the opportunity to see caring for their health as an aspect of Christian stewardship: caring for their bodies is not selfish; to the contrary, it is respectful of the vessel God has chosen to bring Good News to the people. Thus, we encourage pastors to see their health theologically, and we deliver this content through in-person sermons and discussions during Spirited Life's three workshops.

To kick-off the two-year Spirited Life intervention, Cohort 1 pastors attended a three-day workshop in which they received information about the aims and rationale of Spirited Life, participated in worship services centered on the Wesleyan understanding of health and wholeness, and received training in the Williams Lifeskills method of stress management described below. This initial workshop was followed by a two-day workshop 7-10 months later, consisting of additional theological content aimed at deepening conversations on the concepts of Incarnation and the meaning of being embodied, as well as opportunities for pastors to articulate their core values and re-commit to their health goals. In addition, this workshop introduced the small grant awards available in the second year of the program, and allowed pastors to share their initial successes with one another. The third and final two-day workshop took place at the end of the two-year program and allowed pastors to reflect on and

celebrate their successes through worship experiences and facilitated group conversations, with the aim of helping them discern how to sustain their accomplishments in the future.

5.6.3. Williams LifeSkills

Williams LifeSkills (WLS) is a protocol-driven, manualized training program that improves stress coping and interpersonal relationship skills [73] and [74]. Based on principles of cognitive behavior therapy, it focuses on acquiring ten skills. The first six skills involve problematic situations: 1. Log keeping to increase awareness of thoughts and feelings in stressful situations; 2. Evaluation of those thoughts and feelings to decide between action or deflection; 3. Deflection; 4. Problem solving; 5. Assertion; and 6. Saying no. The additional four skills focus on interpersonal relationships: Speaking; Listening; Having empathy with others and oneself; and Increasing positives over negatives in one's encounters. For Spirited Life, we provided 12 hours of in-person content on these skills, consisting of both plenary speakers and small group sessions. The small groups were composed of 5-10 clergy and led by trained Wellness Advocates, who covered structured exercises in the use of each skill. We offered additional Williams LifeSkills content to Spirited Life participants two more times: we sent them a 70-minute DVD portraying dramatizations of the ten skills, with an accompanying workbook (or sent a link to online versions of these, if preferred), and participants were also prompted during a phone call with their Wellness Advocate in September of the first year to discuss a current stressor on the phone and apply the skills to it.

The WLS program was adopted as the stress management component of the Spirited Life program because it has proven effective in reducing stress indices in several clinical trials involving groups that are exposed to stressful life situations, although none previously with clergy. In a randomized controlled trial (RCT) in males following a heart attack, intervention participants experienced an immediate reduction in hostility and resting diastolic blood pressure [75], and, six months later, reductions in hospital stay and medical care costs [76]. In another RCT evaluating the LifeSkills workshop in coronary artery bypass surgery patients, those receiving LifeSkills training showed significant improvements in depression and anger, in satisfaction with life and with social support, and in blood pressure, both at rest and during an anger recall stressor; these improvements were greater at a three month follow-up [77]. An RCT of the LifeSkills Video in distressed community volunteers found significantly larger reductions in both trait-anxiety and perceived stress among the intervention arm participants compared to those randomized to a wait-list control, both two weeks and six months after the end of training [78]. Another RCT evaluating the LifeSkills Video adapted for caregivers of a relative with Alzheimer's Disease – a group exposed to chronic stressors similar in many respects to those experienced by clergy -- found that, compared those in the wait-list control group, those caregivers who used the LifeSkills Video for Caregivers augmented by weekly telephone coaching showed significantly greater improvements in depressive symptoms, trait anxiety, perceived stress and systolic and diastolic blood pressures that were maintained or extended over a six-month follow-up period [79].

5.6.4. Naturally Slim

The weight loss component of Spirited Life utilizes an online program called Naturally Slim Foundations. The Naturally Slim program lasts 10 weeks, with one video each week. It stresses eating only when one is hungry, cutting back on sugar in the diet, learning one's emotional needs, eating smaller portions, and balancing fats, proteins, and carbohydrates. Rather than promoting certain "diet" foods or large amounts of specific foods,

Naturally Slim Foundations encourages eating "regular" foods in moderation. The program also encourages the use of food diaries and daily walking.

All Spirited Life participants are encouraged to sign up for Naturally Slim. Participants in Cohort 1 were given the option of viewing the Naturally Slim Foundations videos starting in either April or May of 2011. Of the Cohort 1 participants, 80% watched one or more videos, and 34% watched all 10 videos. Participants who watched no videos or only one video were offered an additional chance to watch them starting in January of the second year. Naturally Slim also offers seven booster sessions called Naturally Slim Advanced, which repeats much of the original content and adds in new information on nutrition. Participants who had watched two or more of the original Naturally Slim Foundations videos were offered the chance to view the Naturally Slim Advanced videos in January of the second year.

5.6.5. Wellness Advocates

Every Spirited Life participant is assigned a Wellness Advocate. We named Wellness Advocates as such because "wellness" connotes well-being and holistic health, and "advocate" indicates someone who supports and works with a client, but does not "manage" clients or tell them what to do. We also chose "advocate" so that the title would resonate theologically with clergy. In the New Testament, "advocate" is a synonym for the Holy Spirit. The title Wellness Advocate thus aligns well with an intervention that we decided to call "Spirited Life." Pastors spend the majority of their lives in relationships with others, but often those relationships are one-way, with the support going out from the pastor to others. By entering into supportive relationships with pastors, Wellness Advocates reverse the direction of support. In addition, Wellness Advocates provide clergy with a confidential space often not otherwise readily available in the life of United Methodist pastors, who work in a close-knit connectional system, are often in the spotlight, and are held to high moral standards, making them feel vulnerable for even small shortcomings. With regular monthly telephone contact, participants and Wellness Advocates can develop strong, trusting relationships that allow clergy to speak frankly and honestly about their struggles to be healthy.

We based Wellness Advocates in part on a health coaching model. In general, health coaches utilize motivational interviewing [80] and [81] to help individuals establish goals and progress on them. Health coaching is a relatively new profession that has emerged through cross-disciplinary collaboration among executive coaches, life coaches, and health behavior change professionals (e.g., nurses, health educators, physicians). The body of literature supporting the efficacy of health coaching is still young, but a series of recent studies has provided evidence that health coaching is a promising intervention for changing important health behaviors [82], [83], [84], [85], and [86].

In Spirited Life, participants typically meet their assigned Wellness Advocate at the first workshop. Because the Wellness Advocates facilitate small group sessions at workshops, they often get to know participants well. The first workshops are three-day events held between January and March. Starting in April, Wellness Advocates develop or extend rapport with participants through one-on-one phone calls. Wellness Advocates utilize Motivational Interviewing, which is a participant-centered approach that attempts to help the client overcome ambivalence regarding problematic behavior [80]. Motivational Interviewing has been rigorously tested and found to be effective in dietary and physical activity changes [87], glucose control [88], and treatment adherence [89] and [90]. Wellness Advocates use Motivational Interviewing to elicit the participant's vision of

wellness and health goals, and to create an action plan to work toward those goals. They also encourage and celebrate the first steps toward change, discuss habit formation, and anticipate and help overcome barriers.

Wellness Advocates aim to develop the participant's own motivation and commitment to change by utilizing the participant's intrinsic resources. They work individually with participants to promote health literacy skills and enhance feelings of self-efficacy. Wellness Advocates provide temporary scaffolding to help participants learn to access trusted health information for themselves, and to advocate for their own health needs. The monthly phone sessions create an accountability structure to check in on progress, jump start action when it has stalled, and catch and address relapse before much time has elapsed.

In addition to working with Wellness Advocates on personal health visions and goal setting, participants can choose to draw on Wellness Advocates for resource support. Wellness Advocates research and identify specific resources requested by participants, and encourage participants to use that resource information. Participants may also treat their Wellness Advocates as a confidential sounding board in which Wellness Advocates use open-ended questioning, affirmations, reflective listening, and summarizing. In choosing Wellness Advocates, we generally avoided hiring people who themselves had served as pastors, because we did not envision the role as peer or professional support. However, Wellness Advocates receive extensive training on the issues clergy face, so clergy do not have to explain to Wellness Advocates the context and contours of the pastoral life. Although the role of Wellness Advocates is broad in many respects, their scope of practice is strictly limited; they do not serve as therapists or nurses and do not give medical advice or provide counseling.

Finally, because Wellness Advocates develop close relationships with many of the pastors in the intervention, they provide a personal link to the larger Spirited Life program, and reinforce other program components such as the weight loss strategies and stress management skills.

5.6.6. Small grants

During October and November of the first year of intervention services, participants are reminded that they can receive $500 to put toward achieving a health goal. They are encouraged to be creative and to revisit their health goal(s). Once they have ideas on how to spend the small grant, they are required to have a conversation with their Wellness Advocate, who must approve of their plan. Small grant expenditures must fall within seven of the therapeutic lifestyle changes shown to promote mental health: exercise, nutrition and diet, spending time in nature, relationships, recreation and enjoyable activities, relaxation and stress management, and religious and spiritual involvement [91]. Participants complete a brief application and receive a $500 check in February or March of the second year of intervention services. The small grant process is an opportunity for participants to revitalize their health goal(s) and tailor Spirited Life to their individual needs. In addition to the benefit that may come from the expenditure itself, we consider small grants to be key to maintaining motivation across a two-year intervention.

5.7. Design choices and consideration of strengths and limitations

Spirited Life is designed as an effectiveness trial, with the aim of measuring the real-world impact of providing a holistic health intervention to clergy. This principle led to several design choices that differentiate the design from an efficacy trial.

1. The study's inclusion criteria were broad and set by clergy status, not by health status. Some participants entered the study quite healthy and others quite unhealthy. Therefore, participants had different degrees to which they could improve their health.

2. We allowed participants to set their own health goals, which could relate to physical health, mental health, or spiritual well-being. This policy acknowledges that the goal of the clergy employer is a healthy pastorate, with health defined in its broadest sense. This policy also allows people to work on the aspects of health that most motivate them over the course of the intervention. Because of its holistic nature, the range of the intervention is broad, and the exact nature of the intervention varies from pastor to pastor. Some researchers have proposed that studies that take into account the holistic needs of people will forward the evidence-based intervention field faster and more effectively than focusing on a single behavior or outcome [92].

3. We did not require participation in all of the study aspects. For example, we encouraged all participants, regardless of their weight, to view the Naturally Slim weight loss videos. However, we did not require that they do so, which mimics real life. We offered a second opportunity to view the videos eight months later, and very few (16) participants took us up on this offer, suggesting that our initial request for them to view the videos would mimic actual participation outside of a trial. The result may decrease the outcomes in our trial.

4. We selected a randomized multiple baseline design in order to build in a randomized controlled trial while still having three passes at providing the intervention. The advantage of multiple intervention start times is that one can alter the intervention content with each cohort. We therefore had the ability to improve the intervention in each cohort without compromising the initial RCT. Fig. 1 displays the stability of the RCT, even if there are changes to improve the intervention from one cohort to the next, by depicting the multiple points of comparison between and within cohorts. For example, Cohort 2's intervention services can be evaluated by comparing their data to data from Cohort 3 (the waitlist cohort), although the time in which comparable data were collected will be offset by a year. Specifically, one can compare Cohort 2 data collected in November 2011, October 2012, April 2013, and October 2013 to Cohort 3 data collected in November 2010, October 2011, April 2012, and October 2012. Cohort 3's intervention services can be evaluated by comparing Cohort 3 individuals to themselves using an interrupted time series analysis with data from four pre-intervention time points and data during and at the end of Cohort 3's intervention services. Alternatively, any individual time point from Cohort 3 can be compared to a similar time point offset by two years (i.e., November 2010, September 2011, April 2012, and October 2012 pre-services can be compared to November 2012, October 2013, April 2014, and October 2014 during services).

5. The use of a randomized design within a population whose members know each other always runs the risk of spillover effects. The same is true for this study, in which UMC clergy across North Carolina gather several times per year for communication and training. It is likely that participants in Cohort 1 discussed the knowledge and skills they gained from Spirited Life with participants in the other cohorts.

6. Human Subjects Protection and Ethical Approvals

This protocol has been approved by the Duke University Institutional Review Board (IRB) (#ProA0208). During the approval process, we gave particular consideration to informing participants of their biometric screening results, including but not limited to out-of-range values. We also attended closely to issues of confidentiality among pastors and between pastors and their clergy supervisors.

7. Funding and Registry

Spirited Life is funded by The Duke Endowment as part of the Duke Clergy Health Initiative. It is registered in ClinicalTrials.gov (NCT01564719).

8. Current Status and Baseline Data

Enrollment for Spirited Life occurred in October 2010. Participants completed the baseline survey and biometric data collection in November-December 2010, with accommodations made for some participants by extending biometric data collection into 2011 but prior to receipt of any intervention services. In December 2010, we randomized consented participants to the three cohorts. The initial sample sizes from January 1, 2011 were: Cohort 1, 395; Cohort 2, 283; and Cohort 3, 436, for a total of 1,114 participants. We intentionally made Cohort 3 the largest, in case attrition occurred during the two years they waited for services. We also made Cohort 1 larger than Cohort 2 to provide statistical power, since only Cohort 1 counts as the intervention group to compare to the waiting Cohort 3. Table 1 provides baseline data by cohort. The baseline data indicate that randomization was successful for every variable except proportion depressed. In outcome analyses, rather than examining change in proportion depressed, it will be important to examine the change in mean depression scores among those who were depressed at baseline.

For participants to remain in the study, we required that they participate in the first workshop, of which we offered nine for Cohort 1 between January and March 2011, and nine for Cohort 2 between January and March 2012. We plan to offer six for Cohort 3 between January and March 2013. We withdrew some participants who did not attend the required workshop. All participants are free to withdraw from the study at any time, but withdrawal rates have been low. As of February 2013, 1,034 participants (92.4%) were still enrolled. We will continue to collect data and provide intervention services through the end of 2014.

9. Conclusion

Outcomes from the Spirited Life study will be of interest to at least three sets of people: those seeking to promote the health of clergy, those interested in weight loss trials, and those interested in holistic health interventions. For people seeking to promote the health of clergy, the Spirited Life study, if successful, could literally point the way to keeping church doors open. The health care costs of clergy have risen so high that a bishop in North Carolina recently estimated that he closes 10-14 churches each year whose congregants can no longer afford the cost of their pastor's health insurance. Denominational benefits providers are grasping for ways

to improve the health of clergy, and Spirited Life represents the first randomized trial of a health intervention tailored to clergy.

Second, this is one of few randomized trials that we know of which combine stress management with a weight loss program. As noted earlier, one hypothesis is that people who lose weight are unable to sustain their weight loss partly because they are not adaptively responding to stress, and when they hit periods of high stress, they return to higher caloric intake and a metabolic process that leads to weight increases. We will be able to study Spirited Life participants for 18 months after the intervention ends, and thus will be able to determine if, and when, weight gain occurs.

Spirited Life is additionally one of few long-term trials. Long-term interventions with rigorous study are needed to understand making and sustaining changes in weight and metabolic syndrome [93]. As such, Spirited Life will also provide data that can inform weight loss interventions and metabolic syndrome interventions more generally.

Finally, while many researchers have considered the possible benefits of combining physical health, mental health, and spiritual well-being into a single intervention, there are few large-scale trials that have tested this approach. Spirited Life pushes certain content to participants during workshops, but otherwise allows participants to determine and direct their own health goals and activities, bolstered by a personal relationship with a Wellness Advocate who uses Motivational Interviewing. We will be able to determine the impact of this approach on multiple health outcomes. We hope the result will be a healthier pastorate, and a wealth of information that will benefit diverse behavior change researchers.

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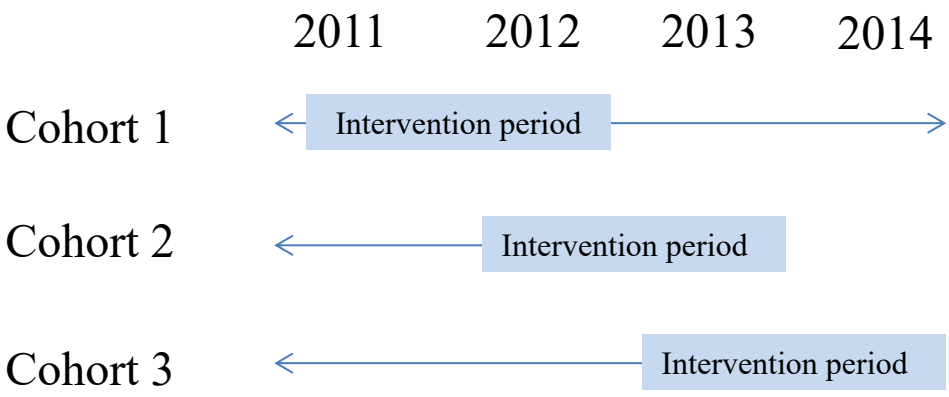

Fig. 1. Intervention and data collection periods by cohort. The arrows indicate the time range of data collection, whereas the boxes indicate the time periods of intervention services.

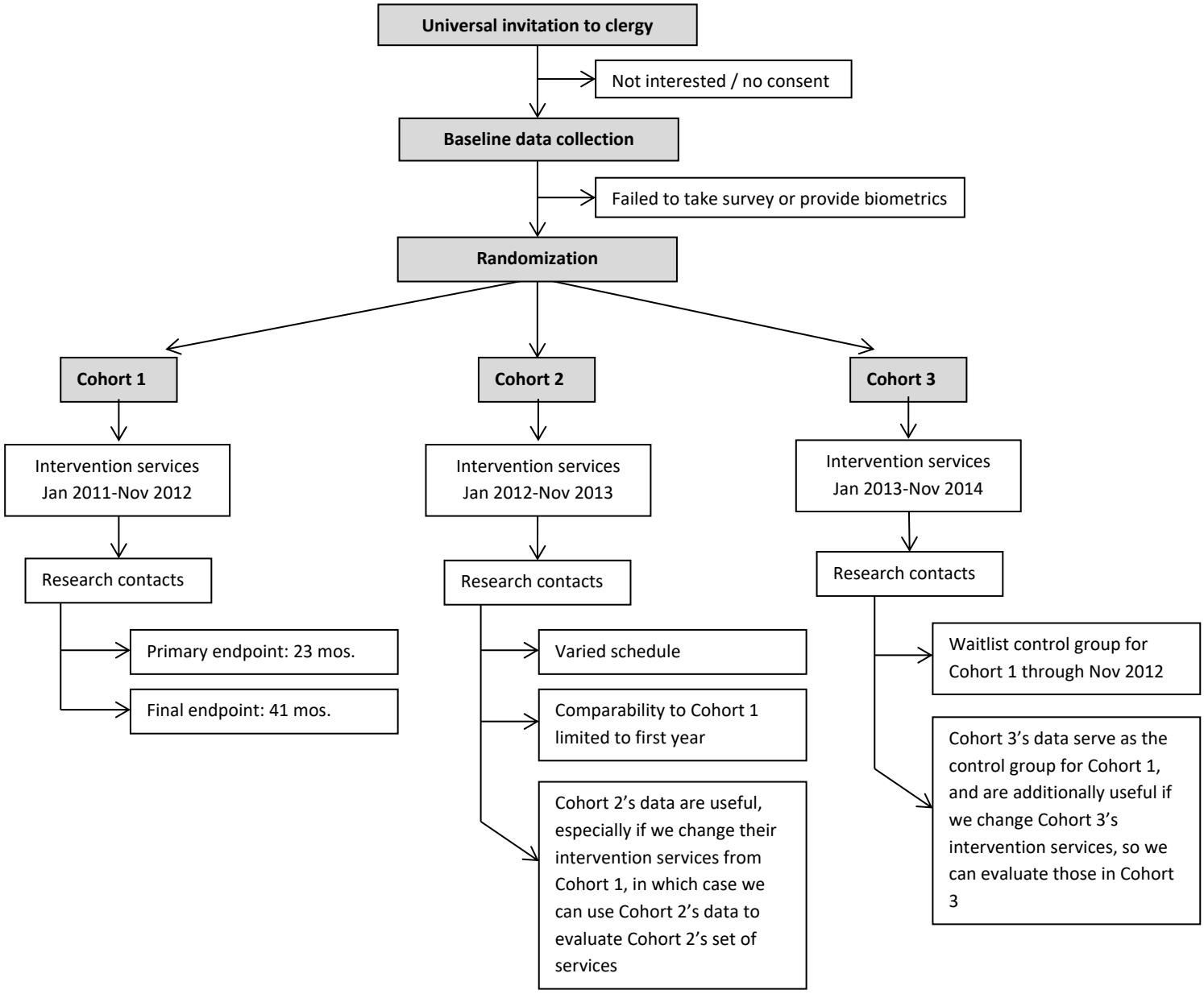

Fig. 2. Flowchart of study activities by cohort.

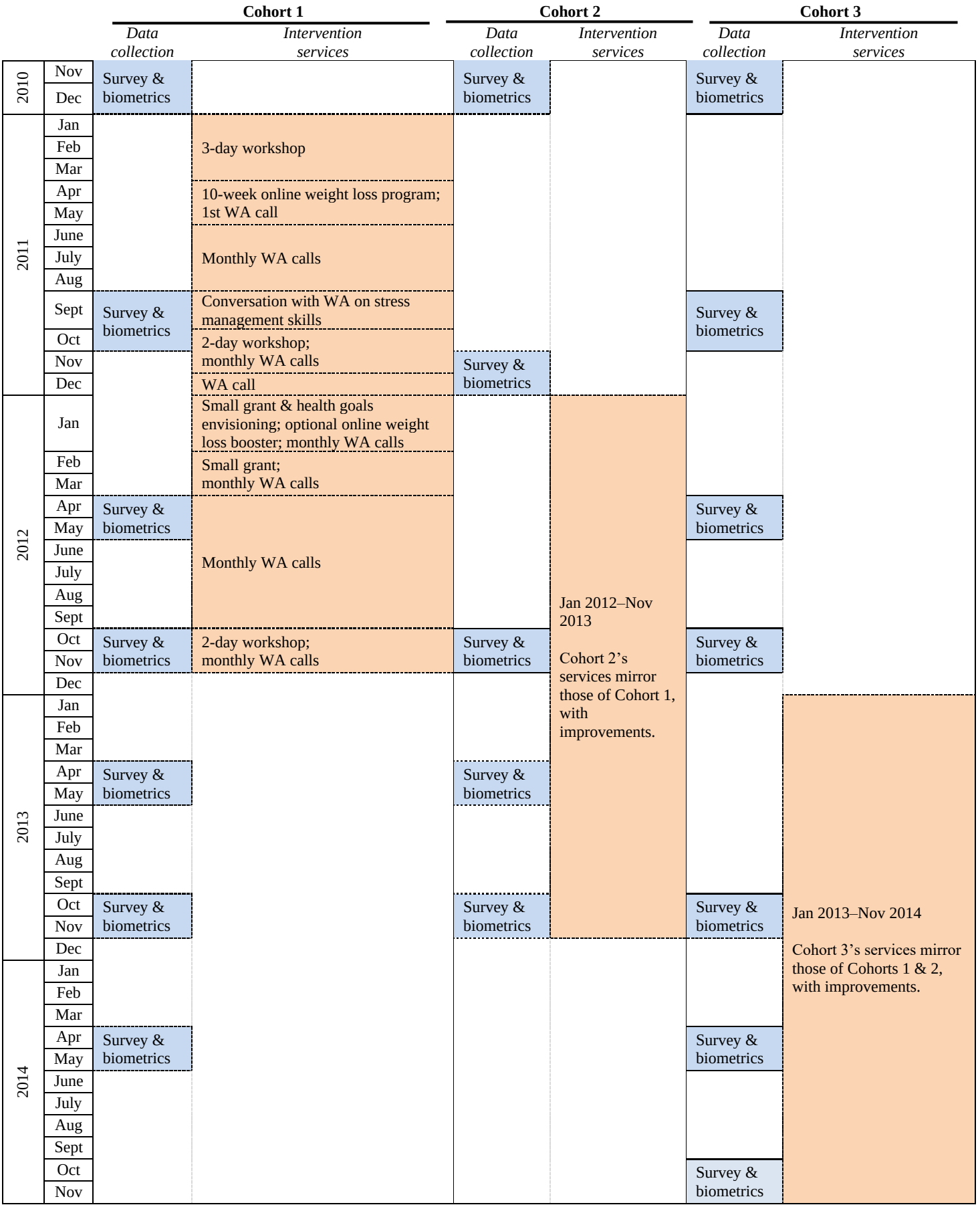

Fig. 3. Timing of data collection and intervention services by randomized cohort. WA = Wellness Advocate.

Table 1
Baseline characteristics of the Spirited Life analytic sample (N=1,114)

Variable	Cohort 1 percent (n)	Cohort 2 percent (n)	Cohort 3 percent (n)	Signifi-cance test[a]
Gender				*p*=0.89
Male	68.6 (271)	70.3 (199)	69.3 (302)	
Female	31.4 (124)	29.7 (84)	30.7 (134)	
Race				*p*=0.95
White	89.9 (355)	89.1 (252)	89.7 (391)	
Black	6.6 (26)	6.4 (18)	6.0 (26)	
Other	3.5 (14)	4.6 (13)	4.4 (19)	
Maximum education				*p*=0.32
<15 years	5.8 (23)	8.8 (25)	9.9 (43)	
College	9.6 (38)	7.8 (22)	9.6 (42)	
Master's	72.2 (285)	71.0 (201)	69.3 (302)	
Doctorate	11.9 (47)	12.4 (35)	11.2 (49)	
Unknown	0.5 (2)	0.0 (0)	0.0 (0)	
Marital status				*p*=0.66
Currently married	86.8 (343)	87.6 (248)	86.9 (379)	
Not currently married[b]	12.4 (49)	12.4 (35)	12.2 (53)	
Other	0.3 (1)	0.0 (0)	0.7 (3)	
Unknown	0.5 (2)	0.0 (0)	0.2 (1)	
Rural / urban status[c]				*p*=0.36
Rural	30.5 (120)	34.3 (97)	34.9 (152)	
Urban	69.5 (274)	65.7 (186)	65.1 (284)	
Unknown	0.3 (1)	0.0 (0)	0.0 (0)	
Average weekly church attendance				*p*=0.51
0-50	17.0 (67)	14.5 (41)	19.5 (85)	
51-100	24.6 (97)	25.8 (73)	29.1 (127)	
101-350	34.7 (137)	34.3 (97)	28.9 (126)	
351-1000	12.2 (48)	11.0 (31)	11.5 (50)	
>1000	2.0 (8)	2.1 (6)	2.1 (9)	
Unknown	9.6 (38)	12.4 (35)	8.9 (39)	

BMI status				p=0.99[d]
Obese	48.4 (191)	46.6 (132)	46.6 (203)	
Overweight	33.7 (133)	34.6 (98)	35.6 (155)	
Normal weight	17.2 (68)	18.0 (51)	17.2 (75)	
Underweight	0.3 (1)	0.4 (1)	0.5 (2)	
Unknown	0.5 (2)	0.4 (1)	0.2 (1)	
Metabolic syndrome				p=0.78
Qualifies	34.6 (136)	36.2 (102)	36.9 (161)	
Unknown	0.5 (2)	0.4 (1)	0.0 (0)	
Depression				
Proportion with PHQ-9 score 10+	15.5 (61)	11.3 (32)	8.3 (36)	**p < 0.01**
Unknown	0.5 (2)	0.0 (0)	0.0 (0)	
	Mean (SD, n)	**Mean (SD, n)**	**Mean (SD, n)**	
Age (years)	51.4 (9.9, 384)	51.7 (10.0, 273)	52.8 (9.9, 419)	p=0.98
Weight (pounds)	209.5 (52.2, 393)	206.9 (52.6, 282)	208.0 (51.7, 435)	p=0.98
BMI (kg/m^2)	31.4 (7.6, 393)	30.8 (7.3, 282)	30.8 (7.1, 435)	p=0.63
Perceived Stress Scale	13.0 (6.3, 393)	12.5 (6.1, 283)	12.5 (6.1, 432)	p=0.79
Depression				
Mean PHQ-9 score	4.8 (4.7, 393)	4.2 (4.3, 283)	4.0 (3.8, 436)	**p=0.02**
Mean PHQ-9 score if score is 10+	13.4 (3.5, 61)	13.5 (3.9, 32)	12.9 (3.1, 36)	p=0.57

a: Significance tests for categorical variables are χ^2 and for continuous variables are homogeneity tests for variance of means.

b: "Not currently married" includes single, divorced, and widowed.

c: Rural/urban status is a self-report survey item of one's church appointment setting, in which rural is "rural or open country" and urban is one of four "town" or "city" options of various population sizes.

d: For the significance test of differences between proportions, we combined the underweight and normal weight data and excluded missing values to avoid small cell sizes.

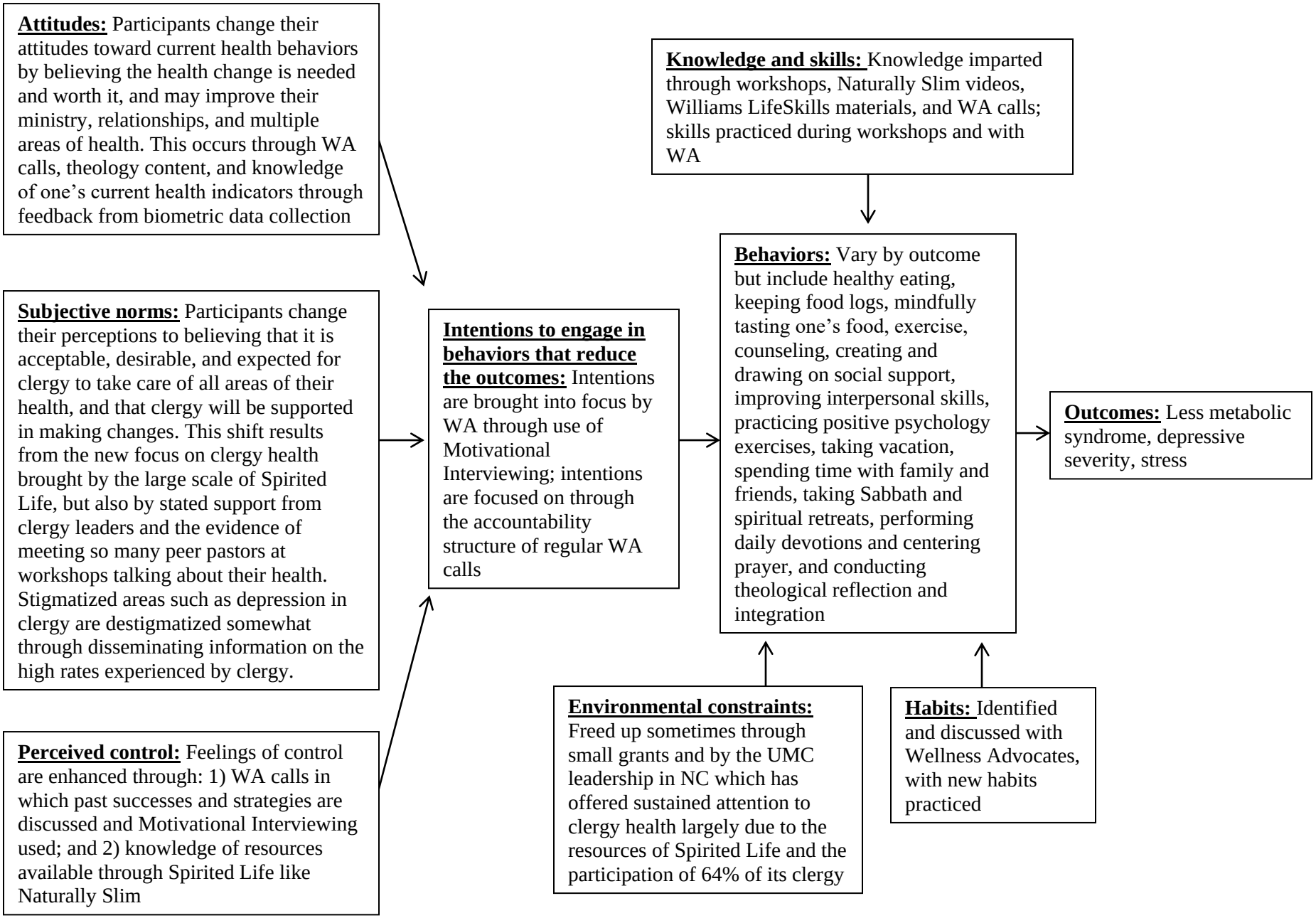

Fig. 4. Spirited Life conceptual model.