

**Pragmatic Implementation Trials:
Understanding the Integrated Research-Practice Partnership Approach
to Lifestyle Obesity Management Across a Transforming Health System**

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ABSTRACT

Obesity is one of the most significant, complex health problems facing U.S. health systems. Driving the growing prevalence of chronic diseases, obesity challenges health systems' ability to achieve its triple aims: improved patient experience, reduced costs, and improved population health. Along the continuum of obesity care, evidence-based lifestyle obesity management, including diet, physical activity, and intensive behavior therapy, is the first line of recommended treatment. However, there is a paucity of evidence-based care delivered to achieve and maintain clinically, meaningful weight loss (i.e., $\geq 3\text{-}5\%$ initial body weight). Integrated research-practice partnerships are a potential mechanism to advance the translation of evidence-based interventions into real-world settings, particularly the transforming healthcare sector. The overall purpose of this dissertation was to develop a greater understanding of how an integrated research-practice partnership approach facilitates and sustains evidence-based lifestyle management strategies across a healthcare system to treat obesity among patients and employees.

From 2013-2016, a series of pragmatic, implementation trials were conducted by teams of interdisciplinary obesity researchers, health system administrators, and program delivery staff. Using the Integrated Research-Practice Partnership Participatory Model, the teams tested strategies for delivering weight loss or weight loss maintenance support adapted from the national Diabetes Prevention Program. Featured trials included studies that focused on: 1) *assessment, prioritization, and engagement of patients through the assessment of behavioral and psychosocial issues during*

chronic care visits, 2) choice and shared decision-making for weight loss maintenance, 3) behavioral strategy integration in existing medically supervised weight loss programs, and 4) action planning and consultation to support nurse care coordinator delivery of evidence-based strategies to support patient weight loss. Guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework, a mixed-methods evaluation detailed implementation processes and analyzed implementation outcomes. For processes, priorities influencing decision-making of strategy selection, adaptations made during implementation, and contextual factors were reported. For outcomes, a RE-AIM summary table highlighting results from each trial was produced.

A synthesis of trial findings offered empirical evidence for the value of the integrated-research practice partnership approach as a translational solution to obesity care gaps. A *shared* priority perspective between research and practice was identified as a mechanism for facilitation and sustainability. The partnership approach supported the following criteria of translational potential: 1) feasibility of implementation as designed, 2) maintenance of critical elements of the evidence-based principles of comprehensive lifestyle obesity management, 3) achievement of clinically, meaningful weight loss, and 4) sustainability of strategy within the system. Each of the tested strategies had strong potential to reach a high proportion of at-risk patients and healthcare employees, effectively supported weight loss, achieved setting and staff-level adoption, were able to be successfully implemented as intended at a reasonable cost, and exhibited potential for individual and organizational-level maintenance. Overall, relevant, local evidence was produced to inform the future development and implementation of a broad-reaching lifestyle obesity management system for patients and healthcare employees.

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GENERAL AUDIENCE ABSTRACT

Obesity, a condition of excess body fat, is one of the most complex problems facing health systems. Lifestyle management programs that combine diet, physical activity, and intensive behavioral therapy have been shown by research to support a degree of weight loss that produces health benefits (i.e., at least a 3-5% initial body weight). However, it has been difficult for research-developed programs to be delivered in typical practice to have a meaningful impact. Integrated research-practice partnerships that involve the coming together of academic researchers, health system administrators, and program delivery staff may help overcome this gap, especially during this transformational time in the healthcare sector. This dissertation aimed to develop an understanding of how using the integrated research-practice approach would facilitate and sustain evidence-based lifestyle management strategies across a health system to treat obesity among patients and employees.

An integrated research-practice partnership with Carilion Clinic, a health system in western Virginia, served as an example for the study. From 2013-2016, the Carilion Clinic integrated research-practice partnership conducted a series of trials testing different strategies for delivering weight loss and weight loss maintenance support. An evaluation guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework was conducted to describe implementation processes and outcomes for each strategy. Lessons learned from the

evaluation support the value of the integrated-research practice partnership approach as a solution for overcoming gaps in obesity care. A *shared* priority perspective between research and practice was identified as the powerful process for supporting facilitation and sustainability of strategies. In addition, findings from the evaluation produced evidence to inform the future development of a system for Carilion Clinic to help patients and employees lose weight and keep it off through lifestyle management.

Dedication

With a heart of gratitude, I dedicate this dissertation:

To the patients and communities of
Delaware, Maryland, North Carolina, Pennsylvania, Virginia, and West Virginia
who I've had the privilege to serve and learn from over the past 20 years,

To my many mentors and colleagues at Mount Saint Mary's, Delaware Tech,
West Virginia University, FirstHealth of the Carolinas, Virginia Tech, and Carilion Clinic who
inspired and have kept the spirit alive in my lifelong journey in health promotion, and

To my Mom and Dad who nurtured my development as a student and
instilled the value of education and service as paths for a life well-lived.

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Throughout my dissertation journey, I analogized the experience as a marathon. From the starting line to the finish line, I was blessed with tremendous coaching services, training plans, and course support from a dedicated team of individuals. I experienced the joy of a "runner's high" as I acquired new research skills, trials materialized, and dissertation milestones were achieved. My pacers were instrumental in helping me meet the target times while simultaneously being enjoyable, thoughtful, running companions. I also, late in the race, experienced the common marathon despair of "hitting the wall". Thankfully, my aid station crew patiently helped me refuel and push through those final miles of analyzing data, making meaning of results, and writing manuscripts. My family and friends lovingly served as a cowbell ringing, spirit squad supporting the effort chapter by chapter. I will be forever appreciative to all members of my team for their active role in my qualifying academic exercise to become a Hokie PhD. The following list highlights the many team members that contributed advice, time, inspiration, and support to this final dissertation product. Together, we may exclaim, like the legendary long-distance messenger Pheidippides on his arrival from Marathon to Athens, "*Rejoice, we conquer!*".

Coaching and Training – My advisor, Dr. Paul Estabrooks, and dissertation committee members: Dr. Fabio Almeida, Dr. Mark Greenawald, Dr. Wendy You, and Dr. Jamie Zoellner; Faculty from the Fralin Translational Obesity Research Center Interdisciplinary Graduate Education Program and Virginia Tech Department of Human Nutrition, Foods and Exercise (HNFE).

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Preface

integrate

[in-ti-greyt]

Verb

~ "To bring together and unite parts" (Webster, 2014)

The heart of this dissertation is about integrated research-practice partnerships. The featured trials involved the bringing together of multiple investigators, healthcare system administrators, and practice delivery staff at Carilion Clinic. Each team was co-led by Dr. Paul Estabrooks, a behavioral and implementation scientist, and Dr. Mark Greenawald, a primary care physician and Vice Chair of Research and Academic Affairs for the Department of Family and Community Medicine. In addition, several graduate, medical, and undergraduate students helped with data collection and intervention delivery.

In each trial, I was an active member of the research-practice partnership and participated in project prioritization. I also coordinated each of the dissertation studies while serving in various additional roles from a health coach, trainer, dual energy x-ray absorptiometry technician, or program evaluator. I led the systematic documentation of each trial's implementation journey, serving as first author of research study briefs and manuscripts included in the dissertation chapters. By uniting this series of studies, I aspire for our findings to contribute to the growing empirical evidence for use of the research-practice partnership approach. Most importantly, I hope to provide actionable, practice-based evidence to support my Carilion Clinic partners in developing a comprehensive system of evidence-based care for obesity, one of healthcare's most complex, 21st century challenges.

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Abbreviations and Acronyms

Abbreviation/Acronym	Meaning
AHA	American Heart Association
ACC	American College of Cardiology
ANOVA	Analysis of variance
5As	Assess, Advice, Agree, Assist, and Arrange
BMI	Body mass index
BP	Blood pressure
CBT	Cognitive behavioral therapy
CDC	Centers for Disease Control and Prevention
CHE	Community health educator
CME	Continuing medical education
CMS	Centers for Medicare and Medicaid Services
DHSS	Department of Health and Human Services
DPP	Diabetes Prevention Program
DXA	Dual energy X-ray absorptiometry
EHR	Electronic health record
HRA	Health risk assessment
HRV	Healthy Roanoke Valley
IOM	Institute of Medicine
IRB	Institutional Review Board
IT	Information technology
Kcal	Kilocalories
LPN	Licensed practice nurse
MOA	Medical office associate
MOHR	My Own Health Report
MUA	Medically underserved areas
NIH	National Institutes of Health
PA	Physical activity
PCP	Primary care provider
PRO	Patient-reported outcomes
RD	Registered dietician
RCT	Randomized controlled trial
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RN	Registered nurse
SD	Standard deviation
S.M.A.R.T.	Specific, Measurable, Action-oriented, Realistic, and Time-based
TSG	Technology Support Group
TOS	The Obesity Society
U.S.	United States
USPSTF	United States Preventive Services Task Force

Section 1 – Background and Overview of Approach

Chapter 1: Background

Lifestyle and Obesity Epidemic

Scope and Consequences of the Problem

Eating the proper amount of nutritious foods, engaging in regular physical activity, and maintaining a healthy body weight over a lifetime positively influences health and wellness (U.S. Department of Health and Human Services [DHSS], 2010). However, most Americans are challenged to adhere to evidence-based, nutrition and physical activity guidelines and successfully manage their weight (Benjamin, 2010; Fisher et al., 2011). Complex interactions between biological, psychological, economic, and social variables contribute to the difficulties Americans face in adopting and maintaining a healthy lifestyle (Friedman, 2009; Froot, Johnston, Matteson, & Finegood, 2013). In a modern culture that promotes an overabundance of unhealthy food options and sedentary behavior, achieving caloric balance, weight loss, and weight loss maintenance becomes an arduous task (Kohl et al., 2012; Swinburn et al., 2011). As a result of both challenging individual and environmental conditions, the United States (U.S.) is facing an unprecedented, national obesity epidemic (Mitchell, Catenacci, Wyatt, & Hill, 2011; Ng et al., 2014; Ogden, Carroll, Fryar, & Flegal, 2015).

Behavioral surveillance strongly associates unhealthy eating and inactivity with America's obesity epidemic. Surveys by the Centers for Disease Control and Prevention (CDC) indicate that only 33 percent of adults consume the recommended servings of fruits and only 27 percent of adults consume the recommended servings of vegetables in dietary guidelines (Moore & Thompson, 2015; Ollberding et al., 2012; National Prevention Council, 2011). Besides a lack of fruit and vegetable consumption, Americans' dietary patterns are typically too low in whole grains and low-fat dairy, too high in refined grains, saturated fat, added sugars, and sodium, and exceed recommended daily

calories (McGuire, 2011). Moreover, only 20 percent of adults are meeting physical activity recommendations (i.e., at least 150 minutes of moderate-level aerobic activity; and at least two days of muscle-strengthening exercise for at least 15 minutes a week) (CDC, 2013a). Modern technologies have transformed Americans' daily life to be dominated by sedentary activities, such as computer use and driving, and work and life stresses are frequently cited as competing priorities over physical activity participation (Pratt, Norris, Lobelo, Roux, & Wang, 2014).

Based on Body Mass Index (BMI), more than one-third (35 percent) of the U.S. adult population is categorized as obese ($BMI \geq 30 \text{ kg/m}^2$) (Ogden et al., 2015). This percentage has grown drastically over the past 25 years (Flegal, Carroll, Ogden, & Curtin, 2010; Levi, Segal, Laurent, & Vinter, 2010). In 1990, no state had an obesity rate over 15 percent (Freedman, Khan, Serdula, Galuska, & Dietz, 2002). In 2015, more than two thirds of states have obesity rates over 25 percent (Ogden et al., 2015). By 2030, it's predicted every state in the country will have obesity rates ranging from 44 percent to more than 60 percent (Finkelstein et al., 2012). These rates have increased in all segments of society, particularly African American and Latino women, individuals living on low-income, adults who did not graduate from high school, Baby Boomers (born between 1946 and 1964), and those who living in the South and Midwest states (Befort, Nazir, & Perri, 2012; Ogden et al., 2010). Also, with these increasing rates, there is great concern that the current six percent prevalence of individuals classified as severely obese ($BMI \geq 40 \text{ kg/m}^2$) is projected to increase by 130 percent over the next two decades (Finkelstein et al., 2012).

As a highly prevalent problem, obesity poses significant health, financial, and social consequences (McGuire, 2012; Puhl & Heuer, 2010; Wang, McPherson, Marsh, Gortmaker, & Brown, 2011; Withrow & Alter, 2011). Related to health, obesity is classified as a multi-metabolic and hormonal disease state by the American Medical Association (AMA, 2013). Classified as a disease or a risk factor, obesity unfavorably impacts morbidity and mortality (Church, 2014). From

osteoarthritis to sleep apnea, obesity is associated with increased risk for over 60 diseases (Hruby & Hu, 2015). During the next two decades, incidence in obesity-related diseases is anticipated to rise steeply (Levi et al., 2010). Specifically, six million new cases of Type 2 diabetes are expected (Wang et al., 2011). In addition, five million new cases of coronary heart disease and stroke (Mozaffarian et al., 2015) and more than 400,000 new cases of cancer (Siegel, Miller, & Jemal, 2015) will be associated with obesity. Besides disease risk, obesity also contributes to fertility and surgical complications (Downs, 2016; Hruby & Hu, 2015). Due to these deleterious impacts on health, obesity is the U.S.'s second leading cause of preventable death, associated with increased risk in all-cause and cardiovascular disease mortality, and is expected to surpass tobacco use in the near future (Wang et al., 2011).

Financially, obesity exacts a tremendous price on national healthcare spending, the workforce, and individuals' expenses (Bilger, Finkelstein, Kruger, Tate, & Linnan, 2013; Spieker & Pyzocha, 2016). Overall, the direct and indirect cost of obesity is estimated to be more than \$275 billion annually (Hammond & Levine, 2010). The estimated annual cost of obesity-related illness in the U.S. is between \$147-\$210 billion (Cawley & Meyerhoefer, 2012; Spieker & Pyzocha, 2016). Obesity accounts for an estimated ten to 21 percent of total annual medical spending (Withrow & Alter, 2011). Typically, individuals with obesity have annual healthcare costs averaging approximately 40 percent higher than those individuals who are normal weight (BMI=18.5-24.9 kg/m²) (Finkelstein, Trogdon, Cohen, & Dietz, 2009). Individuals with severe obesity (BMI \geq 35kg/m²) are reported to account for more than 40 to 60 percent of total costs of obesity (Finkelstein et al., 2012; Wang et al., 2015). The increased costs associated with obesity places an economic burden on both public and private healthcare payers (Withrow & Alter, 2011). In the workplace, workers with obesity have been reported to have higher rates of absenteeism, presenteeism, and cost employers more in medical, disability, and workers' compensation

(Finkelstein, 2014; Spieker & Pyzocha, 2016). Furthermore, the U.S. diet industry is a profitable business. Each year, Americans spend more than an estimated 40 billion dollars on diets and supplements in an attempt to lose excess weight (Hoffman & Saleno, 2012).

Socially, obesity has immediate and long-term consequences threatening the well-being of individuals and society (Mitchell et al., 2011). Across a variety of domains, examples of aversive social consequences of obesity include: a) discrimination in employment, b) barriers in education, c) biased attitudes from healthcare professionals, d) stereotypes in the media, and e) stigma in interpersonal relationships (Puhl & Heuer, 2010). All of these factors threaten to reduce quality of life for vast numbers of American who are obese (Dietz, 2011). Furthermore, obesity jeopardizes the readiness and competence of the American workforce (Finkelstein, 2014). Employment sectors requiring physical fitness, such as emergency medical response and military service, are faced with smaller, eligible applicant pools and are challenged to maintain a workforce fit to safely and efficiently perform duties (Cawley & Maclean, 2012).

To reverse the obesity epidemic and its consequences, both prevention and treatment is deemed necessary (Dietz, 2011; MacLean et al., 2015). From a biomedical perspective, advanced interventions targeting specific physiological causal mechanisms at the level of the individual are needed (MacLean et al., 2015). From a socio-ecological perspective (McLeroy, Bibeau, Steckler, & Glanz, 1988), multi-level interventions are needed to target both individual behavior change, social determinants of health, and environmental factors (McGuire, 2012). A combination of programs, systems, policies, and environmental changes that promote healthful eating and physical activity can aid in preventing obesity and sustaining weight loss (Dietz, Solomon, et al., 2015). **For Americans already classified as obese, there is an overwhelming need for effective, clinical treatment services that support substantial weight loss and long-term weight loss maintenance** (Dietz, Baur, et al., 2015).

Evidence-Based Lifestyle Obesity Management

Critical Intervention Elements

Over the past three decades, scientific evidence has been mounting of efficacious strategies, delivery approaches, and treatment models for changing diet and physical activity for weight control (Pi-Sunyer et al., 1998; Wadden, Webb, Moran, & Bailer, 2012). Rigorous systematic reviews and clinical guidelines summarize the current body of evidence with a strong grade and quality ratings for comprehensive lifestyle interventions (US Task Force on Preventive Services [USTFPS], 2012; Jensen et al., 2014). As shown in Figure 1., evidence-based components of comprehensive lifestyle interventions include diet, physical activity, and behavior therapy. In comparison to usual-minimal care (i.e., providing limited advice or educational materials) or no-treatment control, comprehensive lifestyle interventions are reported to produce up to eight kilograms (18 pounds) of weight loss in six months (Jensen et al., 2014). This level of weight loss is approximately a reduction of five to 10 percent of initial body weight.

Based on this scientific evidence, target levels and rate of weight loss recommendations exist for lifestyle interventions for obesity (Jensen et al., 2014). The percentage of sustained weight loss from initial body weight decreases the severity of obesity-associated, cardio-metabolic risk factors. Modest, sustained weight loss of three to five percent results in clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1c (HbA1c), and the risk of developing type 2 diabetes (Wing et al., 2011). Greater amounts of weight loss (i.e., five to 10 percent) reduce blood pressure (BP), improve low-density lipoprotein cholesterol and high-density lipoprotein cholesterol, and may reduce the need for medications to control BP, blood glucose, and lipids (Kushner, 2014). Setting a realistic, achievable weight loss goal of 10 percent initial body weight is advised (Jensen et al., 2014). Further weight loss may be considered after this initial goal is

achieved and maintained for six months (Jensen et al., 2014). According to guidelines, an initial marked weight loss greater than 10 percent, that is unable to be sustained, is deemed counterproductive in terms of time, costs, and individual's self-esteem (Jensen et al., 2014).

To achieve a clinically meaningful weight loss, the 2013 American College of Cardiology (ACC), American Heart Association (AHA) Task Force on Practice Guidelines, and The Obesity Society (TOS) *Guideline for the Management of Overweight and Obesity in Adults*, along with United States Preventive Services Task Force (USPSTF), and Guide to Community Preventive Services, recommend that primary care providers screen for obesity and offer adult patients with a BMI ≥ 30 kg/m² treatment (Jensen et al., 2014; Moyer, 2012; Wadden et al., 2012). The recommendation components include: 1) diet and physical activity prescriptions, 2) referrals to intensive, multicomponent behavioral, weight loss interventions for six months or greater, and 3) on-going follow-up in a long-term, comprehensive weight loss maintenance program (Fitzpatrick et al., 2015; Jensen et al., 2014). The evidence-based behavioral interventions include frequent, high-intensity on-site treatment (i.e., initially weekly and ≥ 14 sessions) provided by a trained interventionist in either group or individual sessions (Jensen et al., 2014). In the studies reviewed, trained interventionists included a variety of health professionals (e.g., registered dietitians, psychologists, exercise specialists, health counselors, and supervised lay persons) who adhered to formal weight management study protocols (Jensen et al., 2014).

For the diet component, the intervention protocols include a variety of methods to promote the reduction of food and calorie intake (Jensen et al., 2014). Guidelines recommend providers advise one of the following prescriptions: a) prescribe 1,200–1,500 kilocalories (kcal) per day for women and 1,500–1,800 kcal per day for men, b) prescribe a daily 500 kcal or 750 kcal energy deficit, or c) prescribe a diet based on the patient's preferences and health status that includes a reduction in dietary intake (Jensen et al., 2014). For individuals with BMIs in the range of 30 to 35,

a decrease of 500 kcal per day results in weight losses of approximately 1/2 to one pound per week and a 10 percent weight loss in six months. For individuals with BMIs ≥ 35 , deficits of up to 500 to 1,000 kcal per day result in weight losses of about one to two pounds per a week and a 10 percent weight loss in six months. In only very limited circumstances, where tightly supervised medical monitoring and high intensity lifestyle intervention can be provided, is use of a very low calorie (defined as <800 kcal per day) recommended. Overall, guidelines suggest it is preferable for providers to refer an individual to a qualified nutrition professional for counseling on how to adhere to a prescription (Fitzpatrick et al., 2015; Jensen et al., 2014).

Although total caloric intake rather than specific foods or beverages is a key component of diet prescriptions for weight loss, U.S. Dietary Guidelines for Americans provide scientific evidence on healthy eating patterns that contribute to achieving and maintaining a healthy weight (McGuire, 2011). A dietary pattern that replaces foods higher in calories with nutrient-dense foods and beverages that are relatively low in calories has strong evidence for improving weight loss and weight maintenance (Cohen, Sturm, Scott, Farley, & Bluthenthal, 2010). This pattern includes a relatively high intake of vegetables, fruit, and dietary fiber and a relatively low intake of total fat, saturated fat, and added sugars (Freeland-Graves & Nitzke, 2013). The U.S. federal government's food icon, MyPlate, released in 2011 to replace the long-standing food pyramid, illustrates recommendations (e.g., make half your plate fruits and vegetables) and offers consumers tips for applying scientific evidence (e.g., drink water rather than sugary drinks) (McGuire, 2011).

For the physical activity component, lifestyle interventions prescribe a combination of aerobic and muscle-strengthening exercises (Jensen et al., 2014; Swift, Johannsen, Lavie, Earnest, & Church, 2014). The American College of Sports Medicine (ACSM) updated 2001-position stand, *Appropriate Physical Activity Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults*, synthesized the latest research in the field and suggested a dose-response

for physical activity with greater amounts and intensities of activity likely needed to achieve weight loss and prevent weight regain in adults (Donnelly et al., 2009). The panel recognizes varying amounts of moderate-intensity physical activity are needed to achieve goals in the following categories: 150 minutes per week *to maintain and improve health*, 150-250 minutes per week *to prevent weight gain*, 225-420 minutes per week *to promote clinically significant weight loss*, and 200-300 minutes per week *to prevent weight gain after weight loss*. Aerobic activity is to be performed in episodes of at least 10 minutes, and preferably, spread throughout a week. ACSM, like the 2008 U.S. Physical Activity Guidelines, also recommends muscle-strengthening activities of at least moderate intensity that involve all major muscle groups, on two or more days a week, as part of an exercise prescription to increase fat-free mass and maintain metabolic efficiency (Donnelly et al., 2009).

For the behavior therapy component, theories, individual techniques, and a range of delivery channels impact the efficacy of comprehensive lifestyle interventions (Jensen et al., 2014; Wadden et al., 2012). Related to behavior change theory, behavior modification and cognitive behavioral therapy (CBT) have the most evidence for efficacy (Abraham & Michie, 2008; Bandura, 1969; Beck, 2011). Behavioral modification includes classic conditioning and operant conditioning. Social learning theory is a central tenet of CBT (Bandura, 1977). The sentinel Diabetes Prevention Program (DPP) trial (Diabetes Prevention Research Group, 2002) applied behavioral modification and CBT and used a structured curriculum, offered skill-building opportunities, and emphasized self-efficacy, self-esteem, and social support. Techniques incorporated in the DPP curriculum included self-monitoring, stimulus control, goal-setting, problem-solving, relapse prevention, cognitive restructuring, and motivation enhancement (DPP Research Group, 2002). Using this package of behavioral approaches compared to pharmacotherapy approaches, the DPP

trial demonstrated the superior ability of lifestyle modification to achieve clinically meaningful weight loss and effectively delay or prevent diabetes (Knowler et al., 2002).

Besides the known efficacious behavior therapy package, research has focused on identification of "key ingredients" to lifestyle counseling interventions (Dusseldorp, Van Genugten, Van Buuren, Verheijden, & Van Empelen, 2014; Michie, Abraham, Whittington, McAteer, & Gupta, 2009). In a meta-regression across 122 studies of behavior change, Michie and colleagues (2009) aimed to isolate specific techniques to determine the most effective, critical elements of interventions. In the meta-regression, an average of six techniques in each treatment package was reported. The strongest evidence emerged to support the inclusion of self-monitoring of behavior, prompting intention formation, prompting specific goal-setting, providing feedback on performance, and prompting review of behavioral goals (Abraham & Michie, 2008). Overall, behavioral interventions incorporating daily monitoring of food and physical activity by paper or electronic diaries, weekly monitoring of weight, structured curriculum of behavior changes, and regular feedback from an interventionist were more efficacious (Abraham & Michie, 2008; Jensen et al., 2014).

In addition to theory and techniques, factors impacting behavioral intervention efficacy involve delivery approaches (Jensen et al., 2014). Strong evidence for both individual and group delivery in face-to-face delivery modes exists (Renjilian et al., 2001). Furthermore, integrating technologies to deliver lifestyle interventions by phone, email, Internet video, and mobile-based approaches either solely or as a hybrid with traditional face-to-face counseling is building a solid evidence-base (Archer et al., 2012; Donnelly et al., 2013; Okorodudu, Bosworth, & Corsino, 2015). The Guide to Community Preventive Services (CDC, 2013b) reports that technology-supported interventions with multi-component coaching or counseling interventions are recommended to reduce and maintain weight loss. New technologies, such as cellular-connected smart scales and

wearable accelerometers with real-time feedback functionality, are emerging as viable strategies for weight management in the literature (Okorodudu et al., 2015; Steinberg et al., 2013). Combining behavioral counseling techniques and technology-supported delivery modes with modest financial incentives provides further weight loss and weight loss maintenance support (Leahey et al., 2015).

As a means of delivering evidence-based strategies in clinical practice, it is recommended obesity be treated using a Chronic Care Model (Wagner, Austin, & Von Korff, 1996). The model provides a structure for system and practice-level change and encompasses six areas for modifying obesity care so that it is patient-centered and high quality. The six care areas include: 1) healthcare organization, 2) community resources, 3) self-management support, 4) delivery system design, 5) decision support, and 6) clinical information systems. Within this model, obesity is recognized as a life-long condition that cannot be cured, but can be managed (Hill, 1998). Relapse is expected to occur and should be used as learning opportunities. An effective healthcare team is essential to making sure an individual receives advice, guidance, and ongoing support to manage obesity (Dietz et al., 2015; Fitzpatrick et al., 2015).

Along with the Chronic Care Model, the 5As Framework for health behavior counseling is recommended for systematically delivering evidence-based obesity care (Glasgow, Emont, & Miller, 2006; Schlair, 2012). Adopted by the USPSTF, the 5As Framework provides a model approach for screening, referral, and behavioral counseling treatment (Moyer, 2012). The 5As of obesity counseling involves a series of five sequential steps: 1) *Assess* status, 2) *Advise* to change, 3) *Agree* on goals, 4) *Assist* with support, and 5) *Arrange* follow-up for change. Developed originally by the National Cancer Institute to aid physicians in supporting patients with tobacco use cessation, the 5As Framework has been found to promote competent health counseling and useful to activate conversations on health behaviors and sensitive health issues (Goldstein, Whitlock, &

DePue, 2004). The framework is recognized for the potential to facilitate individual as well as system-level behavior change (Estabrooks & Glasgow, 2006).

Across the continuum of obesity care, evidence-based lifestyle obesity management is the first line of recommended treatment prior to pursuing a combination of pharmaceutical and surgical interventions (Jensen et al., 2014). The identification of critical elements of comprehensive lifestyle interventions, along with recommended delivery channels, provides a roadmap for providers and patients to manage obesity. **All three lifestyle components, diet, physical activity, and intensive behavior therapy, are deemed necessary to achieve and maintain a clinically meaningful weight loss (at least 3-10% initial body weight)** (Jensen et al., 2014; Wadden et al., 2012).

Gaps in Translating Obesity Research into Real-World Practice

Although there is growing consensus for adult obesity management and mounting research evidence of efficacious strategies for delivering treatment (Wadden et al., 2012), implementation of evidence-based care in typical healthcare settings is limited (Bleich, Pickett-Blakely, & Cooper, 2011; Kraschnewski et al., 2012). Like a lot of scientific evidence, a considerable gap exists between obesity research, policy, and practice (McGuire, 2012; Institute of Medicine [IOM], 2012). Balas and Boren (2000) have estimated that it takes approximately 17 years to translate 14 percent of research discoveries into routine clinical practice. Other reports estimate time lags of 10 to 25 years with a production rate of return from 13 to six percent, respectively (Contopoulos-Ioannidis, Alexiou, Gouvias, & Ioannidis, 2008; Morris, Wooding, & Grant, 2011). The traditional research approach has variable, excessive times and barriers that jeopardize the uptake and impact of translational research (Brownson & Jones, 2009).

Limitations of Traditional Research Approach

Several limitations exist within the traditional research process, typically presented as an unidirectional, "bench to bedside" or efficacy to demonstration pipeline model (Green, 2008). As outlined by Flay in his Preventive Medicine seminal article (1986), intervention research moves in this smooth, linear pipeline from *efficacy* trials that are highly controlled using a homogeneous population to *effectiveness* trials that include a large and representative portion of the target population. Then, the pipeline continues to *implementation effectiveness* trials that include typical members from the target population and the typical staff that would ultimately implement an intervention, and then finally to *demonstration* projects across large systems. With an emphasis on internal validity, magnitude of intervention effect is the key indicator of translational readiness in this traditional research approach (Mercer et al., 2007; Kessler & Glasgow, 2011).

Unfortunately, translating the research products (i.e., interventions) from the lengthy, linear path of the pipeline model has been problematic and lacked relevance for practice, especially outside of the realm of pharmaceutical trials (Green & Glasgow, 2006; Fixsen, 2005). End-users and key stakeholder input is limited, and the often overwhelming complexities of translating evidence into practice at the point of care are overlooked (Harrison & Graham, 2012). As a result, there is often a lack of fit between pipeline-produced interventions and the structure, value, and culture where interventions are ultimately delivered (Brownson & Jones, 2009; Green & Glasgow, 2006).

Clinical guidelines are produced to speed up the transfer of research evidence from a multitude of studies for use at point of care, but optimization of the discovery to delivery process through this mechanism is unseen (Leeman, Jilcott-Pitts, & Myers, 2014). The evidence-base for recommended lifestyle obesity management originates from a rigorous, systematic review of peer-reviewed, published scientific studies (Jensen et al., 2014; Moyer, 2012). To reach scholarly

publication standards, studies are required to meet an established criterion that frequently prioritizes internal over external validity (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004). As a result, a majority of evidence is generated from randomized controlled trials (RCTs) conducted in academic environments with highly motivated patients, highly trained intervention delivery personnel, and optimal delivery conditions (Estabrooks & Glasgow, 2006; Kessler & Glasgow, 2011). Efficacy trials are free from time and resource limitations or competing demands of patients and providers in typical settings (Green & Glasgow, 2006). The practicality of delivering the recommended evidence-based strategies on a large scale to reach a large number of patients in need and the ability of organizations to afford to implement and sustain the strategies in practice has not been demonstrated (Brownson & Jones, 2009; Glasgow, Lichtenstein, & Marcus, 2003).

Paucity of Evidence-based Obesity Screening, Counseling, and Treatment

Although clinical guidelines exist for adult obesity management, systematic delivery of obesity screening, counseling, and comprehensive lifestyle interventions receives limited attention (Kraschnewski, Sciamanna, Pollak, Stuckey, & Sherwood, 2012). Providers report a lack of time, skills, incentives, and infrastructure within their current workflow to support obesity management (Bleich, Pickett-Blakely, & Cooper, 2011). Within health systems, providers are reported to suggest weight loss counseling to only 20 to 30 percent of patients with obesity (Bleich et al., 2011; Kraschnewski, Sciamanna, Stuckey, et al., 2012). Many providers acknowledge having low self-efficacy for evidence-based obesity counseling during the typical office visit (Bleich, Bandara, Bennett, Cooper, & Gudzone, 2015). Research also suggests that some physicians and other health care professionals have bias or possess a negative characterization of patients with obesity (Bleich et al., 2011) and may believe that counseling patients to lose weight is futile (Bleich et al., 2015). Some report feeling that there are too many factors beyond their control, such as the environment

and patients' genetic predisposition and lifestyle preferences (Kraschnewski, Sciamanna, Stuckey, et al., 2012). In general, many providers often report a feeling of being unprepared to counsel due to a lack of adequate training, resources, and referral options that are accessible and affordable for patients (Schlair et al., 2012).

When obesity counseling does occur, it is often reported as poor quality and does not follow the recommended evidence-based counseling procedures (e.g., 5A's) or include the recommended behavioral components essential for weight loss and weight loss maintenance (Jay, Gillespie, Schlair, Sherman, & Kalet, 2010; Schlair et al., 2012). Typically, if providers are able to counsel, only an Assess and Advise is conducted; meaning the provider calculates a patient's BMI and then if classified as obese instructs the patient to lose weight (Jay et al., 2010). Patients are not offered any specific assistance on "*how*" to lose the pounds. The most useful of the 5As model (*Assist*), where patients are directed through a barrier identification and resolution process, is least practiced (Bleich et al., 2011). Assisting patients with goal-setting, problem-solving, and support systems is lacking. Arranging participation in intensive behavioral lifestyle programs, such as the DPP, is not readily accessible in most communities (Kraschnewski, Sciamanna, Stuckey, et al., 2012). As a result, evidence-based weight management strategies proven efficacious in research studies have not proven scalable or sustainable in real-world clinical practice (Fitzpatrick et al., 2015; Kraschnewski, Sciamanna, Pollak, et al., 2012).

Overall, the translation of research to practice and implementation of obesity screening, counseling, and treatment has been a difficult and ongoing challenge. New approaches are needed to accelerate the integration of evidence-based weight loss and weight loss maintenance strategies.

Integrated Research-Practice Partnerships as Translational Solution

Recognizing the gaps between evidence-based research and real-world practice, there is a national call for alternative paradigms and agenda priorities to advance research translation (Chambers & Azrin, 2013; Kessler & Glasgow, 2011). For instance, the National Institutes of Health (NIH) Roadmap for Research Teams of the Future encourages a change in the academic culture to promote collaborative partnerships with stakeholders (Zerhouni, 2003). Rather than operating in silos, research and practice communities are encouraged to engage with each other during all stages of developing, implementing, and evaluating intervention options (Kessler & Glasgow, 2011). A participatory approach to conducting research through integrated research-practice partnerships offers a promising solution to translation challenges (Estabrooks & Glasgow, 2006).

To address the complexities of treating obesity, the updated 2013 Strategic Plan for NIH Obesity Research prioritizes translational research that is conducted by inter-or-transdisciplinary teams through multi-sector partnerships (DHHS & NIH, 2013). The strategic plan recognizes the importance of bidirectional and iterative knowledge and evidence generation from all sectors. Partnerships with clinical and community settings are deemed critical for advancing later-stage translational research that address issues such as intervention feasibility, adaptation, generalizability, adoption, implementation, and sustainability. Related strategic priority objectives include: 1) identifying promising strategies for obesity prevention and treatment in real-world settings, and 2) integrating research results into community programs and medical practice (DHHS & NIH, 2013). A focus on initiating research within real-world, typical settings and existing programs and services is a major shift from the traditional NIH research approach and offers a potential remedy to long and ineffective pipeline model of translation (Brownson, Colditz, & Proctor, 2012).

Systems-based Participatory Dissemination Model

A model for partnerships to conceptualize integrating research and practice is the systems-based participatory dissemination model. Introduced by Estabrooks and Glasgow (2006), the model synergizes the evidence between research and practice and demonstrates the collaborative, participatory process for implementing, evaluating, and sustaining interventions within a complex, adaptive healthcare system. A key distinction of an integrated research practice partnership approach compared to the traditional research approach is its systems perspective. Features of a systems perspective include a focus on context, multi-level complexity, and the interrelationships among the many elements and rules of a system (Glasgow & Chambers, 2012; Plsek & Greenhalgh, 2001). Theoretically, systems may be understood as a set of interacting, interrelated, or interdependent elements that work together within an environment to perform the functions that are required to achieve the system's aim (Von Bertalanffy, 1968). The macro-level system is made of many micro-level interrelated parts coexisting to make it whole. Each level is connected to and impacts the other. Within the interrelationships, change is viewed as an ongoing process (Senge, 1994). The systems perspective may overcome the insufficiencies of traditional research methods in the behavioral sciences by addressing the dynamics and complexities of pressing population health challenges (Livingood et al., 2011).

The participatory dissemination model involves systematic processes for integrating research and practice evidence (Estabrooks & Glasgow, 2006). Researchers develop and test a program, practice, or policy approach in collaboration with key decision makers and delivery staff within the multi-levels of an existing clinical or community organization. Critical elements of an intervention shown to have promise in a research setting are also tested in the practice setting by those whom will serve as the system's delivery team. There is a matching of intervention strategies to the core principles of the intervention in a way that fits with the target population as well as

system resources, delivery staff expertise, and administrative priorities. The partnership then identifies, selects, and implements a research design that will answer questions not solely for the purpose of generating new knowledge, but to inform decision-making and improve practice for the system. This process takes place within the realities of systems that also are influenced by broader health policy and cultural contextual factors (Estabrooks & Glasgow, 2006; Glasgow & Chambers, 2012). Ultimately, the systems-based participatory dissemination model of translation is focused on producing rigorous research that is simultaneously relevant and timely for practice (Estabrooks & Glasgow, 2006; Glasgow & Chambers, 2012).

Updating the Systems-based Participatory Dissemination Model

A more recent refinement of the model presented by Estabrooks and Glasgow in 2006 includes more descriptive processes for systematic strategies that may be used by partnerships to overcome the translational gap between research and practice (Appendix 1.1). Specifically, as shown in Figure 2, the fit between research and practice evidence, process and structures details participatory processes added to the model to present a series of iterative steps research-practice partners may follow when seeking solutions to priority health problems.

The five participatory steps are located strategically in the heart of the model, while surrounded by contextual factors related to integration. First, a collaborative agreement among research and practice partners is established. Using the best practices of team science (Vogel et al., 2013) is recommended at this initial stage to determine the overall goals, structure, and roles of the partnership. Candid discussion of leadership, complementary skills, communication, meeting plans, cohesion, and conflict resolution is valuable (Hall, Feng, Moser, Stokols, & Taylor, 2008; Bennett & Gadlin, 2012). Second, the partnership prioritizes the health problem impacting practice and identifies its target population (i.e., patient, provider, or practice) in need of intervention. Research

questions relevant to all stakeholders, including researchers, administrators, practice delivery staff, and the target population are generated—however, as demonstrated through the series of implementation trials, the primary interest in any one priority area may be from a research, practice, or shared perspective. Third, the partnership selects an evidence-based or evidence-informed strategy to test within the system to address its priorities and research questions. Fourth, the selected strategy is adapted to fit within the existing delivery system and needs of the target population. A balance between fidelity to the critical elements of the evidence-based intervention and adaptation to local setting is considered. Fifth, the partnership designs an integration trial to test its adapted strategy. Trial research designs are driven by the question and available resources for investigation.

Throughout the five steps of the integration process, the concept of bi-directionality between researchers, administrators, and the practice delivery staff takes place in decision-making (Estabrooks & Glasgow, 2006). Furthermore, the broader health policy, community, and cultural context surround the entire processes of an integrated research-practice partnership. The focus on context can help foresee, anticipate, and understand problems with strategy integration. Across trials, while both research and practice personnel valued the trials, some were more researcher driven, some more practice driven, and some were driven equally by practice and research personnel (Smits & Denis, 2014).

Several processes identified in the refined Integrated Research-Practice Partnerships' Participatory Model were theoretically influenced by prominent implementation science models. Rogers' Diffusion of Innovation (2003), especially its construct of compatibility, was applied in the strategy selection and adaptation steps. The Prevention Synthesis construct of the Interactive Systems Framework for Dissemination and Implementation by Wandersman et al. (2008) contributed to the strategy selection process. A role of research is helping to distill scientific knowledge into understandable and actionable information for practice. Lastly, the Consolidated Framework for

Implementation Research (Damschroder et al., 2009), with its five major domains (e.g., intervention characteristics, outer setting, inner setting, characteristics of individuals involved, and the process of implementation) informed the assessing of barriers and facilitators for implementation in strategy selection, adaptation, and testing.

Strengths of Participatory Research Approach

From more collegial, accessible working arrangements to greater insights into the challenges of the delivery setting, the participatory approach to research offers many strengths to advancing the implementation of evidence-informed practice (Chamber & Azrin, 2013; Estabrooks & Glasgow, 2006; Harrison & Graham, 2012). Integrated research-practice partnerships follow the principle that "research is conducted *in*, and *with*, practice rather than done *to*, or *on*, practice" (Green & Ottoson, 2004). Researchers become equal working partners with representatives from the system where interventions will ultimately be delivered. This often leads to more buy-in, sharing of resources, and willingness to discuss real barriers and facilitators to implementing an intervention (Estabrooks & Glasgow, 2006; Glasgow & Chambers, 2012). Unlike the 'helicopter' fly in and out of a community stereotype often used to depict research teams (Wallerstein & Doren, 2010), partnerships aim to establish long-term, reciprocal relationships. There is active engagement of all key stakeholders involved in organizational decision-making and intervention delivery (Estabrooks & Glasgow, 2006; Peek, Glasgow, Stange, Klesges, Purcell, & Kessler, 2014). Partnerships evolve to address and serve the prioritized needs of the delivery system (Estabrooks & Glasgow, 2006; Harrison & Graham, 2012; Ovretveit, Hempel, Magnabosco, Mittman, Rubenstein, & Ganz, 2014).

Although integrated research-practice partnerships vary in composition based on local context, common characteristics include being multi-level, team-based, and strategically representative (Estabrooks & Glasgow, 2006). Partnerships involve experts from the scientific

community and individuals with experience close at the point of care and delivery of routine practice (Estabrooks & Glasgow, 2006). Research-oriented members often include an interdisciplinary team of investigators, data managers, and student research assistants. Practice-oriented members often include an inter-professional team of organizational administrators, clinic program managers, and front-line program delivery staff. In addition, partnerships frequently engage patient and community representatives from the delivery system's target population. The number of members and overall composition of teams involved in a partnership depends on the scope of practice, research design, and available resources (Harrison & Graham, 2012). Decision-making for complex problems are served well by the diversity of expertise offered by integrated research-practice teams (Riemer, Kelley, Casey, & Taylor Haynes, 2012).

Researchers and practitioners work jointly together with multiple, dynamic roles in an integrated research-practice partnership (Estabrooks & Glasgow, 2006). At partnership formation, collaborative activities include agenda setting that aligns research interests with systemic needs (Harrison & Graham, 2012). Research questions, design, data reporting and dissemination, implementation, and integration into practice are all informed through collaborative, participatory methods (Ovretveit et al., 2014). Roles are flexible and likely to change during different stages of a partnership's ventures (Estabrooks & Glasgow, 2006). For instance, research staff may deliver an intervention component during the first phase of a pilot trial as a means to test materials without posing a burden to practice time and workflows. Partnerships can increase the quality improvement and innovation capacity of a delivery system (Glasgow & Chambers, 2012).

Carilion Clinic Integrated Research-Practice Partnership

To gain an understanding of how an integrated research-practice partnership may facilitate translation of evidence-based strategies and break-down the silos between research and practice, the

projects described in this dissertation provide a series of cases resulting from an integration of Carilion Clinic (Carilion) and researchers from the Virginia Tech Fralin Translational Obesity Research Center. Carilion epitomizes a system that has ventured to participate in a transformation to value-based population health management as part of healthcare reform (O'Donnell, Anand, Ganser, & Wexler, 2015; Porter, 2009; Porter & Lee, 2016). As part of this journey, its healthcare leaders are exploring obesity treatment delivery options to improve performance on the triple aims (Berwick, Nolan, & Whittington, 2008).

Overview of Carilion Clinic

Carilion is a nationally ranked, private, not-for-profit \$1.5 billion integrated healthcare delivery system based in Roanoke, Virginia. Carilion owns and operates seven hospitals with 1,026 beds and has more than 750 physicians in 200 practice sites, including primary care clinics, residency and fellowship programs, medical fitness facilities, laboratories, an aeromedical program and multi-specialty physician services. The organization governance includes a president, a Board of Directors, consisting of leaders from organizations from throughout western Virginia, and a Board of Governors, made up of a team of physicians and nurses who oversee Carilion management. The system serves close to one million people in a unique blend of 18 predominantly rural counties and six cities in western Virginia. As the largest private employer in its region, Carilion has 11,700 employees with annual benefits adding to \$817 million.

Since its founding in 1899, Carilion's mission has been "to improve the health of the communities we serve". Its corresponding vision is "to provide better patient care, better community health, and at a lower cost". Carilion expresses its values through the 5Cs: *CommUNITY* – "a value for working in unison to serve our community, Carilion family and loved ones", *Courage* – "doing what's right for our patients without question", *Commitment* – "unwavering in our quest

for exceptional quality and service", *Compassion* – "putting heart into everything we do", and *Curiosity* "fostering creativity and innovation in our pursuit of excellence" (Carilion, 2016).

In 2006, Carilion began a major transformation to its current system operating as a clinic model. Cornerstones of the clinic model, the three pillars of Carilion are: 1) patient care, 2) education, and 3) research. The pillars replicate the service priorities of pioneering, integrated healthcare delivery systems such as Mayo Clinic and Cleveland Clinic (Beckman, 2014; Cosgrove, 2014). Several drivers lead to transformation to a clinic model including: rising healthcare costs, unstable economy, changes in consumer demand, advances in technology, generational differences in physician work/life balance, working 'to license'-team-based care, and workforce shortages (Brown, 2016; Milani, 2015; Schill, 2015, Schieber, 2009; Shortell & Casalino, 2008).

For patient care, the organization functions as an accountable medical group with physicians, hospitals, and insurers coordinating care while simultaneously aiming to improve quality and reduce patients' costs. In 2011, it formed a shared-savings accountable care organization with Aetna with over 3,000 participants. Furthermore, in 2013, it enrolled in the Medicare Shared Savings Program with over 46,000 Medicare beneficiaries (Kutscher, 2013). With accountable care participation, Carilion assumes great risk for its patients and employees. Payment with the accountable medical group is based on disease management, prevention, and wellness, i.e., pay for performance (O'Donnell et al., 2015). Since Carilion is self-insured as an accountable medical group, its employees are also served as a population for health management. The organization offers an extensive array of employee wellness benefits through Aetna and supports organizational policies and environmental changes to promote healthy lifestyles, (i.e., tobacco use cessation, healthy cafeteria, and vending options).

Serving both urban and rural, low-income populations, Carilion's primary care practices transformed to recognized patient-centered medical homes, converted to system-wide use of the

electronic health record (EHR), and implemented MyChart, an online patient portal - healthcare management tool (Green et al., 2012). Introducing the first medical homes in Virginia, the medical home is a primary care model that promotes population health management by providing coordinated and comprehensive care to high-risk patients to improve health outcomes (Green et al., 2012).

"We are in relentless pursuit of clinical integration.

We want to be managing patient health, not reacting to it."

– Nancy Agee, President and Chief Executive Officer, Carilion Clinic

For education, the system is an academic medical center with its own residencies and fellowship programs, direct partnerships with Virginia Tech Carilion School of Medicine and Jefferson College of Health Sciences, an office of Student Affairs and office of Continuing Professional Development providing practical internships and training opportunities throughout the healthcare system. The curricula of Carilion partners uniquely focuses on building skills for patient-centered care, introducing the inter-professional teamwork approach, and the importance of integrating research and quality improvement into practice. Its medical residencies and fellowship positions have recently expanded to 267 slots, and provide rotations in the hospital and ambulatory care settings.

For research, the organization recognizes clinical research as a fundamental and integral component of quality patient care. An active Research & Development department maintains an infrastructure to support initiatives, including a host of clinical trials and quality improvement initiatives. Carilion also is a partner with Virginia Tech Carilion Research Institute, a public-private partnership focused on bridging basic and applied research at Virginia Tech with clinical expertise

at Carilion. Faculty, clinicians, and students are involved in research locally, as well as with regional, state, national, and international affiliates.

As a leader of a network of non-for-profit hospitals, Carilion Clinic is required by federal tax exemption standards under the Affordable Care Act to develop and implement community benefit strategies based on community health needs assessments (Corrigan, Fisher, & Heiser, 2015). The Internal Revenue Service's Schedule H worksheet to Form 990 is a national effort to improve transparency and accountability, along with addressing the priorities of preventive care and population health through community health improvement activities (Rosenbaum, Byrnes, & Rieke, 2013). Carilion has a history of involvement in community health needs assessment since 1999, long before the 2009 mandate. It currently is involved in needs assessments in Roanoke Valley, New River Valley, Franklin County, Bedford County, Rockbridge Area, Giles County, and Tazewell County (Carilion, 2016). Similar to 78 percent of hospitals across the country (Health Research & Educational Trust, 2014), each of the needs assessments identifies obesity, along with nutrition and physical activity as priorities. Carilion is working with local communities on implementation plans to address needs.

In its main service area, Carilion is an active member of Healthy Roanoke Valley (HRV), a coalition of over 50 health and human service providers. HRV was established as a response to health inequities in care coordination identified in Carilion's 2012 Roanoke Valley Community Health Needs Assessment. The HRV's goal is to "mobilize community resources to improve access to care, coordination of services, and promote a culture of wellness". The target population of HRV initiatives is focused on the uninsured, low-income, and underserved residents of the Roanoke area. Related to obesity, HRV has a *Wellness- Nutrition, Weight Status, and Physical Activity* work group. The overall goal of this work group area is to create a culture of wellness and manage

chronic disease by promoting a healthy lifestyle. Consuming a nutritious diet and achieving an optimal body weight are target behaviors.

Overview of Partnership Development

In Spring 2013, an integrated research-practice partnership was initiated by Carilion to address weight loss and weight loss maintenance among patients and healthcare employees. The partnership consisted of researchers with content expertise, organizational decision-makers, as well as Carilion weight loss practitioners. Initiation of the partnership stemmed from healthcare system leaders representing the **Department of Family and Community Medicine**, **Carilion Wellness**, and **Carilion Community Outreach**, an office of the Carilion Department of Planning and Community Development, formerly known as Strategic Development. To improve its population health management efforts, Carilion physician leaders and human resource representatives from each of these departments were requesting weight loss services to offer high-risk patients and employees.

Carilion Wellness began efforts by adapting its sixty-day, practitioner-developed, exercise prescription program called FIT Rx to become a ninety-day, employee weight loss program called FIT Rx 90. With concern about weight loss maintenance after program completion, the program's Medical Director approached a new research-focused colleague for his expertise. At that time, the colleague was serving in multiple roles, including Carilion Senior Director of Research, a faculty member of the Department of Family and Community Medicine and Virginia Tech Department of Human Nutrition, Foods and Exercise, and co-director of the newly formed, Fralin Translational Obesity Research Center. The exchange between the two led to a FIT Rx 90 weight loss maintenance program trial, practice participation in the My Own Health Report project, and the kick-off to an ongoing research-practice partnership.

During this same time period, a manager from Carilion Strategic Development was charged with forming a system-wide Carilion Weight Loss Steering Committee to conduct a needs assessment and business proposal for patient weight loss services. The expert committee offered input for a matrix of components for a successful weight loss program and outlined existing Carilion services supporting weight management. The committee also created a vision for the Carilion Healthy Hub, an online Healthy Weight Center that would connect patients, providers, employees, and community members to weight loss and weight loss maintenance programs and resources. A copy of the 25 successful weight loss components, matrix of existing programs identified by the committee, along with the initial outline of the Healthy Hub is shown in Appendix 1.2-1.4. The formation and pilot trials of the Carilion Healthy Lifestyles program for patient weight loss were a Phase I result of this committee's work. The Steering Committee did not continue beyond kick-off of the Phase I work.

Pilot Pragmatic Trials and Timeline

Since its formation, the Carilion integrated research-practice partnership has conducted seven pragmatic trials as part of a rapid, learning series to inform an evidence-based system of lifestyle obesity management. Each pilot trial tested an evidence-based strategy to integrate into existing practice services and workflows. Carilion stakeholders and research partners worked collaboratively throughout the planning, implementation, and reporting phases of each trial. The selected integration strategies for testing and associated trials are shown in Figure 4.

Aligned with elements of pragmatism defined in the CONSORT extension guidelines (Zwarenstein, et al., 2008), the trials included: 1) diverse participants, practitioners, and practices that were not narrowly selected, 2) interventions that were intentionally implemented without intense standardization efforts to burden practitioners, 3) comparator groups that received usual

care, and 4) multiple outcomes of importance to key stakeholders and decision-makers. Study protocols were intentionally developed to be flexible and adaptable. Measurements were designed to be reported in ways that were meaningful, actionable, and aligned with other Carilion reports (Glasgow, Brownson, & Kessler, 2013). Outcomes in each pragmatic trial focused on practical issues, such as the reach and costs of using a strategy, rather than solely on the effectiveness for weight loss (Glasgow, 2013).

For this dissertation, trials were presented in the chronological order in which they emerged as implementation efforts within Carilion. Table 1 provides a timeline of partnership activities from 2013-2016. Active trial periods included in this dissertation occurred from 2013-2015. Ongoing program delivery, post-trial evaluation, and new system initiatives based on conclusions of trial findings occurred throughout 2016. Initiatives based on conclusions were highlighted in Chapter 7, but not fully detailed in this dissertation. The excluded trials were preliminary, feasibility studies with small sample sizes and high attrition rates.

Each Carilion trial involved unique integrated research-practice partnership implementation teams and aimed to serve either patients or employees with an overweight or obesity classification within the healthcare system. The teams and trials developed organically from Carilion's organizational structure and service priorities. Chapters 3 through 6 report on the background, methods, results, discussions, and conclusions of each trial.

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Table 1. Timeline of integration activities and implementation trials, 2013-2016

<p align="center">CARILION CLINIC INTEGRATED RESEARCH-PRACTICE PARTNERSHIP 2013-2016 TIMELINE</p>													
<p align="center"><i>Integration Activities and Trials</i></p>													
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	
	<p align="center"><-----MY OWN HEALTH REPORT-----> Early Site Intervention with Patient Experience Survey</p>												
	<p align="center"><-----CARILION WEIGHT LOSS COMMITTEE-----> Strategic Development Meetings, Assessment, and Business Plan</p>												
	<p align="center"><-----FIT Rx 90-----> Assessment</p>		<p align="center"><-----FIT RX 90-1.0-----> Weight Loss</p>			<p align="center"><-----FIT RX 90-1.0-----> Weight Loss Maintenance with Choice</p>							
<p align="center"><i>Integration Activities and Trials</i></p>													
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	
2014	<p align="center"><-----MY OWN HEALTH REPORT-----> Delayed Site Intervention with Patient-Provider Experience Surveys</p>												
				<p align="center"><-----CARILION HEALTHY LIFESTYLES (CHL)-----> Community Health Educator Delivery with Jefferson College of Health Sciences-Fleet Feet</p>									
	<p align="center"><-----FIT RX 90-2.0-----> Weight Loss (Site 1 & 2)</p>		<p align="center"><-----FIT RX 90-2.0-----> Weight Loss Maintenance (Site 1 & 2)</p>										
					<p align="center"><-----FIT RX 90-2.0-----> Weight Loss (Site 3)</p>			<p align="center"><-----FIT RX 90-2.0-----> Weight Loss Maintenance (Site 3)</p>					
									<p align="center"><-----FIT RX 90-3.0-----> Tech Survey and Fitnet Group Demos</p>				
						<p align="center"><-----CARILION HEALTHY LIFESTYLES-----> Nurse Care Coordinator Delivery in Medical Home Clinics Training Consult Consult Consult</p>							
<p align="center"><i>Integration Activities and Trials</i></p>													
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	
2015	<p align="center">CHL-----> Health Educator</p>												
	<p align="center">2.0---> (Site 3)</p>												
	<p align="center"><-----FIT RX CUSTOM-----> Weight Loss</p>			<p align="center"><-----FIT RX CUSTOM-----> Weight Loss Maintenance</p>									
	<p align="center"><-----FIT RX 90-3.0-----> Fitnet Development, Weight Loss</p>						<p align="center"><-----FIT RX 90-3.0-----> Weight Loss Maintenance</p>						
	<p align="center">CARILION HEALTHY LIFESTYLES-----> Nurse Care Coordinator Consult</p>				<p align="center"><-----CARILION HEALTHY LIFESTYLES-----> Nurse Care Coordinator Retrospective Patient Chart Review</p>								
<p align="center"><i>Integration Activities and Trials</i></p>													
2016	<p align="center"><-----CARILION HEALTHY LIFESTYLES-----> Ongoing Program Delivery for Patients</p>												
	<p align="center"><-----RE-AIM EVALUATION-----> Summary of Trial Outcomes; Plans for Future Services and Trials</p>												
							<p align="center"><-----WEIGHT WELLNESS STEERING COMMITTEE-----> Medical Weight Loss Program with Interdisciplinary Care Team Metabolic and Bariatric Services</p>						

Figure 1. Evidence-based components of comprehensive lifestyle interventions

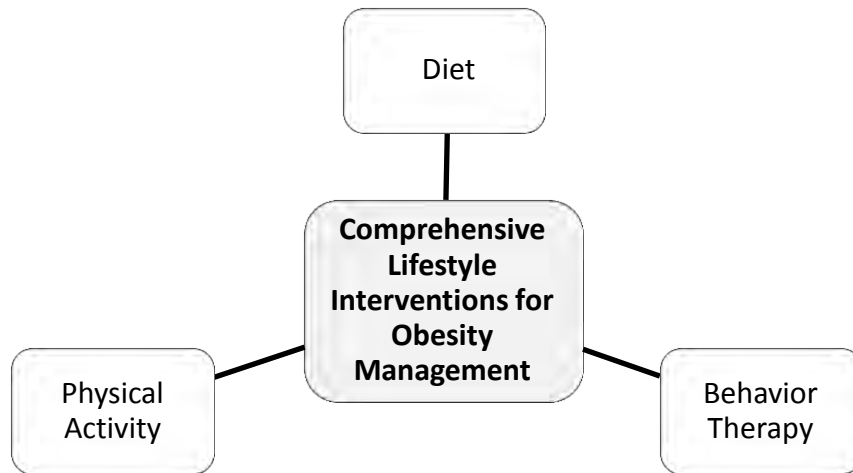
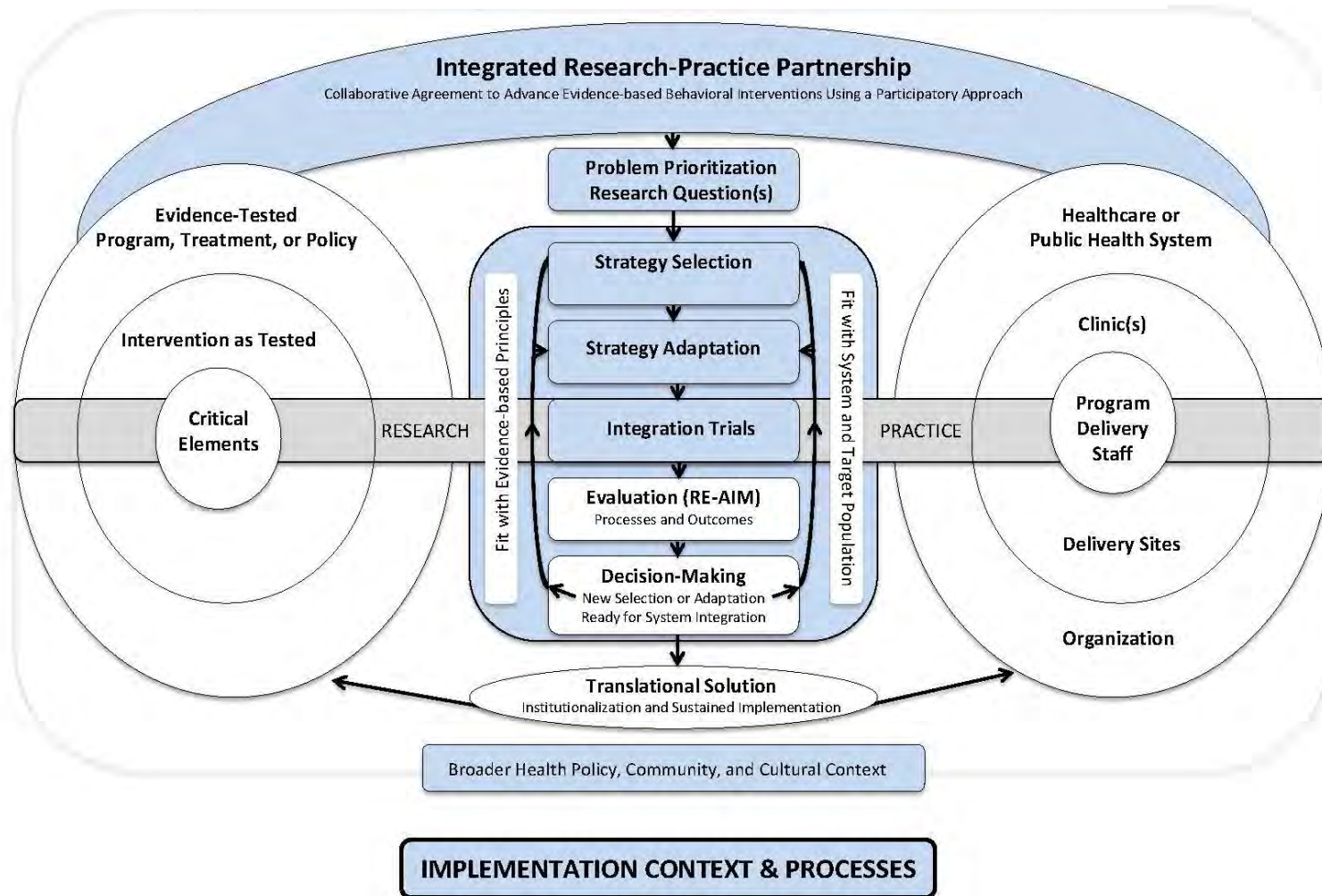


Figure 2. Highlighted areas of Integrated Research-Practice Partnership Model guiding assessment of implementation context and processes



Notes. Highlighted areas of integration process: 1) Integrated Research-Practice Partnership Collaborative Agreement, 2) Problem Prioritization-Research Questions, 3) Strategy Selection, 4) Strategy Adaptation, and 5) Integration Trials; Context: Broader Health Policy, Community, and Cultural Context

Figure 3. Overall structure of the Carilion Clinic Integrated Research-Practice Partnership

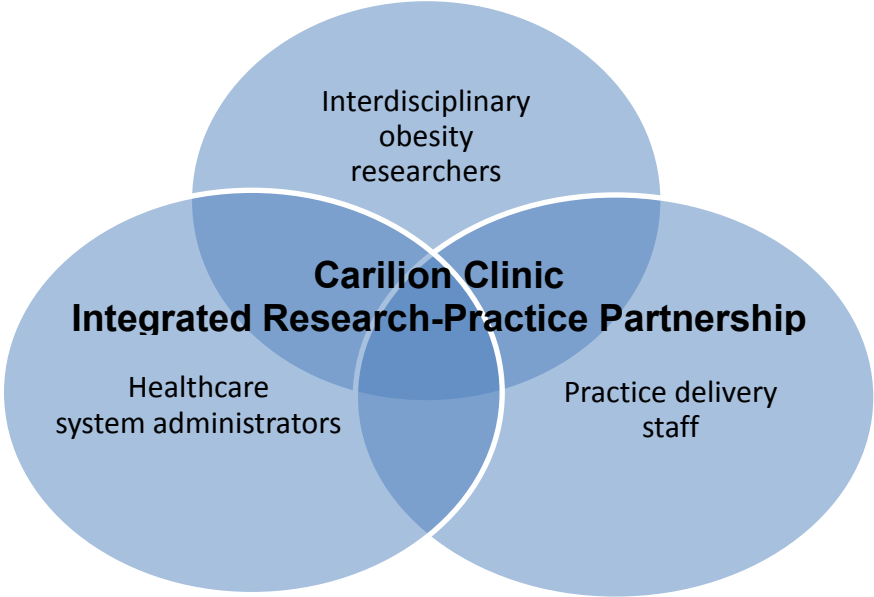
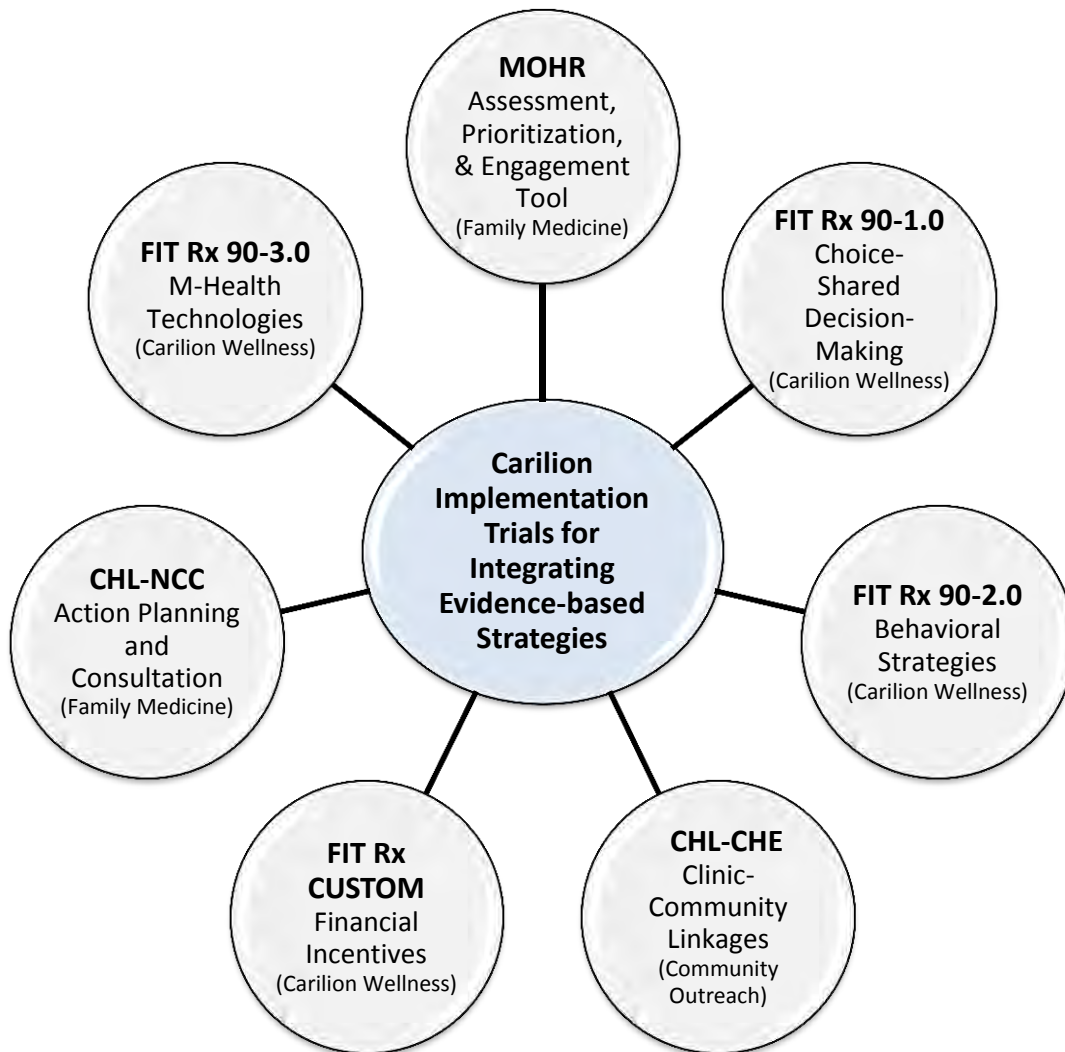


Figure 4. Carilion's pragmatic implementation trials with strategies and lead teams



Notes.

- **MOHR:** My Own Health Report trial
- **CHL-CHE:** Carilion Healthy Lifestyles-Community Health Educators
- **CHL-NCC:** Carilion Healthy Lifestyles-Nurse Care Coordinators

Chapter 2: Purpose, Aims, and Methodologies

Purpose and Aims

The overall purpose of this dissertation was to develop a greater understanding of how an integrated research-practice partnership approach facilitates and sustains evidence-based lifestyle management strategies across a healthcare system to treat obesity among patients and employees.

Across the trials presented in this dissertation, there were common aims and outcomes related to the degree to which strategies to deliver the three components of comprehensive lifestyle obesity management (i.e., healthful eating, physical activity, and intensive behavior therapy) may be integrated into existing Carilion services. The intent of each trial was that the findings would provide actionable, practice-based evidence to inform decision-making (Ammerman, Smith, & Calancie, 2014) for the development of a system of obesity care. The goal of the future system is to have a broad-reaching, meaningful impact on treating obesity among Carilion patients, employees, and the community of western Virginia. The partnership structured objectives around two major aims—1) developing context and action for implementation and sustainability (when appropriate) of project strategies, and 2) providing consistent outcome assessment, when possible, across pragmatic trials.

Aim 1- Implementation Context and Processes

The partnership agreed to work towards the goal of a comprehensive approach to weight management through the implementation of evidence-based strategies and to describe the implementation processes used within and across trials. In addition, the partnership developed the following objectives, guided by the Integrated Research-Practice Partnership Participatory Model's

steps described in Chapter 1, Figure 2. These objectives were intended to refine the implementation process and provide additional contextual description for future implementation.

- **Objective 1a:** To identify the collaborative, participatory structures developed by each research-practice team
- **Objective 1b:** To identify the problem prioritization and research questions
- **Objective 1c:** To identify strategy selection
- **Objective 1d:** To identify strategy adaptations, and
- **Objective 1e:** To outline the research design for supporting testing of integration.

Each objective was accompanied by a description of the degree to which the process fit with evidence-based principles and fit with system resources and target population needs.

Aim 2- Implementation Outcomes

The partnership also agreed to the use of metrics to assess implementation outcomes that included, but moved beyond, the assessment of effectiveness. Offering a structure to assess implementation outcomes, for each trial, the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) was used to plan and guide the evaluation approach. RE-AIM has been applied widely in the evaluation and decision-making of behavior change interventions for multiple health issues among diverse settings and populations (Harden et al., 2015). Extending beyond an assessment of efficacy, the RE-AIM framework is highly recommended as an evaluation tool for determining the likelihood of interventions to have a broad reaching, sustainable public health impact. The framework encourages attention to critical program elements including external validity that may improve the likelihood of effective, generalizable, evidence-based interventions to be implemented and sustained. In the Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE) randomized controlled trial (Yank, Stafford, Rosas, & Ma, 2013), RE-AIM

was used to evaluate the potential of two DPP-based interventions to reach target patient populations and be adopted into routine primary care use. It was also used in the state of West Virginia to present weight management program findings to insurance agencies and public health decision-makers for potential statewide uptake (Abildso, Zizzi, & Reger-Nash, 2010).

The framework assesses five dimensions – *Reach, Effectiveness, Adoption, Implementation* and *Maintenance*, that may support the translation of research into practice (Glasgow et al., 1999). Dimensions may be operationalized at the individual and organizational-setting/staff level. At the individual level, reach is defined as the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program. Effectiveness is the impact of an intervention on important stakeholder outcomes, including potential negative effects, quality of life, and economic outcomes. Individual-level maintenance is the long-term effects of an intervention on outcomes after 6 or more months of program contact. At the organizational level, adoption is the absolute number, proportion, and representativeness of settings and staff who are willing to initiate a program. Implementation refers to fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention. Organizational-level maintenance is the extent to which an intervention becomes institutionalized or sustained as part of the routine practice.

All RE-AIM dimensions have equal importance, provide a target for intervention, are likely inter-related, and combined could lead to more informed decision-making. In literature reviews, adoption and maintenance have received limited attention (Harden et al., 2015). In addition, costs for participants and program implementation are often overlooked (Glasgow et al., 2012). Table 1 highlights partnership's priority evaluation questions for each RE-AIM dimension. Overall, the partnership was seeking implementation strategies that may be adopted and delivered broadly, have the ability for sustained and consistent implementation at a reasonable cost, and reach large

numbers of patients or healthcare employees (especially those who can most benefit). A primary outcome across trials was the ability of a strategy to produce replicable and long-lasting effects on achieving and maintaining clinically meaningful weight loss (i.e., $\geq 3\text{-}5\%$ initial body weight).

To the extent feasible, each trial in this dissertation addressed these critical dimensions for translation, though as can be noted, not all RE-AIM dimensions, were applicable across all trials.

The aim was operationalized through the following three objectives:

- **Objective 1:** To produce a RE-AIM dimensions summary table highlighting implementation outcomes for each integrated, evidence-based strategy trial
- **Objective 2:** To compare each integrated, evidence-based strategy at the *individual level* by retention rate, adherence to critical elements, and % initial body weight loss produced (i.e. $\geq 3\%$ and $\geq 5\%$)
- **Objective 3:** To compare each integrated, evidence-based strategy at the *organizational level* by staff fidelity to critical elements, time, and intervention costs

As shown in Table 2, the focus of analysis for each RE-AIM dimension may have been used to provide a descriptive assessment of the integration strategy or serve as a target of change in the trial. Use of the RE-AIM framework permitted consistent taxonomy to discuss the outcomes of each trial and compare the effectiveness of implementation strategies. Findings were synthesized across the series of pragmatic trials to provide system administrators with practical recommendations about specifics on what implementation strategies work, where, under what circumstances, and with whom (Kessler & Glasgow, 2011).

Methodology

Mixed, Multi-level Approach

This study used a mixed methods approach to improve the breadth and depth of understanding and data corroboration (Tashakkori, 2010). With mixed methods, this study included both quantitative research strategies assessing the magnitude and frequency of constructs and qualitative research strategies exploring the meaning and understanding of constructs. Mixed methods have been recognized as an approach that has been deemed valuable for research questions that call for real-life contextual understandings, multi-level perspectives, and cultural influences. The methodology generates rich data to complex research questions understanding trial results and the success or failure of implementation efforts (Albright, Gechter, & Kempe, 2013).

The variety of quantitative data collection methods included throughout the dissertation trials included anthropometric measurements, blood lab work, behavior and experience surveys, chart review, and implementation fidelity checklists. Qualitative data collection methods included key informant interviews, focus group discussions, open-ended survey questions, field notes, and direct observation. The collection and analysis of quantitative and qualitative data occurred using a parallel approach in each trial.

Using recommended best practices (Creswell, 2011), quantitative and qualitative data were merged and triangulated to provide a more holistic understanding of outcomes at multiple levels. The levels of analyses for the trials included the individual-levels of either patient or healthcare employee. At the organizational-level, the settings of a practice or medical fitness facility were part of study review. Staff-level analyses included clinicians throughout the system, such as physicians, residents, fitness managers, registered dietitians, personal trainers, and nurse care coordinators.

Research Designs

As described in Chapter 1, all trials were designed to be pragmatic and inform practice-based decision-making. An overview of research designs, brief descriptions, and the total number of individual and organizational-level participants involved in each trial are included in Table 3. Each research design was selected based on the appropriateness to the specific integration strategy and research questions being examined. Striking a balance between rigor and relevance, along with the capacities and resources available to the research-practice team were deciding factors in design selection. To the degree deemed appropriate and viable, trials included a comparison control condition. For strategies new to the system, feasibility trials were first employed to assess the practicality and appropriateness for patients and healthcare employees.

Analysis

For quantitative measures in each trial, descriptive, parametric, and non-parametric status frequencies, overall effects, and between group effects were used for analysis. Values were reported as mean \pm standard deviation (SD) or as frequency in percentage. Pearson's chi-square tests of independence were used for categorical variables. An analysis of variance (ANOVA) tests were used to test associations of continuous variables. Demographics, characteristics, costs (staff hourly time and program materials) and weight change between conditions were analyzed in each trial. Each statistical test report related directly to a trial's hypothesis. All statistical tests were two-sided and used an alpha level of .05, unless the pilot trial's sample size was very small in which an alpha level of .10 was used. SPSS statistical analysis software (versions 22 and 23, SPSS Inc., Chicago, IL) was used for all quantitative analyses.

For qualitative measures in each trial, focus group discussions and interviews were recorded and transcribed. Transcripts, field notes, progress notes extracted from patient charts, and open-

ended responses to survey questions were independently reviewed for each trial for common themes and categories. Two to three separate research assistants were involved in each trial's qualitative data review teams. (Creswell, 2000). Dedoose (version 6.1.18, SocioCultural Research Consultants, LLC, www.dedoose.com) was used to organize all qualitative data. Typically for each trial, findings were summarized in a tabular form representing common themes, categories, and illustrative quotes. Member checking occurred with the practice team to confirm interpretation of findings.

Assumptions, Delimitations, and Limitations

For assumptions, it was accepted as true in each trial that all reporting by both the research and practices teams were truthful and candid. Double data entry was performed and cross-referenced where possible to assure all participant responses and weight reports were recorded accurately. Partners were deemed to have made honest efforts in delivery of each of the evidence-based strategies within the context of their specific work setting. Furthermore, it was taken for granted that all study participants had a sincere interest in weight loss and weight loss maintenance when they enrolled in a trial.

For delimitations, this dissertation focused solely on obesity lifestyle management treatment strategies for Carilion's adult patients and healthcare employees. The full spectrum of obesity care (i.e., pharmacological therapy and bariatric surgical procedures) was not covered. The target population for weight management did not include youth, adolescents, and/or geriatric participants. Obesity prevention, policy-related activities, and other weight management programs tied to cardiac rehabilitation and diabetes management within the healthcare system were not addressed. Worksite wellness initiatives, such as healthy vending machines, StairWellness, and local produce box subscriptions, were not included in evaluations or targets for intervention. In addition, patient or

employee participation in commercial weight loss programs, such as Weight Watchers, Jenny Craig, or Nutrisystem, or involvement in church, civic, or worksite contests, such as Biggest Loser or Weight Wars, were not part of the investigation.

The overall dissertation with the goal of understanding how an integrated research-practice partnership approach advanced evidence-based obesity care was focused mainly on the implementation processes. The influences of collaborative partnership processes, such as measurements of capacity, readiness, and team functioning (Leeman et al., 2015), were identified as areas for future investigation. Outcomes of this study focused specifically on achieving and maintaining clinically meaningful weight loss (i.e., $\geq 3\text{-}5\%$ initial body weight). Other anthropometric, behavioral, and quality of life outcomes, such as blood pressure, A1C3, lipid profiles, dietary intake, physical activity, and self-reported health reports, were noted as measures to systematically address and comparatively evaluate across trials in future studies.

For limitations, a majority of the trials included in this dissertation were small, pilot quality-improvement-like projects. As pilot trials, power calculations were not used to determine what sample size, α level, and effect size were necessary to detect a difference between groups. Trials were not powered to determine the effect of components or investigate mediators for behavior change or weight loss. In addition, studies were not fully controlled for all potential contamination or influences that may have occurred in each real-world setting. The dynamic pace of innovation impacted the availability of products and technologies available to both practitioners and study participants. For instance, during the trial period, smartphone apps targeting weight loss and wearable fitness tracking devices infused the market. Moreover, the field of implementation science was still defined as relatively new with evolving definitions, models, and measures (Brownson, Colditz & Proctor, 2012). Implementation instrumentation has been described as underdeveloped and the psychometric quality of existing instruments lacks strong validation (Lewis et al., 2015;

Proctor et al, 2011). Most trials relied upon self-report questionnaires, except for weight and body composition measurement. Finally, in interpretation of findings, especially qualitative results, past experiences, personal biases, and idiosyncrasies of the research-practice team were subjective and may have influenced the reporting of findings. For several trials, members of the research-practice teams were involved in both intervention delivery and evaluation.

Summary of Value

This dissertation offers several valuable contributions to research, practice, and policy in the domains of health-related partnerships and lifestyle obesity management. By investigating the integrated research-practice partnership approach, a promising solution for accelerating the slow, challenging translation of evidence-based obesity treatment strategies to routine, clinical practice is proposed. A focus on this late stage of translation is paramount to maximizing the population health impact of obesity treatment discoveries (Sampson, 2016).

In regards to research, the study provides empirical evidence to support and inform the integrated research-practice partnership approach to research endeavors. Although highly encouraged, this approach currently lacks supportive data on structures, processes, and outcomes (Ovretveit, 2014). Each trial documents contextual factors, barriers, and facilitators, while testing strategies for integrating components of comprehensive lifestyle obesity management into the Carilion healthcare system's practice and workflows. This provides meaningful, influential contextual factors impacting implementation and intervention effectiveness that are seldom identified or reported in the literature (Kessler & Glasgow, 2011). Likewise, very few studies report costs or specific staff time commitments associated with interventions, which ultimately impact uptake, sustainability, and scalability potential (Gold, 2016; Peek, 2014). For researchers, this dissertation provides firsthand insights into the realities and challenges of delivering evidence-based

lifestyle obesity treatment for patients and healthcare employees. The experiences documented in each trial offer a holistic understanding of how events naturally unfold in clinical settings and what is really important to stakeholders, including healthcare system administrators, practitioners, patients, and healthcare employee participants, when selecting obesity treatment options. Recommendations for future obesity-related research endeavors for the Carilion integrated-research practice partnership to pursue were generated and prioritized.

Related to practice-related value, this dissertation provides a systematic evaluation of quality improvement initiatives addressing obesity, a critical health problem threatening healthcare systems' triple aims and health advancement across the U.S (Dietz et al., 2015). The pragmatic trials produce real-world evidence to inform decision-making on strategies to implement as part of clinical and cost-effective interventions to improve obesity care within the Carilion system (Kyratsis, 2012; Glasgow, 2013). Emphasizing external validity in design, the trials may be generalizable to many other healthcare systems throughout the country that are also investing in population health, employee wellness, and community health initiatives related to treating obesity (Green, 2006). Furthermore, the work featured throughout the dissertation helps demonstrate that the Carilion integrated research-practice partnership has the expertise, capacity, and environment to successfully carry out study aims. The preliminary data generated in each trial may be included in future grant applications and business case proposals for developing a system of obesity care.

For policy makers, the work featured in this dissertation aligns with the objectives of several national health initiatives and offers insights into the degree to which current obesity-related policies are being implemented into practice. Focused on lifestyle obesity treatment, studies align with health promotion priorities of healthy eating, active living, and weight management prioritized in the National Prevention Agenda (National Prevention Council, 2011). In addition, trial activities support progress toward several Healthy People 2020 objectives; including 1) reducing the

proportion of adults who are obese, 2) increasing the proportion of physician office visits that include counseling or education related to nutrition or weight; and 3) increasing the proportion of worksites that offer nutrition or weight management classes or counseling (DHHS, 2010). The trials test adaptations of strategies included in the national DPP (Aziz, Absetz, Oldroyd, Pronk, & Oldenburg, 2015) and explore the proposed intervention delivery structure recommended in CMS' intensive obesity counseling reimbursement policy (CMS, 2011). Findings may inform policy makers on the needed infrastructure in healthcare systems, along with providing evidence on potential alternative delivery structures and staffing models to improve the impact of current obesity policies. For instance, recent proposals in the Treat and Reduce Obesity Act of 2015 advocate for the U.S. Congress to expand Medicare coverage to include the delivery of intensive behavioral therapy by non-providers and community organizations (Buchholz, 2015).

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Table 1. Research-practice partnership’s priority questions for each RE-AIM dimension

Reach	<ul style="list-style-type: none"> • What is the potential of the strategy to <u>reach</u> a high proportion of at-risk patients/healthcare employees?
Effectiveness	<ul style="list-style-type: none"> • Does the strategy <u>effectively</u> support patients/healthcare employees in achieving a clinically significant weight loss ($\geq 3\%$ initial body weight) without unintended negative consequences?
Adoption	<ul style="list-style-type: none"> • Is the strategy scalable to improve potential <u>adoption</u> across health systems?
Implementation	<ul style="list-style-type: none"> • Can the strategy be <u>implemented</u> with existing staff as intended at a reasonable cost?
Maintenance_{io}	<ul style="list-style-type: none"> • Can the strategy support weight loss <u>maintenance</u> and be sustained in typical healthcare settings?

Notes. i-individual, o-organizational

Table 2. Overview of focus of analysis for each RE-AIM dimension by integration strategy

Integration Strategy	Reach	Effectiveness	Adoption	Implementation	Maintenance_i	Maintenance_o
• Assessment, Prioritization, & Engagement Tool	Descriptive assessment	Targeted change	Descriptive assessment	Descriptive assessment	Descriptive assessment	Descriptive assessment
• Choice & Shared Decision-Making	Descriptive assessment	Targeted change	Beyond scope of pilot phase	Descriptive assessment	Targeted change	Descriptive assessment
• Behavioral Strategies	Descriptive assessment	Targeted change	Descriptive assessment	Descriptive assessment	Descriptive assessment	Descriptive assessment
• Financial Incentives	Descriptive assessment	Targeted change	Beyond scope of pilot phase	Descriptive assessment	Descriptive assessment	Descriptive assessment
• Mobile Health Technologies	Descriptive assessment	Descriptive assessment	Descriptive assessment	Descriptive assessment	Descriptive assessment	Descriptive assessment
• Clinic to Community Linkages	Descriptive assessment	Targeted change	Beyond scope of pilot phase	Descriptive assessment	Targeted change	Descriptive assessment
• Action Planning & Consultation	¹ Descriptive assessment	Targeted change	Beyond scope of pilot phase	Descriptive assessment	Descriptive assessment	Descriptive assessment
	² Descriptive assessment	Targeted change	Targeted change	Targeted change	Targeted change	Descriptive assessment

Notes. i-individual, o-organizational, 1- Implementation strategy, 2-Clinical weight loss intervention

Table 3. Overview of evidence-based strategies, trials, research designs, and participants

Evidence-based Strategy	Integration Trial Name	Research Design and Brief Pilot Trial Description	Individual-Organizational Level Participants
Assessment, Prioritization, and Engagement Tool	<ul style="list-style-type: none"> My Own Health Report 	<ul style="list-style-type: none"> Case study for investigating the integration of an enhanced health risk assessment including physical activity and dietary intake into workflow with post patient-provider experience surveys 	N= 1,506 Primary care patients N= 2 Practice sites N= 20 Providers
Choice-Shared Decision-Making	<ul style="list-style-type: none"> FIT Rx 90-1.0 	<ul style="list-style-type: none"> Randomized control trial testing Standard vs. Choice of support strategies in 6-months employee weight loss maintenance phase 	N=50 Healthcare employees N= 2 Fitness managers, 1 Registered dietician
Behavioral Strategies	<ul style="list-style-type: none"> FIT Rx 90-2.0 	<ul style="list-style-type: none"> Quasi-experimental comparative effectiveness trial testing FIT Rx 90 vs. FIT Rx 90 Plus behavioral strategies 	N=68 Healthcare employees N= 2 Fitness managers, 1 Registered dietician, and 9 Personal trainers
Financial Incentives	<ul style="list-style-type: none"> FIT Rx CUSTOM 	<ul style="list-style-type: none"> Feasibility, pre-post trial of offering financial incentives for fitness to high-risk employee department (i.e., patient transport) 	N=25 Healthcare employees
Mobile Health Technologies	<ul style="list-style-type: none"> FIT Rx 90-3.0 	<ul style="list-style-type: none"> Feasibility trial exploring the integration of commercially available, Fitnet mobile exercise app into employee weight loss program 	N= 46 Healthcare employees
Clinic to Community Linkages	<ul style="list-style-type: none"> Carilion Healthy Lifestyles – Community Health Educators 	<ul style="list-style-type: none"> Feasibility, pre-post trial assessing weight loss program delivered by community health educators with community-based support 	N= 16 Primary care patients N= 5 Community health educators
Action Planning and Consultation	<ul style="list-style-type: none"> Carilion Healthy Lifestyles – Nurse Care Coordinators 	<ul style="list-style-type: none"> Type 3 hybrid effectiveness-implementation trial testing an enhanced implementation strategy for nurse care coordinators in a Continuing Medical Education event (CME only vs. CME Plus) 	N= 780 Primary care patients N= 37 Practices N= 45 Nurse care coordinators

*Studies included in the dissertation

Section 2 – Implementation Trials

Chapter 3: Integrating an Assessment, Prioritization, and Engagement Tool

Trial: *My Own Health Report*

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Abstract

Objective: My Own Health Report (MOHR) is an assessment, prioritization, and engagement tool for behavioral and psychosocial patient-reported outcomes (PRO; diet, exercise, tobacco, alcohol use, drug use, stress level, anxiety/depression, and sleep). The objective of this study was to evaluate the feasibility of routinely administering the tool in primary care.

Methods: Guided by the RE-AIM framework, an in-depth case study explored the implementation methods—mailing and onsite completion versus telephone administered completion before the visit—used for tool integration at an early and delayed site of a matched clinic participating in the national MOHR trial. Using mixed methods, the multi-level study assessed reach of the tool, intervention effectiveness, adoption by site and provider, implementation strategies and costs, and sustainability intention. Frequencies of PRO and post experience surveys were compared by early versus delayed and patient versus provider reports. Field notes and exit interviews offered contextual factors surrounding implementation.

Results: At both sites reach was low when patients were mailed the survey and cued to complete it on their own in the practice or at home (3%-10%), however when the tool was administered by telephone before the visit the range jumped to approximately 62%-64% in both clinics. Those who

completed were representative of the clinical population. Significantly higher reports between control and intervention occurred in all areas of screening except tobacco (31% vs. 30%) and drug use (65% vs. 68%). For collaborative-goal setting, significantly higher reports were noted for the diet (44% vs. 51%), exercise (38% vs. 48%), and stress level (28% vs. 36%) domains, ($p<.05$). For referrals, significantly higher reports were noted for the exercise (16% vs. 28%) and stress level (14% vs. 20%), and a significantly lower report for sleep (26% vs. 20%) domains, ($p<.05$). For positive change since visit, significantly higher reports were noted for diet (47% vs. 58%), exercise (35% vs. 48%), tobacco use (18% vs. 27%), stress level (25% vs. 33%), anxiety/depression (21% vs. 33%), and sleep (24% vs. 29%, all $p<.05$). Organizational factors found that a high proportion of physicians used the tool though patients reported lower use than physicians. Qualitative data reflected the value practice personnel placed on the tool, but also noted the difficulty of sustaining it due to time and workflow interruptions.

Conclusion: Adding the MOHR tool to chronic care and well-visits led to high rates of screening and patient-centered support from providers. However, integration into typical primary care workflow was challenging and not sustainable for the practice.

Introduction

Patient health behaviors and psychosocial outcomes are recognized as prime underlying, changeable causes of chronic disease, but are not routinely or adequately addressed in primary care (Bodenheimer, Chen, & Bennett, 2009; Glasgow, Kapla, Ockene, Fisher, & Emmons, 2012). Common and costly medical conditions, such as obesity, diabetes, and cardiovascular disease, are often attributable to or complicated by patients' poor diet, lack of physical activity, substance use, or strained mental health (Fisher, 2011). However, due to the complexities of behavior change, multiple competing demands, and number of clinical measures needed for screening, primary care has been challenged to integrate protocols into practice to address these critical patient-reported outcomes (PROs; Estabrooks et al, 2012; Glasgow & Riley, 2013). With the prioritization of population health management and meaningful use of electronic health records (EHR), new tools and technologies that are feasible to implement and effective for supporting the systematic collection and follow-up on PROs within existing practice workflows are in demand (Estabrooks et al., 2012; Krist et al., 2015; Harle et al., 2016).

For decades, research and practice communities have worked to integrate health risk assessments (HRAs) and evidence-based, intensive behavioral counseling into primary care to monitor and improve patient health behaviors (Dickey, Gemson, & Carney, 1999; Ory, Jordan, & Bazzarre, 2002; Goldstein, Whitlock, & DePue, 2004; James et al., 2014). For instance, the *Prescription for Health 2003-2007* initiative aimed to test practical, evidence-based techniques to improve the delivery and effectiveness of health behavior change strategies for tobacco use, risky drinking, unhealthy diet, and physical inactivity in over 17 practice-based research networks (Cohen, Tallia, Crabtree, & Young, 2005). Guided by the 5As (*Assess, Advise, Agree, Assist, and Arrange*) framework, primary care practices integrating HRAs with brief counseling, collaborative

action planning, resource connection, and follow-up achieved improvements in patient health behaviors (Cohen et al., 2005). However, practices were challenged with the time, effort, training, and changes required for successful HRA implementation (Cohen et al., 2005). Other lessons learned included recognition of the overlap of prevention and chronic care, the value for all practice stakeholders to offer input on HRA administration, and the need for interactive technologies to assist with assessment and counseling processes (Cohen et al., 2005; MacGregor, Wong, Sharifi, Handley, & Bodenheimer, 2005). Since this initiative, interest in HRAs in primary care has grown, but understanding how to routinely support their use and improve their impact on care is still lacking (James et al., 2014; Glasgow et al., 2011).

More recently, policy makers and payers have supported the administration of HRAs and follow-up on areas of concern as part of patient-centered, preventive and chronic care services (Landon, Grumbach, & Wallace, 2012; Krist et al., 2015). Integrating HRAs that routinely measure PROs enable a shift from medical problem-oriented care to goal-oriented care (Reuben & Tinetti, 2012). Since 2011, HRAs have been a reimbursed component of the Medicare Annual Wellness Visit authorized by the Centers for Medicare and Medicaid Services (CMS) (Goetzel et al., 2012). Chronic care management services covered by CMS also includes systematic assessment of beneficiary's medical, functional, and psychosocial needs, documentation in the EHR, and patient engagement in developing comprehensive care plans that address health behavior change (Basu, Phillips, Bitton, Song, & Landon, 2015). Furthermore, the Core Quality Measure Collaborative led by America's Health Insurance Plans and leaders from CMS added body mass index (BMI) and tobacco screening and follow-up to its consensus core set of primary care clinical quality measures (Kassler, Howerton, Thompson, Cope, Alley, & Sanghavi, 2016). Payers are encouraged to commit to using the clinical quality measures for standardized reporting of value-based reimbursement

activities within accountable care organizations and patient-centered medical homes (Saver et al., 2015). Although promising advancements, uptake of these services and the collection of PROs have been limited and benefits have yet to be realized due to a lack of efficient systems and practical tools for implementation within the context of clinical practice (Estabrooks et al., 2012; Glasgow et al., 2012).

To address the need for practical tools and technologies to assist with the systematic collection and use of PROs in primary care, the My Own Health Report (MOHR) trial, a national, pragmatic implementation study, was initiated in 2013 (Krist et al., 2013). The trial assessed the implementation and impact of the MOHR tool within the existing workflow of 18 matched primary care practices located across the United States. As an automated assessment, prioritization, and engagement tool, MOHR systematically addressed health behavioral and psychosocial risks and provided both patients and healthcare providers with feedback for collaborative action on areas of concern (Kirst et al., 2013).

The primary aim of this study was to test the feasibility and effectiveness of systematically collecting patient-reported health behavior and psychosocial outcomes in primary care using the MOHR tool. Secondary aims focused on comparing similarities and differences in early and delayed practice implementation, along with patient and provider experiences. Comparisons were made by assessing: 1) screening, 2) collaborative goal-setting, 3) referrals, and 4) perceptions of positive, behavior change after fielding the tool. It was anticipated that implementation of the MOHR tool would be feasible in practice and lead to higher rates of screening and patient-centered support from providers in improving behavioral health risks. As a timely and relevant study for Carilion Clinic research-practice priorities, findings were expected to provide empirical evidence to inform screening, referral, and counseling follow-up processes for a future system of obesity care.

Further, with the addition of BMI as a core quality indicator, the assessment of physical activity and dietary intake as targets for intervention was also hypothesized to increase the likelihood of uptake of the MOHR tool.

Methods

Design

This was an in-depth, case study of two matched clinic sites that participated in the MOHR national trial. Nationally, the trial design was a 18-month pragmatic, practice-level, cluster, randomized implementation-focused study (Krist et al., 2013). A mixed-methods approach was used to assess early and delayed site implementation of the MOHR tool at the practice level, and compare experiences with the MOHR tool at the provider and patient-level (Creswell & Clark, 2011). For temporal trends, the delayed practice site served as a usual care control during early implementation and then six-months later served as an intervention condition. Local contextual factors surrounding implementation were collected during all study phases (Tomoaia-Cotisel et al., 2013). The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework guided the evaluation of implementation processes and outcomes (Glasgow, Vogt, & Boles, 1999). The trial was submitted to the Carilion Clinic Institutional Review Board (IRB) and approved as expedited research with informed consent documentation exempted. The IRB mandated a written information sheet be provided to providers and patients regarding the research. Appendix 3.1-3.13 includes copies of approved study materials (e.g., tool, scripts, letters, Patient and Provider experience surveys, and exit interview discussion guides).

Setting

The two clinic sites of focus for this case study were part of a family medicine residency practice within Carilion Clinic, a private, non-profit integrated healthcare delivery system serving western Virginia. The sites served two medically underserved areas (MUA) of Roanoke City, Virginia; Southeast (SE) and Northwest (NW). Roanoke City ranked 116 out of 133 counties in Virginia for overall health outcomes and 126 out of 133 counties in Virginia for health factors (UW Population Health Institute, 2013). Approximately 38,000 individuals lived in the MUAs, with median household income of \$30,000 in MUA SE and \$29,800 in MUA NW; considerably lower incomes than the state median of \$64,000. For poverty indicators, 36% of the population lived below 100% federal poverty level (MUA SE-37%, MUA NW-34%). Only 75 % of the population 25 years and over had a high school diploma as compared to 89% of Virginians. While residents of both MUAs were similarly impacted by poverty and education factors, MUA SE residents were 85% white and 11% black, and MUA NW residents were 65% black and 28% white; resulting in one of the most segregated cities in the state.

The practice was operating as a level-3 patient-centered medical home (PCMH) recognized by the National Committee for Quality Assurance (Bitton, Martin, & Landon, 2010). Team-based practice organization, optimization of health information technologies, quality measures, and the patient experience were focus areas in its PCMH transition (Carver & Jessie, 2011). The practice had been using an electronic health record (EHR) since 2007. Approximately 17 percent of patients were registered MyChart patient portal users, an EPIC operated system feature adopted by the practice in 2012. Neither practice site was systematically offering a HRA prior to participating in the study.

Participants

As a multi-level study, participants included practice administrators, care teams, providers, and patients. The practice was led by a Medical Director and an administrative Practice Director. The care teams included physicians, residents, advanced care providers, nurses, and medical office associates (MOA). The three-year residency program at the practice operated as a 10x10x10 with five residents per year at each site. A social worker, pharmacist, and a registered dietician were on-site and shared time between sites. The practice averaged 5 full-time equivalent providers and 15 full-time equivalent rooming staff at each site.

Demographically, the practice panel size totaled 15,200 with 42% Medicaid, 26% Medicare, and 17% uninsured/self-pay. The site in MUA SE had a panel of 7,800 patients, 60% female, 74% white, 19% black; 72% between 18-64 years, 10% 65 years and older, and a mean BMI=30.47. The site in MUA NW had a panel of 7,400 patients; 63% female; 50% white, 43% black; 71% between 18-64 years, and 11% 65 years and older; and a mean BMI=30.63. Approximately, 4,800 patients were seen annually. The target study patient population was adult patients (18-75 years) seen in each practice site for a non-acute sick visit. Chronic disease and wellness visits were expected to be targeted patient appointments for MOHR intervention.

Intervention

My Own Health Report Fielding

The intervention for this case study involved the systematic implementation and fielding of the MOHR tool. Within the national trial, practices were asked to adopt the tool and initiate the assessment with a minimum of 300 primary care patients at each randomly selected early site between March and December 2013 (Krist et al., 2013). Fielding at the delayed site within each

practice pairing was optional. Research-practice partnerships were formed at each study location (e.g., California, North Carolina, Virginia, Vermont, and Texas) to assist with planning, implementing, and evaluating the fielding process. Local research teams worked with their practice leaders to determine the most effective workflow for administering the MOHR assessment. Factors for implementation consideration included: 1) which patients would be invited, 2) when the MOHR would be completed, 3) where the MOHR would be completed (home or practice), 4) whether it would be offered in an electronic or paper-based format, and 5) how providers would receive MOHR feedback summaries to counsel patients (Krist et al., 2013). Priorities in workflow decision-making were placed on minimizing staff burden and enhancing consistency of implementation.

Fielding Strategy 1. This strategy initially included patients receiving a letter with a request to complete MOHR on the web approximately 2 weeks before the patient's appointment. Patients also received a reminder call for their visits and during this time the MOA offered to complete the tool over the telephone with the patient, if he/she had not completed it. Finally, patients who had not completed the tool before the visit were given the opportunity to complete it at an in-office computer kiosk. Based on feedback from fielding the MOHR tool at the early site, the delayed site strategy included similar principles, but used a telephone call rather than a letter as the initial invitation and encouraged patients to arrive early for their appointments.

Fielding Strategy 2. Carilion Direct, the healthcare system's centralized call center, staffed by nurses, was used as the second strategy at both the early and delayed locations. The nurses called with the specific purpose of completing the MOHR tool. The nurses administered the tool over the telephone and recorded the responses on the MOHR website.

Assessment Tool

For this study, the MOHR assessment tool was offered as a stand-alone, publically available website (www.MyOwnHealthReport.org). On the website, the patient assessment and feedback instrument asked patients 17 screening questions including basic demographics. MOHR screening question topics and measures were defined by a NIH-sponsored, expert consensus panel based on being brief, practical, and actionable (Estabrooks, 2012). Screening topics were also noted recommendations from the U.S. Preventive Services Task Force and areas of action included in the National Prevention Strategy (NPS, 2011). Questions are shown in Appendix 3.1.

MOHR tool risk factors were grouped into three categorical domains: *general health* (BMI, health status), *health behaviors* (dietary-consumption of fruits and vegetables, fast food, and sugary beverages; physical activity; sleep; use of alcohol; tobacco and illegal drugs; and miss use of prescription drugs), and *psychosocial* factors (stress, anxiety or worry, and depression). Eating pattern questions were modified from Starting the Conversation instrument (Paxton, Strycker, Toobert, Ammerman, & Glasgow, 2011) and physical activity questions were based on the Exercise Vital Sign (Sallis, 2011). In response to positive alcohol, drug, depression, and anxiety screening questions, algorithms embedded within the website seamlessly prompted the patient to complete more in-depth assessments, including the Alcohol Use Disorders Identification Test (AUDIT-C), the Drug Abuse Screening Test (DAST-10), the Patient Health Questionnaire (PHQ9), and the Generalized Anxiety Disorder (GAD) questionnaire (Krist et al., 2013).

Considered a HRA-Plus, the automated MOHR website scored patients' responses for each domain and provided feedback to elicit prioritizing, collaborative goal-setting, referrals, and behavior change. Scoring for each domain was characterized as being of 'no concern', 'some concern', or 'high concern' based on benchmarks and national guidelines. For measures with

'some' or 'high concern', patients were asked to select which topics they were ready to change and/or wanted to discuss with their physician at their upcoming visit. When multiple topics were prioritized, patients were prompted to select the one topic they felt was most important to them to address. After MOHR tool completion, patients received a summary feedback page to review, download, and print. As displayed in Appendix 3.2, the feedback page highlighted the health domains in which patients were doing well, offered recommendations for domains where improvements were needed, and directed patients to set three S.M.A.R.T. (Specific, Measurable, Action-oriented, Realistic, and Time-based) goals to support their change process. Simultaneously, a healthcare team summary report shown in Figure 1 was faxed to patients' practice site for provider review and use during the upcoming visit. At Carilion, the summary report was scanned into patients' chart in EPIC after the visit.

Data collection and measures

RE-AIM measurement

As shown in Table 1, each dimension of the RE-AIM framework was pragmatically operationalized for evaluating the feasibility and effectiveness of the MOHR tool. At the individual, patient-level, reach and effectiveness in patient perceptions of screening, collaborative goal-setting, referrals, and reports of positive change. Individual maintenance of change was beyond the scope of this trial. Secondary outcomes included perceptions of care delivery processes. At the organizational level, adoption, implementation, and maintenance were assessed as descriptive indicators of the setting and staff.

A variety of quantitative and quality instruments and processes were used for data sources:

- 1) Practice appointment record – A list of upcoming, weekly practice appointments

was generated from the EHR and sorted by visit type by the MOA. The record was used for identifying patients eligible for MOHR invitation and determining the denominator for intervention

2) MOHR administrative report – A password-protected dashboard linked to the MOHR website provided real-time patient and practice-level data on assessment completion. The report was used by the study coordinator for tracking weekly completion and determining the numerator for intervention reach and adoption. Patient-reported frequency of unhealthy behaviors and psychosocial issues were extracted through the MOHR administrative site.

3) Patient experience survey – Based on the 5As framework, a standardized questionnaire was administered to patients asking about patient-provider discussions, collaborative goal-setting across the MOHR tool health domains, recommendations for referrals, and positive behavior change since last clinic visit. Five questions were included from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group survey, a validated instrument assessing patient trust in their healthcare team (Fowler, Saucier, & Coffin, 2013). Surveys were mailed to the first 300 patients per site starting 2 weeks after their visit using a modified Dillman technique and a \$2 cash compensation (Dillman, 2011). A cover letter from a practice's provider and an information sheet was given for informed consent. Non-responders were called, and the survey was administered over the phone by research staff. The survey was estimated to take 10 to 15 minutes to complete. Survey response rate was 52% at the early site and 60% at the delayed site.

4) Provider experience survey – Adapted by the local research team from the patient experience survey, this post-assessment collected provider reports of screening, collaborative goal-setting, referrals, and perception of patients' behavior change after fielding the MOHR tool. Additional open-ended questions asked about integrating the MOHR tool into primary care workflows and recommendations for future implementation. The survey, available in an online and

paper-based format, was administered after 300 patients completed the MOHR assessment at the delayed intervention site. The practice's clinical research coordinator administered the survey using a modified Dillman technique (Dillman, 2011). It was estimated to take providers approximately 10 minutes to complete. An information sheet was given for informed consent. Survey response was 100% (n=20). This survey was a unique assessment at the Carilion delayed site and administered based on physician request and system interest in the Quadruple Aim, noting the need for considering and improving the provider and staff experience during practice improvement (Bodenheimer & Sinsky, 2014).

5) Contextual factors worksheet – Provided by the national MOHR evaluation team, the 'Context Matters' standardized worksheet template systematically collected local-level data on contextual factors influencing implementation, i.e., practice culture, staffing, motivation (Tomoaia-Cotisel, et al., 2013). The worksheet was completed by the study coordinator with input from the research-practice team at pre-mid- and final time points of the study. The worksheet offered space to systematically document practice field notes. Notes were used to report on contextual factors and offer discussion during bi-weekly national learning collaborative conference calls (Krist et al., 2013).

6) Costs spreadsheet – To estimate the costs of a practice replicating administration of the MOHR tool, a standardized costs spreadsheet tracked time for delivery within each practice site using minimally, burdensome costing procedures (Ritzwoller, Sukhanova, Gaglio, & Glasgow, 2009; Krist, Cifuentes, Dodoo, & Green, 2010). Time spent querying visit records, inviting patients to take the MOHR assessment, matching patient summary reports to the visit, counseling patients, and other tasks were included in the assessment. Cost was based on direct observation of the

intervention at early intervention and once the intervention reached a steady state near trial end point of reaching 300 patients.

7) Exit interviews – Mutual learning and feedback sessions were conducted with clinical and support staff involved with MOHR implementation at both the early and delayed intervention sites. Using a semi-structured discussion guide, the purpose of the sessions was to elicit positive and negative experiences about the MOHR implementation process, share lessons learned, provide suggestions for improvement, and explore interest in sustaining MOHR in its current or a modified format. Occurring within a month of post-fielding at the early site, the two sessions were moderated by the Principal Investigator and study coordinator, recorded, and transcribed.

Copies of assessment and data collection tools are shown in Appendix 3.3-3.14.

Data analysis

Quantitative data in the study was reported as frequencies, means, and percentages. For patient-reported outcomes obtained from MOHR tool completion, proportions of patients classified as at risk, ready to change, and wanting to discuss a behavioral risk factor were calculated. Post-fielding patient and provider experience survey results were tabulated using Pearson's Chi-square analysis for comparison of categorical variables with level of significance set at 5%. Qualitative data from interviews, field notes, and open-ended survey questions were reviewed by research assistants for common themes, categories, and illustrative quotes. Findings were compiled in tabular format and member checked to confirm interpretation.

Results

Reach

At the national-level, 3,591 patients were approached and 1,707 patients initiated the MOHR tool (Reach=48%). Reach varied by implementation strategy with higher reach when MOHR was completed with staff support rather than by patients alone (71% vs 30%, $p<.001$) (Krist et al., 2014). Locally, at the Carilion early site, reach was 3% when using Strategy 1 and 64% when using Strategy 2. Findings were similar at the delayed site (10% and 62%, respectively). The number of patients at the early site ($n=291$) and delayed site ($n=306$) were similar, but, while the patients completing the tool were representative of the respective practice sites, there were differences in the racial distribution of patients across clinics (early site—65% female, 84% white, 13% black, and 79% BMI \geq 25 kg/m²; delayed site—73% female, 58% white, 39% black, and 82% BMI \geq 25 kg/m²). Figure 2 displays the number of patients completing the MOHR assessment by week and the increased reach at both sites with Carilion Direct engagement.

Table 2 displays PROs for each health behavior, psychosocial, and general health risk factor assessed by the MOHR tool for national sites ($n=1,707$), and Carilion's early ($n=291$) and delayed intervention sites ($n=306$). On average out of the 13 risk factors, patients had a mean 5.8 ($SD=2.1$) risk factors nationally with mean ranges of 6.6 ($SD=2.0$) at Carilion's early site and 6.1 ($SD=2.4$) at the delayed site. Risks factors for sugary beverages, lack of sleep, tobacco use, use of illegal drug/prescriptions drug abuse, anxiety, depression, and overall health status were areas where Carilion patients completing the MOHR exceeded the report of all national sites. Early site patients were more likely to report poor dietary, stress, and overall health status risk factors. Delayed site patients were more likely to report alcohol intake and anxiety risk factors.

Related to obesity, a majority of Carilion patients were classified as overweight or obese, BMI \geq 25 kg/m² (79% at early site, 82% at delayed site). Carilion patients reported poor dietary behaviors for sugary beverages, fruits and vegetables, and fast food consumption (56%-83% at early site, 51%-71% at delayed site) and a lack of physical activity (73% at early site, 71% at delayed site). For patients with an elevated BMI, the area was identified as the most important priority to address at both clinics (24% at early site, 32% at delayed site). Of this selection of patients, wanting to discuss elevated BMI with their provider at an upcoming visit was expressed by 13% of early site patients and 20% of delayed site patients. In addition, 15% of early site patients and 22% of delayed site patients with an elevated BMI reported they were ready to make change in this area.

Effectiveness

Primary effectiveness outcomes of screening, collaborative goal-setting, referrals, and perception of positive health behavior change are shown in Tables 3-6. Each table details patient and provider survey questions along with the results of intervention and control sites at the national level and the early and delayed sites at Carilion's matched practice-level. At the early site, patients reported screening of domains in 60% to 88% of visits, collaborative goal-setting ranged from 12% to 52%, referrals ranged from 6% to 31%, and perceptions of positive change ranged from 12% to 59% across domains. At the delayed site, patients reported screening in 68% to 85% of visits, collaborative goal-setting ranged from 10% to 51%, referrals ranged from 6% to 29%, and perceptions of positive change ranged from 11% to 58% across domains.

Significantly higher reports between control and intervention occurred in all areas of screening except tobacco (31% vs. 30%) and drug use (65% vs. 68%), $p<.05$. For collaborative-goal setting, significantly higher reports were noted for eating/diet (44% vs. 51%), PA/exercise (38% vs.

48%), and stress level (28% vs. 36%) domains, $p < .05$. For referrals, significantly higher reports were noted for PA/exercise (16% vs. 28%) and stress level (14% vs. 20%), and a significantly lower report for sleep (26% vs. 20%) domains, $p < .05$. For positive change since visit, significantly higher reports were noted for eating/diet (47% vs. 58%), PA/exercise (35% vs. 48%), tobacco/smoking (18% vs. 27%), stress level (25% vs. 33%), anxiety/depression (21% vs. 33%), and sleep (24% vs. 29%), $p < .05$.

Patients reported tobacco was addressed most for screening, while diet was addressed most for other domain areas. Drug use was the least approached topic across domains, along with alcohol use referrals. For providers, similarities to patient reports existed in areas receiving the most attention; screening (tobacco-90%), goal-setting (eating/diet-80%), referrals (eating/diet-30%), and perceptions of positive change (eating/diet and PA/exercise-95%). However, differences existed in providers' areas of least attention; sleep screening (21%) and tobacco referrals (5%). Provider reports were consistently higher than patients, especially among perceptions of positive change.

Secondary effectiveness outcomes of care delivery processes are shown in Table 7. Patients assessed their care team significantly higher in caring (77% vs. 81%) and significantly lower in trust (80% vs. 74%), $p < .05$ post-MOHR fielding.

Adoption

At Carilion, 100% (n=2) of practice sites initiated use of the MOHR tool. The practice implementation team at the early site was led by the medical director and lead MOA. At the delayed site, implementation leadership expanded to include the practice manager and lead clinical nurse. At the staff level, 63% (n=12) of providers reported initiating use of the MOHR tool.

Implementation

Table 8 highlights the implementation strategies selected and time series tested at each site, along with the time to complete additional tasks associated with MOHR administration. At both Carilion sites, 100% of planned implementation strategies were attempted. The implementation strategy deemed successful for workflow integration at both sites was Strategy 2, engagement of Carilion Direct nurse operators for MOHR administration. Overall staff times averaged 25 ($SD=4.8$) minutes per patient visit beyond usual care at the early site and averaged 22 ($SD=2.9$) minutes per patient visit beyond usual care at the delayed site. Reported contextual factors impacting implementation at both sites included a low-literate patient population, a lack of patient interest in taking the HRA, the excess time to complete the MOHR tool, competing practice demands for staff and providers, and challenges with practice technology.

Poor functioning of technology impacted the MOHR implementation process at both sites. First, the assessment pages of the MOHR site were slow to download due to sites' network capabilities. MOAs struggled with the excess download time while trying to administer the tool over the phone, and patients often were unable to complete the tool in the 15 to 20 minute waiting time period prior to being called for their appointment. Second, the installed computer kiosk at the delayed site had repeated start-up difficulties and would freeze on patients while taking the MOHR assessment. Third, print outs of the healthcare team summary were not including needed patient identifying information for a brief period during kick-off of trial activity at the delayed site. Fourth, when Carilion Direct nurse operators completed the tool over the phone with patients using the paper format and then entered data into the MOHR website as daily patient batches, the healthcare team fax summaries to the delayed practice site experienced missing patient reports. MOHR site

administrators helped troubleshoot each of the technical challenges with the clinic sites, but poor functioning interfered with workflow and trial momentum.

Maintenance

Individual-patient level data was not assessed in the study due to a lack of resources for MOHR follow-up by the research-practice team and a lack of functionality for generating patient reports from the EHR. Organizational leadership expressed value in the MOHR tool and a desire for integration into future practice. However, current technological support, resources, and practice priorities prevented the progression of sustainability efforts. Neither site continued to use the MOHR tool after reaching the pilot intervention goal of 300 patients.

Qualitative inquiry

Exit interview sessions included leaders from the practice implementation teams at the early (n=2 physicians, 1 nurse, and 1 MOA) and delayed (n=3 physicians, 1 practice manager, 1 nurse, and 1 MOA) sites. Three topical themes emerged from the interviews: 1) Perceptions of tool, 2) Workflow, and 3) Future recommendations. Table 9 outlines the categories for each theme and provides an illustrative quote by early and delayed intervention sites. Similarities in responses existed between sites. Teams at both sites valued the capabilities of the MOHR tool, but expressed concern with the number of questions and time for administration. Not posing a burden to patients, staff, and providers was a common feature for decision-making regarding implementation strategies. Overall, integrating MOHR into existing practice workflow was more difficult than expected at both sites. Future recommendations from the teams included pursuing full EHR integration, with built-in linkages to the patient portal, for optimization. Linking referral resources

to MOHR was recommended as a means of promoting ongoing assessment and follow-up. In addition, providing additional training on the MOHR tool for the full care team was suggested.

Discussion

This case study provided highly relevant insights into facilitators and challenges for systematically integrating an assessment, prioritization, and engagement tool into primary care practice. Implementation of the MOHR tool was successful at improving screening rates and showed modest impacts on goal-setting, referrals, and reports of positive change for health behaviors and psychosocial issues. However, similar to the national MOHR trial and other studies investigating the implementation of HRAs (Krist et al., 2014; James, et al., 2014), integration proved difficult for practice sites without auxiliary support and was unsustainable beyond a pilot phase. For developing a system of obesity care, a HRA-Plus similar to the MOHR-like tool would offer an automated option for delivering the 5As of behavioral counseling, but additional care team engagement and technology investments are needed to support practice's implementation capacity.

Although both early and delayed sites were able to reach the national study goal of 300 patients completing the MOHR tool, patient engagement was extremely low using existing staff and on-site resources. Reach goals were only attainable by initiating a partnership with the Carilion Direct centralized call center. A major inflection point in uptake occurred at both sites when Carilion Direct nurse operators started calling all eligible patients and completed the assessment over the phone. The extended practice support helped overcome time limitations, patient low computer literacy, and on-going technological challenges, which are common obstacles reported in the HRA literature (James et al., 2014; Krist et al., 2014).

Interestingly, the delayed site's ability to use lessons learned from the early site did not improve rate of uptake. The site was greatly stymied with technology challenges and experienced significant wait times with their practice's Technology Support Group (TSG) . This observation of limited technological capabilities and overwhelmed technical assistance support for computer-related difficulties has been documented in other healthcare systems (Glasgow et al., 2012; Dickinson et al., 2013). Even with senior administrator support and grant incentives, research initiatives may be challenged to receive priority within a system's TSG work queue compared to regulatory requirements and tasks with payer reimbursement. For patients with at home or mobile Internet access and a MyChart account, administering MOHR through the patient portal was deemed the most promising option for long-term use. However, practice leadership questioned if their disparate patient population had access or would be willing to use limited mobile data for this cause. Likewise, MyChart enrollment remained low at the practice (<20%) and is in need of ongoing promotion and patient-centered problem-solving for scalability with this delivery option.

Carilion's MOHR pilot study identified a concerning, high number of health behavior and psychosocial risk factors among its patient panel. This finding was in accordance with the national trial and is reflective of the growing prevalence of multiple chronic disease diagnoses and multi-morbidity seen in primary care (Phillips et al., 2014). All obesity-related risk factors (i.e., elevated BMI, fruit and vegetable consumption, and PA/exercise) were consistently the most prevalent among Carilion sites. The MOHR tool's automated patient engagement and summary report abilities became a recognized advantage and value for helping providers assess and counsel patients with multiple high-risk areas. However, Carilion providers had limited exposure to the full capacity of the tool due to low patient interest, fragmented processes for reviewing MOHR results and goal-setting, and a lack of built-in systems for referrals and follow-up.

Aligned with the national trial (Phillips et al., 2014), elevated BMI was identified as patients' most important topic, but at Carilion the low interest in wanting to discuss with providers and readiness to change were surprising. One explanation for the finding may have been survey timing. As the last section of the MOHR tool, the length of administration and time for page download may have interfered with patients having an opportunity for full consideration of their summary results to articulate their desires for discussion and readiness for change. Similarly, some patient calls were abbreviated due to patients' concerns about using minutes on their mobile phone plans. Notwithstanding, increased application of motivational interviewing practices, such as exploring resistance and ambivalence to change, and more discussion on the role of weight in chronic disease management were noted by the practice. Greater attention to excess weight with these strategies and proactively addressing the sensitivity, stigma, and discrimination often surrounding the topic are supported in the literature (Dietz et al., 2015).

Comparison of the patient and provider experience reports post-MOHR fielding demonstrated the tool's impact on care, revealed opportunities for improvement, and identified discrepancies in perceptions. Overall, the MOHR tool was effective at facilitating the 5As for health behavior change. Carilion patients reported significant change for screening (*Assess* in seven domains, collaborative goal-setting (*Agree* in three domains, referrals (*Assist*) in two domains, and positive behavior change at follow-up (*Arrange*) in five domains. The ability of the MOHR tool to *advise* and activate a patient, while proactively alerting providers of patients' areas of high-risk and interests served as a potential mechanism for observed improvements (Krist et al., 2013). Patient screening reports were at least 60 percent for all domains using the MOHR tool. However, noteworthy, the patient-reports of *Agree*, *Assist*, and *Arrange* activity for domains were much lower and included a wider variation (6-58%). Interestingly, providers reported higher levels

of activity than patients in all 5A components. The differences in reporting illuminate potential recall bias. This phenomenon has been reported in previous studies where patients infrequently recall counseling from providers (King, Dube, Babb, & McAfee, 2013; McCarthy et al., 2014). As a result, the literature calls for research-practice teams to work on identifying better strategies to convey critical messages (McCarthy et al., 2014).

Providers were particularly more likely to report patients had made positive changes in each domain since their last clinic visit. However, gleaned from follow-up calls, many patients reported barriers with taking action and were in need of tangible support to follow-through on goals (i.e., specific instructions on dietary choices and food prep; money for medical fitness facility membership). In addition, in some cases, it was evident patients were expecting themselves to have complete adherence or cessation of activity, such as tobacco use, by the post-visit call and rated their change poorly. On the other hand, providers may have been more likely to recognize patients' incremental change in reporting.

Several observations may explain the degree of positive change achieved with administration of the MOHR tool. The significant improvements reported in diet, PA/exercise, and stress for goal-setting may be explained by patients' areas of greatest need, preferences, and values. PA/exercise and stress for referrals may be related to readily accessible clinical and community resources. The practice had the ability to refer patients to an exercise prescription program available at Carilion's medical fitness facilities through the EHR. In addition, an on-site social worker was available to assist patients with psychosocial needs including financial, transportation, family, and employment challenges; common stressors faced by the low socioeconomic patient population served by the practice. The MOHR domains of significant change also aligned with the practice's population health management goals to improve diabetes and hypertension self-management.

In contrast, not observing significant change between control and intervention also occurred in some domains, especially for counseling processes. No change in tobacco screening may be attributed to already existing high rates and tobacco screening inclusion in clinical quality measures and meaningful use (Kassler et al., 2016). A lack of significant change in drug use screening may be attributed to patients being seen regularly and known well at the practice; asking the sensitive question may have seemed unnecessary. The lower reports of referrals for sleep in the intervention condition may be explained by an increased waiting period for appointments at Carilion's sleep clinic. Although nurse care coordinators, behavioral health, and dieticians were co-located within sites, referral uptake related to MOHR was not evident. Patient interest, costs of services, lack of a seamless referral system, and competing staff demands may have been a contributor. For instance, during the pilot phase, nurse care coordinators were focused on patients discharged from the emergency department. In comparison to national control sites, the overall degree of change may have been affected by previous quality improvement work in the area.

The impact of the MOHR on care delivery processes was mixed and not as strong as seen in national sites. Patients' perceptions of caring significantly increased, but the degree of trust in medical care declined. Contextual factors impacting results may have been: 1) the patient experience survey was administered during the annual turnover in the residency program, 2) a new practice policy had just been implemented where if a patient had three no-shows for appointments they were dismissed from the practice, and 3) urine drug testing for prescribing chronic opioid therapy to patients had been implemented. From follow-up calls, it was clear some patients were distressed with the changes. Furthermore, some patients expressed concerns with sharing personal health information electronically.

Strengths and limitations

Several strengths and limitations were present to consider in interpretation of study findings. First, as a major strength, the study was highly, pragmatic on the explanatory/pragmatic continuum with strong-levels of stakeholder involvement that increased the relevancy of results to practice decision-makers (Glasgow & Riley, 2013). The examination of MOHR delivery feasibility solely involved Carilion's practice-based personnel rather than research assistants common in other studies (Krist et al., 2014; Goodyear-Smith, Warren, & Elley, 2013). Second, this case study uniquely contributed to the national MOHR trial by assessing the provider experience and comparing patient and provider reports. Third, the study included an array of quantitative and qualitative data sources, including reach, costs, and in-depth insights on contextual factors surrounding the implementation. Contextual factors that affect real-world research projects are often not identified or reported (Tomoaia-Cotisel et al., 2013). Fourth, the study was able to engage a vulnerable, underserved patient population (i.e., low-income, low literacy) with multiple chronic conditions and co-morbidities who are frequently not fully represented in research trials (Peek et al., 2014). Each practice site reached its patient completion goal for MOHR assessments and survey response rate was high.

A major limitation to the study was the lack of full integration of the MOHR tool into the EHR as intended in initial trial plans (Krist et al., 2014). The Carilion system lacked the capacity and resources to pursue integration and the timing would be excessive for a pilot trial. Other limitations involved the sample, data collection, and study measures. The case study was focused on only one practice setting located within a highly resourced health system, which is not representative of all small and medium-sized primary care practices nationally. Data collection was cross-sectional and only addressed an initial offering of MOHR to patients. It did not directly

measure behaviors to validate self-reported perceptions of positive change or review patient records to assess short and long-term change in health outcomes, i.e., weight, blood pressure, or A1C3. The MOHR assessment was not linked at the individual, patient-level to the follow-up patient experience survey. Outcome values were not adjusted for patient age, race, ethnicity, health history, time in current practice, or quality of the patient-provider relationship. Furthermore, the patient experience survey did not collect patient feedback on the administration or format of the MOHR tool. Lastly, the provider experience survey adapted by the research team was not validated, collapsed scoring categories, and was only administered to providers at the delayed implementation site.

Future research will focus on determining how to build an infrastructure to support the administration of a MOHR-like tool and optimize integration into the EHR and patient portal. Advocating EHR vendors would further advance PROs work and support behavioral counseling (Glasgow et al., 2012; Krist et al., 2014). Staffing models that engage other members of the integrated care team, including central nurse care coordinators, health coaches, and community health workers are areas for investigation. Studies with repeated administration of the MOHR tool would be of value for determining appropriate follow-up intervals and assessing patient health outcomes overtime (Phillips et al., 2014). This would be of particular interest for obesity care where patients could regular document progress toward weight loss goals and self-report, influential behaviors such as dietary intake, physical activity, stress, and sleep. As healthcare systems continue to invest in technology and population health management, the PROs in the MOHR are highly likely to play a greater role in value-based care payment models and reimbursement decisions (Harle et al, 2016).

Conclusions

Overall, this study demonstrated that the MOHR tool is relevant for primary care practice and patients, but challenges exist with integration into routine care. Implementation of the assessment tool brought attention to patients' high number of behavioral and psychosocial health risks, particularly related to nutrition, physical activity, and weight management. It also brought attention to the significant workflow efforts required by practices to effectively assess risks and counsel patients using the 5As model even with access to interactive technologies. Revised, integrated care staffing models and additional patient resources are needed to successfully implement and sustain optimal use of an assessment, prioritization, and engagement tool for monitoring and feedback on health behavior risks. EHR and patient portal integration with linkages to clinical and community follow-up support are deemed critical for success in future implementation efforts.

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Table 1. Operational definition, level, focus, and source of data for each RE-AIM dimension in MOHR tool evaluation

RE-AIM Dimension	Operational Definition	Level	Focus	Source of Data
Reach	<ul style="list-style-type: none"> Number, proportion, and representativeness of eligible patients invited who completed a MOHR assessment 	Individual; Patient	Descriptive assessment	<ul style="list-style-type: none"> Practice appointment record MOHR administrative report
Effectiveness	<ul style="list-style-type: none"> Proportion of patients reporting screening, collaborative goal-setting, referrals, and perceptions of health behavior change after fielding of MOHR tool Proportion of patients reporting satisfaction with care delivery process 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Patient experience survey
Adoption	<ul style="list-style-type: none"> Number, proportion, and representativeness of practice sites and providers that initiated delivery of MOHR tool 	Organizational; Practice, Provider	Descriptive assessment	<ul style="list-style-type: none"> MOHR administrative report Provider experience survey
Implementation	<ul style="list-style-type: none"> Degree to which implementation strategies were delivered as planned to integrate MOHR tool into practice workflow Contextual factors influencing implementation Costs of intervention delivery (i.e., time and staff needed to carry out intervention steps) 	Organizational; Practice	Descriptive assessment	<ul style="list-style-type: none"> Context Matters worksheet Costs spreadsheet Practice exit interviews
Maintenance _i	<ul style="list-style-type: none"> N/A – Beyond the scope of pilot phase 	N/A	N/A	<ul style="list-style-type: none"> N/A
Maintenance _o	<ul style="list-style-type: none"> Sustained delivery of MOHR tool within practice 	Organizational; Practice	Descriptive assessment	<ul style="list-style-type: none"> MOHR administrative report

Notes. i-individual, o-organizational

Table 2. Patient-reported unhealthy behaviors and psychosocial issues using the MOHR tool

Patient-reported Outcomes	All Sites Intervention National (N=9)	Early Site Intervention Carilion Clinic (N=1)	Delayed Site Intervention Carilion Clinic (N=1)
Respondents, No.	1,707	291	306
Risk factors per patient, Mean (SD)	5.8 (2.1)	6.6 (2.0)	6.1 (2.4)
Patients “at risk” for given risk factors, No. (%)			
Health behavior risk factors			
Fast food (1 or more times per week)	975 (57%)	175 (60%)	172 (56%)
Fruits and vegetables (<5 servings a day)	1,443 (85%)	241 (83 %)	224 (73%)
Sugary beverages (1 or more per day)	763 (45%)	164 (56%)	154 (51%)
Insufficient physical activity/exercise (<150 minutes per week)	1,209 (71%)	215 (73%)	216 (71%)
Sleep (Sleep often, always, snoring)	1,091 (64%)	199 (68%)	205 (68%)
Alcohol intake (≥ 1 binge episode per year)	407 (24%)	52 (18%)	72 (24%)
Tobacco use	407 (24%)	126 (43%)	124 (41%)
Illegal drug use or prescription drug abuse	55 (3%)	18 (6%)	20 (7%)
Psychosocial risk factors			
Anxiety or worry (Score ≥ 4)	265 (16%)	79 (27%)	90 (30%)
Depression (Score ≥ 4)	146 (9%)	46 (16%)	42 (14%)
Stress (Level ≥ 7)	1,017 (60%)	197 (68%)	167 (55%)
General health risk factors			
Body mass index (BMI ≥ 25 kg/m ²)	1,358 (80%)	231 (79%)	250 (82%)
Overall health status (Rated fair/poor)	767 (45%)	162 (56%)	158 (53%)

Table 3. Patient-provider reports of behavioral and psychosocial screening post-MOHR fielding

Screening Survey Questions									
Patient: Thinking about your visits to the clinic within the last month, were you asked about the following? (Yes/No)									
Provider: Thinking about your patients' chronic disease/wellness visits to the clinic within the last month, how often did you ask about the following health topics? (Never/Sometimes/Usually/Always)									
Topic	Overall Study 9 Matched National Practice Sites		Case Study – 1 Matched (Early and Delayed) Carilion Clinic Practice Sites						
	Intervention Sites PATIENT n=1,513	Control Sites PATIENT n=1,400	Early Intervention Site PATIENT n=151	Delayed Intervention Site PATIENT n=176	Control Site PATIENT n=155	Delayed Intervention Site PROVIDER n=20			
	Yes	Yes	Yes	Yes	Yes	Never	Sometimes	Usually	Always
Eating/Diet	74%	59%*	71%	77%	71%*	0%	10%	55%	35%
PA/ Exercise	79%	70%*	67%	82%	69%*	0%	10%	55%	35%
Tobacco/ Smoking	77%	72%*	88%	85%	84%	0%	10%	45%	45%
Alcohol Use	75%	68%*	81%	76%	70%*	0%	42%	37%	21%
Drug Use	69%	60%*	79%	68%	65%	0%	63%	37%	0%
Stress Level	64%	51%*	60%	84%	66%*	0%	58%	42%	0%
Anxiety/ Depression	65%	49%*	71%	79%	67%*	0%	32%	63%	5%
Sleep	66%	53%*	65%	77%	66%*	0%	79%	21%	0%

* $p < .05$

Table 4. Patient-provider reports of collaborative goal-setting post-MOHR fielding

Collaborative Goal-Setting Survey Questions									
Patient: Did anyone work with you to set specific goals to make changes in any of these areas? (Yes/No)									
Provider: Thinking about your patients' chronic disease/wellness visits to the clinic within the last month, how often did you work with your patients to set specific goals to make changes in any of these areas? (Never/Sometimes/Usually/Always)									
Topic	Overall Study 9 Matched National Practice Sites		Case Study – 1 Matched (Early and Delayed) Carilion Clinic Practice Sites						
	Intervention Sites PATIENT n=1,513	Control Sites PATIENT n=1,400	Early Intervention Site PATIENT n=151	Delayed Intervention Site PATIENT n=176	Control Site PATIENT n=155	Delayed Intervention Site PROVIDER n=20			
	Yes	Yes	Yes	Yes	Yes	Never	Sometimes	Usually	Always
Eating/Diet	48%	32%*	52%	51%	44%*	0%	20%	65%	15%
PA/ Exercise	46%	34%*	45%	48%	38%*	0%	20%	60%	20%
Tobacco/ Smoking	17%	15%	27%	30%	31%	0%	20%	60%	20%
Alcohol Use	15%	11%*	12%	13%	15%	5%	79%	11%	5%
Drug Use	12%	10%	12%	10%	10%	20%	75%	5%	0%
Stress Level	27%	19%*	30%	36%	28%*	5%	70%	25%	0%
Anxiety/ Depression	29%	21%*	50%	37%	35%	0%	40%	50%	10%
Sleep	28%	22%*	36%	31%	33%	11%	47%	37%	5%

* $p < .05$

Table 5. Patient-provider reports of referrals post-MOHR fielding

Referral Survey Questions									
Patient: Did anyone in the clinic recommend you seek assistance from another provider or program to help you make changes in any of these areas? (Yes/No)									
Provider: How often did you recommend your patients seek assistance from another provider, service, or program to help make changes in any of these areas? This could include referring patients to a specialist, health education program, or a community resource. (Never/Sometimes/Usually/Always)									
Topic	Overall Study 9 Matched National Practice Sites		Case Study – 1 Matched (Early and Delayed) Carilion Clinic Practice Sites						
	Intervention Sites PATIENT n=1,513	Control Sites PATIENT n=1,400	Early Intervention Site PATIENT n=151	Delayed Intervention Site PATIENT n=176	Control Site PATIENT n=155	Delayed Intervention Site PROVIDER n=20			
	Yes	Yes	Yes	Yes	Yes	Never	Sometimes	Usually	Always
Eating/Diet	20%	16%	31%	29%	28%	10%	60%	15%	15%
PA/ Exercise	17%	16%	23%	28%	16%*	0%	75%	10%	15%
Tobacco/ Smoking	7%	7%	11%	14%	16%	53%	42%	5%	0%
Alcohol Use	5%	4%	6%	6%	7%	37%	42%	20%	0%
Drug Use	4%	4%	6%	6%	7%	42%	53%	5%	0%
Stress Level	10%	8%	20%	20%	14%*	16%	63%	21%	0%
Anxiety/ Depression	11%	9%	23%	23%	19%	11%	74%	16%	0%
Sleep	12%	11%	20%	20%	26%*	30%	60%	5%	5%

* $p < .05$

Table 6. Patient-provider reports of positive health behavior change post-MOHR fielding

Positive Change Survey Questions							
Patient: Have you made any positive changes in these areas since your visit? (Yes/No)							
Provider: To your knowledge, have any of your patients made any positive changes in these areas since their visit? (Yes/No/I Don't Know)							
Topic	Overall Study- 9 Matched National Practice Sites		Case Study – 1 Matched (Early and Delayed) Carilion Clinic Practice Sites				
	Intervention Sites PATIENT n=1,513	Control Sites PATIENT n=1,400	Early Intervention Site PATIENT n=151	Delayed Intervention Site PATIENT n=176	Control PATIENT n=155	Delayed Intervention Site PROVIDER n=20	
	Yes	Yes	Yes	Yes	Yes	Yes	I Don't Know
Eating/Diet	63%	50%*	59%	58%	47%*	95%	5%
PA/Exercise	54%	46%*	54%	48%	35%*	95%	5%
Tobacco/Smoking	13%	13%	24%	27%	18%*	80%	20%
Alcohol Use	11%	10%	14%	15%	15%	45%	35%
Drug Use	10%	9%	12%	11%	9%	32%	42%
Stress Level	29%	22%*	31%	33%	25%*	60%	25%
Anxiety/Depression	26%	21%*	40%	33%	21%*	80%	15%
Sleep	30%	25%*	37%	29%	24%*	50%	35%

* $p < .05$

Table 7. Patient-reported care delivery process assessment post-MOHR fielding

Care Delivery Survey Questions					
Patient: Think about the doctors, nurses, and other clinic staff you saw during your visits to the clinic over the past month. Did you feel like: (e.g., they really cared about me as a person)? (Yes- Yes Definitely, Yes Somewhat) or (No/ Never)					
Topic	Overall Study 9 Matched National Practice Sites		Case Study – 1 Matched (Early and Delayed) Carilion Clinic Practice Sites		
	Intervention Sites PATIENT n=1,513	Control Sites PATIENT n=1,400	Early Intervention Site PATIENT n=151	Delayed Intervention Site PATIENT n=176	Control Site PATIENT n=155
	Yes	Yes	Yes	Yes	Yes
They really cared about me as a person	82%	75%*	76%	81%	77%*
I could really trust them with my medical care	85%	80%*	77%	74%	80%*
I was encouraged to ask questions	57%	48%*	57%	57%	54%
Showed interest in my concerns and questions	71%	64%*	65%	65%	68%
Explained things in a way that was easy to understand	74%	69%*	74%	69%	69%

* $p < .05$

Table 8. MOHR implementation strategies by practice sites and time to complete tasks

Carilion Intervention Site	Implementation Strategy	Target Population	Minutes per Visit Beyond Usual Care, by Task Completed							
			Query Visit Records	Mail Invitation	Invite on Phone	Match Summary to Visit	Counsel Patients	Follow-Up	Other Tasks	Total
Early Site	Strategy 1 <ul style="list-style-type: none"> Patients mailed letter to complete MOHR on the web 2 weeks before appointment, MOA offered to complete MOHR on appointment reminder calls, or Patients offered to complete MOHR at in-office computer kiosk 	Randomly selected 30 scheduled chronic disease/wellness patients a week	2	2	15-20	2	5	N/A	10 (In-office help at kiosk)	21-31
	Strategy 2 <ul style="list-style-type: none"> Carilion Direct called patients and asked MOHR questions over the phone 1 week before visit 	All chronic disease/wellness patients	2	2	10-15	2	5	N/A	10 (In-office help at kiosk)	21-26
Delayed Site	Strategy 1 <ul style="list-style-type: none"> MOA invited patients to visit web or come 15 minutes early to complete MOHR at in-office computer kiosk on appointment reminder calls 	All chronic disease/wellness patients	2	N/A	5	2	5	N/A	10 (In-office help at kiosk)	24
	Strategy 2 <ul style="list-style-type: none"> Carilion Direct called patients and asked MOHR questions over the phone 1 week before visit 	All chronic disease/wellness patients	2	N/A	10-15	2	5	N/A	N/A	19-24

Notes. MOHR – My Own Health Report; MOA-Medical Office Associate; Carilion Direct-centralized call center

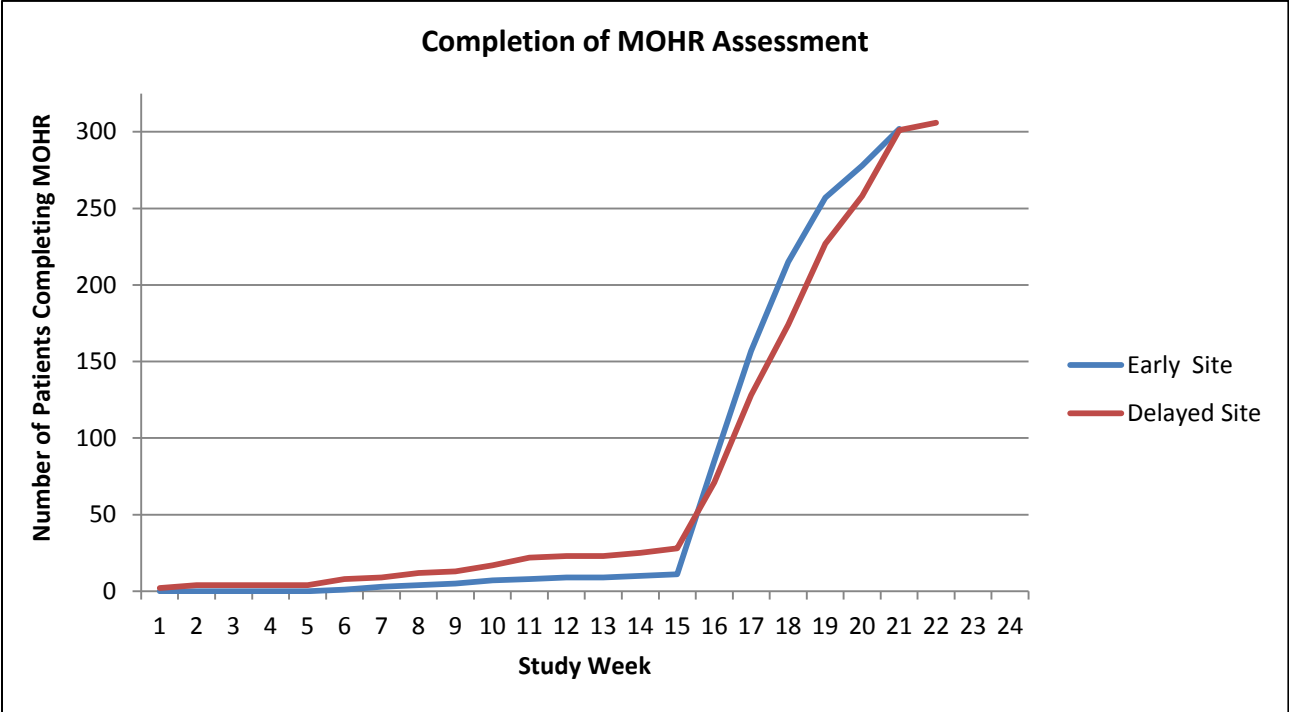
Table 9. Common themes, categories, and illustrative quotes from practice team at early and delayed intervention sites

Common Themes	Categories	Carilion Early Intervention Site	Carilion Delayed Intervention Site
Perception of MOHR Tool	Value	<ul style="list-style-type: none"> “It helped focus what the patient wanted to talk about. In terms of preventative care, it showed what they were interested in.” 	<ul style="list-style-type: none"> “It was a very helpful, time-saving, and valuable tool for providers.”
	Length	<ul style="list-style-type: none"> “I just think it is very long. I think that if it was shorter, it would be much easier.” 	<ul style="list-style-type: none"> “On the phone or before their appointment, patients would not have time to answer all its questions.”
MOHR Workflow	Implementation Facilitators	<ul style="list-style-type: none"> “We did have patients that when they came in, if they came in early enough before the doctor was ready they were very interested in filling it out online in the office [at kiosk].” 	<ul style="list-style-type: none"> “We put it [kiosk] right in front of the window, so that the staff would be able to see what patients were doing, see if there were difficulties, and help answer any questions.”
		<ul style="list-style-type: none"> “I was only sending 30 letters a week. They [Carilion Direct] were calling every single eligible patient. So, that made a huge difference in completions.” 	<ul style="list-style-type: none"> “Carilion Direct was awesome at helping us reach the project goal by calling patients.”
	Implementation Barriers	<ul style="list-style-type: none"> “It became a burden for the front office staff that had to try to reach patients by phone.” 	<ul style="list-style-type: none"> “The computer at the kiosk kept freezing and the pages were taking over 5 minutes to load. It was too slow for patients to try to complete.”
		<ul style="list-style-type: none"> “It was very confusing from the nursing side, trying to figure out when the patient had done it [MOHR assessment].” 	<ul style="list-style-type: none"> “I didn’t know of a MOHR completion until it was placed on a patient’s door who usually was presenting for 3+ chronic conditions. No time to review or act upon info.”
	Expectations	<ul style="list-style-type: none"> “This appeared on the surface to not be as intensive in terms of provider time. We were hoping that the patients would be the ones that filled this out. It wouldn’t be staff time.” 	<ul style="list-style-type: none"> “It just turned out to be a lot more difficult than it appeared on paper.”
	Engagement	<ul style="list-style-type: none"> “It was tough for the providers to get on board initially because the responses came trickling in so slowly. It really fell off the radar of the providers.” 	<ul style="list-style-type: none"> “Only had a few patients with reports and none had issues they cared to discuss.”
Behavioral Change Support	<ul style="list-style-type: none"> “So instead of putting more things on the provider, we simply said for things patients want to discuss, you would do that discussion in the way that you would do any discussion with a patient.” 	<ul style="list-style-type: none"> “You see in the progress notes that is says, ‘patient instructed to eat more fruits and vegetables or to exercise more’, but they walk out of here with that recommendation, but no real tools to help them.” 	
MOHR Future Recommendations	Integration	<ul style="list-style-type: none"> “All patients should have access to the MOHR on MyChart, and then monthly follow-up on their goals through MyChart.” 	<ul style="list-style-type: none"> “There needs to be closer ties to the EHR, like embed with Epic so that MyChart could be used for follow-up.”
	Resource Linkage	<ul style="list-style-type: none"> “I think to make them actionable the things that we would access need to be able to be immediately turned around and implemented; i.e., strategies for weight reduction, referrals for exercise, or clinic for better sleep.” 	<ul style="list-style-type: none"> “We need a consistent set of tools readily available in .dot phrases, I think that would be an invaluable resource, because we don’t have time to look for it.”

Figure 1. My Own Health Report healthcare team summary report



Figure 2. Number of patients completing the MOHR assessment each week by practice site



Chapter 4: Integrating Patient Choice and Shared Decision-Making

Trial: FIT Rx 90-1.0

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Abstract

Objective: A shared decision-making approach was employed to assess if healthcare employee choice of behavioral components improved the effectiveness of weight loss maintenance support following the pilot FIT Rx 90 program. Adherence and costs were monitored.

Methods: Healthcare employees were recruited into a pragmatic, randomized pilot trial following the completion of the FIT Rx 90 weight loss program (n=30; 90% female; 47±8.5 years) and assigned to a standard maintenance program (weekly motivational messages/weight reporting via email/text, 9 support calls, and 3 group sessions) or an individually designed maintenance program based upon choice of support. Shared decision-making (SDM) was used for preference selection.

Results: Participants in Standard (-3.5%±3.0) and Choice-SDM (-3.6%±3.7) had similar initial weight loss. Two thirds of Choice-SDM selected all components. Calls and group sessions were declined most. On average, participants maintained weight loss similarly (Standard=-3.9%±4.6, Choice-SDM=-4.9%±6.0; p>.05), though Choice-SDM had higher adherence. Standard involved 6 hours/\$173, while Choice-SDM involved 5 hours/\$151 per participant.

Conclusions: Choice of behavioral components does not reduce effectiveness, but does improve adherence and modestly reduce delivery costs.

Introduction

Although research has demonstrated the efficacy of behavioral lifestyle programs to help patients achieve a modest, clinically meaningful weight loss (i.e., 3%-5% of initial body weight) (Jensen et al., 2014; Wing et al., 2011), it is well documented that a majority of patients experience weight regain following program termination (Thomas, Bond, Phelan, Hill, & Wing, 2014). Efficacious behavioral strategies for weight loss maintenance also exist, but the degree to which these strategies are preferred by participants is unknown (Akers, Estabrooks, & Davy, 2010). With preference-sensitive decisions, shared decision-making (SDM) is considered a client or patient-centered model of care (Stiggelbout, Pieterse, & De Haes, 2015). However, integration of SDM is limited in practice (Shay & Lafata, 2015). Healthcare administrators and educators, rather than participants, typically decide the weight loss maintenance services that will be offered and how delivery will take place. To gain support for SDM implementation, further empirical evidence regarding its impact on outcomes (i.e., treatment adherence and healthcare utilization) is necessary (Shay & Lafata, 2015).

The use of SDM aligns with behavioral choice theory (Epstein, 1992), which proposes that participants will achieve better weight loss maintenance outcomes when their choice and preferences are integrated into treatment. However, some approaches using behavioral choice theory in the context of weight loss have suggested choice may have no effect or result in worse outcomes (Burke et al., 2008; Coles, Fletcher, Galbraith, & Clifton, 2014; Yancy et al., 2015). For instance, studies providing delivery options, such as individual or group, have found no differences between groups who received their preferences (Burke et al., 2008; Coles et al., 2014).

While the findings on providing participant choice in weight loss treatments is somewhat equivocal, there are pragmatic reasons to provide participants with choice of weight loss maintenance program components, especially in an employee wellness initiative. By matching preferences to treatment, it could be hypothesized that employees provided a choice are more likely to adhere to the treatment regimen and to benefit from it (Street, Elwyn, & Epstein, 2012). Choice over treatment alternatives is suggested to improve treatment effectiveness by enhancing personal control (Geers et al., 2013). Concurrently, this would, hypothetically, allow for more efficient use of healthcare resources and wellness incentives. In addition, some employees may choose less intensive components, yet still achieve and maintain weight loss treatment goals. This scenario has the potential to improve scalability, where a greater number of employees may be served within an organization (Milat, King, Bauman, & Redman, 2013; Oshima, Lee, & Emanuel, 2013). Furthermore, choice aligns with patient-centered care through respect of preferences and active involvement of participants in decision-making regarding treatment (Institute of Medicine, 2001).

The purpose of this pilot trial was to employ a SDM approach to assess if participant choice of program components improved the effectiveness of weight loss maintenance services following a fitness-based weight loss program (FIT Rx 90) for healthcare employees. The secondary purpose was to monitor program adherence and implementation costs. It was hypothesized that choice would not impact healthcare employees' ability to maintain weight loss, but would contribute to higher program adherence and lower delivery costs.

Methods

An integrated-research practice partnership (Estabrooks & Glasgow, 2006) was used to balance scientific and practice-based evidence (Ammerman, Smith, & Calancie, 2014), and to consider available delivery resources. The partnership consisted of researchers with expertise in physical activity, nutrition, and weight management, Carilion Clinic organizational decision-makers, as well as practitioners who implemented the weight loss program with Carilion Wellness. As a private, not-for-profit health care organization, Carilion serves approximately one million patients throughout western Virginia through a healthcare workforce of approximately 11,700 employees. All trial procedures were approved by the Carilion Institutional Review Board. Informed, written consent was obtained from each patient.

A participatory dissemination model (Estabrooks & Glasgow, 2006) was used to inform the selection of behavioral components for the maintenance program. Scientific partners performed a literature review and conducted expert interviews to obtain recommendations (Ramaer, Farmer, Apps Eccles, & McCargaer, 2014; Thomas, Bond, Phelan, Hill, & Wing, 2014). This process generated a list of evidence-based strategies for practice partners' consideration (Fjeldsoe, Neuhaus, Winkler, & Eakin, 2011; Peterson et al., 2014; Svetkey et al., 2012; Swift, Johannsen, Lavie, Earnest, & Church, 2014;). Selected strategies were perceived as practical, affordable, and possessing scalability and sustainability potential.

Study design

This was a pragmatic, randomized pilot trial (Glasgow, 2013) testing a standard maintenance program (Standard) versus an individually designed maintenance program based upon employee preferences (Choice-SDM). The RE-AIM framework guided the development of

the intervention as well as the evaluation strategies (Glasgow, Vogt, & Boles, 1999). Aligned with RE-AIM, the study was designed to develop and test a weight loss maintenance intervention that has the potential to reach a large proportion of the target population, effectively maintain weight, and be adopted, implemented, and maintained at a reasonable cost throughout the Carilion organization.

Participants

The target population included Carilion Clinic employees with a BMI ≥ 30 kg/m². For the maintenance phase, employees were eligible for inclusion if they completed the initial weight loss program, lost greater than one pound, and/or improved body composition (e.g., decreased body fat percentage). Employees were excluded if they did not complete the weight loss post-program assessment, were pregnant, or were unwilling to share their results from the weight loss program.

Intervention

Initial weight loss program: FIT Rx 90

Developed by practice partners from Carilion Wellness, FIT Rx 90 was a weight loss program emphasizing physical activity and dietary change over a 90-day period. Physician referral was required. Intervention components, overseen by a Medical Director, included: a pre-post fitness assessment, six one-on-one personal training sessions, five group nutrition sessions, a deposit contract, three-month fitness center membership, and a physician feedback report.

Maintenance programs

Standard maintenance program (Standard). Four behavioral components were selected to comprise the six-month Standard program including: 1) weekly motivational messages via email/text, 2) weekly weight-reporting via email/text, 3) nine support calls (biweekly for three months, then monthly; 15-20 min.), and 4) three group sessions (bi-monthly; 60 min.). Each call followed the 5As (Assess, Advice, Agree, Assist, and Arrange) model (Jensen et al., 2014). Two health educators from the research team, along with two exercise physiologists and a registered dietitian from the practice team, delivered the program.

Individually designed maintenance program based upon employee preferences (Choice-SDM). Employees randomly assigned to Choice-SDM chose which and how much of the Standard components they would like to receive. Using an information sheet, a master certified health educator used a SDM approach to guide selection: (1) *choice talk*, making sure the employee knows options are available, (2) *option talk*, providing more detailed information about each option, and (3) *decision talk*, encouraging employee to consider preference and make a decision (Elwyn et al., 2012). The same personnel delivered both the Standard and Choice-SDM.

Data collection and measures

Four dimensions of the RE-AIM framework, *Reach, Effectiveness, Implementation, and Maintenance*, were assessed based on definitions and suggested reporting criteria at www.re-aim.org (Glasgow, Vogt, & Boles, 1999). Table 1 provides operational definitions, level, focus, and source of data for each RE-AIM dimension. Assessing *Adoption* was beyond the scope of this trial, though a description of the delivery setting and staff was provided. Measures were

collected at baseline, post-program (90 days), three-months maintenance and six-months maintenance.

Reach was assessed as the number and proportion of FIT Rx 90 participants that enrolled in the maintenance study and the degree to which those that enrolled were representative of the healthcare employees that participated in the initial weight loss program by age, gender, and weight status. In addition, preferences of program components for Choice-SDM participants and participant adherence were assessed as an indicator of the potential and temporal reach, respectively, of different intervention components.

Effectiveness was assessed after three months of the maintenance program with sustained reductions of initial body weight as a primary outcome. Weight was measured using a calibrated digital scale with the employee wearing light, indoor clothes without shoes. Secondary outcomes included BMI, body circumference measurements, percent body fat by hand-held bioelectrical impedance analysis, blood pressure, self-reported physical activity, dietary intake (Ahuja et al., 2012), and beverage consumption (Hedrick et al., 2013). A practice-developed tool assessing self-rated overall health and a composite wellness rating was used as a proxy for quality of life.

Implementation was assessed as the degree to which the intervention sessions were delivered as intended and the costs associated with intervention delivery. Staff hours, materials, and labor costs based on U.S. Bureau of Labor Statistics, Occupational Employment and Wages were inventoried.

Maintenance was assessed using the same indicators as effectiveness at the completion of the maintenance intervention (e.g, 6 months after FIT Rx 90 post-program assessment).

Data analyses

Baseline descriptive statistics were calculated for each group and values were reported as mean \pm standard deviation (SD) or as frequency in percentage. Overall effects and between group differences were assessed by repeated measures ANOVA using SPSS (version 22 for MAC, SPSS Inc., Chicago, IL). Analyses were present at follow-up. As a small pilot trial seeking preliminary evidence, the statistical significance level was set at 10% (Leon, Davis, & Kraemer, 2011; Thabane et al., 2010).

Results

Reach

Characteristics of FIT Rx 90 participants (n=50) are shown in Table 2. Program dropouts and healthcare employees declining the maintenance program were heavier, had a higher BMI, and smaller percentage weight loss during initial program ($p < .10$). Seventy-seven percent of eligible employees (n=30) enrolled (Standard=15, Choice-SDM=15; 90% female; mean age=47 \pm 8.5; Figure 1). No significant differences existed between randomized conditions. All Choice-SDM participants selected motivational messages and weight-reporting, four declined support calls and three declined group sessions. Adherence varied by component and condition (weight-reporting, Standard=67%, Choice-SDM=73%; call completion, Standard=53%, Choice-SDM=70%; and session attendance, Standard=39%, Choice-SDM=48%, $p > .10$). Eighty percent of healthcare employees completed the maintenance program (Standard=11, Choice-SDM=13).

Effectiveness

At three months maintenance, healthcare employees in both conditions, on average, maintained weight loss (Standard=-4.8%±3.4, Choice-SDM=-3.7%±5.4 initial body weight, $p>.10$). Most anthropometric changes and self-rated overall health were maintained, but physical activity and the composite wellness rating significantly decreased over time ($p<.10$) in both conditions. Table 3 presents short-term maintenance effects of anthropometric changes and health behaviors. Table 4 presents short-terms maintenance effects of quality of life and confidence in maintaining weight, nutrition, and activity.

Implementation

Twenty-four weekly motivational and weight-report feedback messages were delivered to both conditions (73% via email; 27% via text messaging). A total of 3, one-hour group sessions were planned and delivered by the research-practice team. For Standard and Choice-SDM, respectively, 135 and 99 calls were planned with a corresponding 85% and 89% attempted as intended; reflecting an overall 87% implementation. The primary reason for incomplete attempts was healthcare employees' requests to discontinue calls ($n=3$) due to schedule conflicts, family commitments, and a lack of continued interest. Calls averaged 17.5±3.7 minutes.

During Standard delivery staff time involved 36 hours for messaging and weight-reporting feedback, 45 hours of telephone support, and 10.5 hours for group sessions. Staff wages totaled \$2,314 and supplies, including cellular service, handouts, and session incentives, totaled \$281. For the Choice-SDM, delivery staff time involved 36 hours for messaging and weight-reporting feedback, 30 hours of telephone support, and 10.5 hours for group sessions. Choice-SDM staff wages totaled \$1,994 and supplies totaled \$275. Google Voice was used for

free text messaging. Total delivery costs varied by condition (Standard=6.1 hours/\$173, Choice-SDM=5.1 hours/\$151 per healthcare employee).

Maintenance

At the completion of the 6-month maintenance intervention, healthcare employees in both conditions, on average, maintained weight loss (Standard=- 3.9%±4.6, Choice-SDM=-4.9%±6.0 initial body weight, $p>.10$). Most anthropometric changes and self-reported overall health rating were maintained, but physical activity, water consumption, and composite wellness rating significantly decreased over time ($p<.10$) with no differences by condition (Tables 3 and 4). Post-trial, Carilion Wellness planned to maintain the Choice-SDM as a follow-up to future FIT Rx 90 sessions.

Discussion

Considering weight regain following weight loss is a common challenge, this pragmatic trial addressed the need to translate efficacious weight loss maintenance interventions into practice using practical and affordable strategies (Akers et al., 2010). Examining the role of patient choice provided interesting findings that have implications for organizations seeking ways to scale and sustain evidence-based weight loss maintenance programs. Findings supported the authors' hypotheses and outcome trends aligned with SDM literature reviews (Shay & Lafata, 2015; Stigglebout et al., 2015) and behavioral choice theory (Epstein, 1992).

Overall, providing participants a choice did not adversely impact Choice-SDM effectiveness in comparison to Standard. Program adherence for weight-reporting, call participation, and group session attendance was higher for SDM. This finding concurs with other

studies reporting increased engagement when participants are provided preferred treatment and delivery format (Emmons et al., 2014; Goode, Reeves, & Eakin, 2012).

While the conditions differed in terms of delivery staff hours, the cost differential wasn't large. Having infrastructure for intervention components was a necessity in both conditions. However, with infrastructure in place and expansion beyond a pilot, a greater cost differential for the less resource intensive Choice-SDM is likely. This provides empirical evidence for the Choice-SDM approach and actionable implications for healthcare systems like Carilion Clinic in seeking ways to provide the minimal intervention needed for change (Glasgow et al., 2013), along with scaling and sustaining evidence-based programs for healthcare employees (Milat et al., 2013).

There were strengths and limitations to this trial. Involving stakeholders in all phases, the trial included internal and external validity components and involved real-life settings and populations (Glasgow, 2013). The integrated research-practice partnership developed program structure and resources that aligned with stakeholder needs and values. Intervention delivery involved practice partners that would be able to sustain the program in the organization. The employee eligibility criteria were inclusive. Unlike many studies, both quality of life and costs were also considered (Ammerman et al., 2014; Glasgow, 2013). Limitations included the small pilot sample size of predominantly female employees, short-term maintenance period of six months, and small number of participants achieving and maintaining the trial goal, $\geq 5\%$ initial body weight loss. One potential explanation for this result and area for future program improvement was the lack of behavioral strategies (i.e., goal-setting, self-monitoring, problem-solving, and relapse prevention) introduced in the initial weight loss program. Conversely, the

maintenance interventions: (1) were able to sustain the initial participant weight loss, (2) were implemented as intended, and (3) reached a large proportion of participants who initiated FIT Rx 90. Broader implementation in typical practice settings is needed to replicate trial findings.

Conclusions

Integrating choice-SDM appears to improve program adherence and modestly reduce implementation costs without diminishing weight loss maintenance program effects. As patient-centered health care organizations are challenged with limited staff time and clinical resources, choice with SDM is a practical implementation strategy that may increase scalability and sustainability of weight loss maintenance support for healthcare employees.

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Table 1. Operational definition, level, focus, and source of data for each RE-AIM dimension in FIT Rx 90-1.0 evaluation

RE-AIM Dimension	Operational Definition	Level	Focus	Source of Data
Reach	<ul style="list-style-type: none"> Number, proportion, and representativeness of healthcare employees enrolled and retained in FIT Rx 90 maintenance phase 	Individual; Patient	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report
Effectiveness	<ul style="list-style-type: none"> Mean % initial body weight loss maintained at 3-months post-FIT Rx 90 program % of enrolled healthcare employees maintaining ≥3% initial body weight at 3-months % of enrolled healthcare employees maintaining ≥5% initial body weight at 3-months 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Fitness assessment reports; calibrated digital scale
Adoption	<ul style="list-style-type: none"> N/A – Beyond the scope of pilot phase 	N/A	N/A	<ul style="list-style-type: none"> N/A
Implementation	<ul style="list-style-type: none"> Degree to which maintenance support and intervention sessions were delivered as intended Costs of intervention delivery (i.e., time and staff needed to carry out intervention steps) Contextual factors influencing outcomes 	Organizational; Staff	Descriptive assessment	<ul style="list-style-type: none"> Activity and call tracker Session delivery checklist Costs spreadsheet
Maintenance _i	<ul style="list-style-type: none"> Mean % initial body weight loss maintained at 6-months post-FIT Rx 90 program % of enrolled healthcare employees maintaining ≥3% initial body weight at 6-months % of enrolled healthcare employees maintaining ≥5% initial body weight at 6-months 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Fitness assessment reports; calibrated digital scale
Maintenance _o	<ul style="list-style-type: none"> Sustained delivery of maintenance support within practice 	Organizational; Practice	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report

Notes. i-individual, o-organizational

Table 2. Baseline characteristics of weight loss maintenance study

Characteristics	Employees Enrolled in Weight Loss Program (n=50) Mean (SD)	Weight Loss Program Drop Outs (n=11) Mean (SD)	Employees Enrolled in MP (n=30) Mean (SD)	Declined to Participate in MP (n=9) Mean (SD)
DEMOGRAPHIC	46	46	47	45
Age, mean years	(9.8)	(11.7)	(8.5)	(12.0)
Gender, female %	90%	91%	90%	89%
ANTHROPOMETRIC	106.6	113.2**	102.8	111.3**
Initial body weight, kg	(15.5)	(19.7)	(10.7)	(20.6)
BMI, kg/m ²	38.4	40.8**	37.1	40.0**
	(4.7)	(6.0)	(3.1)	(6.0)
Body weight loss, % initial body weight	- 2.9*	N/A	-3.6**	-.5**
	(3.3) n=39		(3.3)	(1.8)

Notes. MP= Maintenance Program, *Overall effect, $p \leq .10$, **Between group differences, $p \leq .10$

Table 3. Maintenance effects, anthropometric and behaviors at baseline, 3-months, and 6-months maintenance

Outcome	Completion of Weight Loss Program			3-Months Maintenance			6-Months Maintenance		
	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)
ANTHROPOMETRIC									
Weight, kg	97 (11.4)	94 (9.8)	100.2 (12.3)	97.1 (11.8)	93.5 (9.7)	100.2 (12.9)	96.8 (11.7)	94.3 (10.0)	99 (13.1)
BMI, kg/m ²	35.1 (3.3)	33.7 (3.0)	36.3 (3.1)	35 (3.5)	33.7 (3.0)	36.1 (3.6)	35 (3.3)	34.1 (3.0)	35.7 (3.5)
Body weight loss, % initial	-4.0 (3.5)	-4.3 (3.0)	-3.6 (4.0)	-4.2 (4.6)	-4.7 (3.5)	-3.7 (5.3)	-4.4 (5.3)	-3.9 (4.6)	-4.9 (6.0)
Body fat, %	41 (4.4)	40.7 (4.5)	41.6 (4.6)	40.9 (4.4)	40.4 (4.5)	41.4 (4.4)	41.3 (4.6)	41.3 (5.1)	41.2 (4.4)
Blood pressure									
Systolic, mm Hg	119 (9.2)	121 (7.9)	117 (10.3)	122 (10.7)	121 (11.7)	122 (10.3)	123 (11.0)	126 (12.2)	121 (9.5)
Diastolic, mm Hg	70.8 (7.3)	72.6 (8.6)	69.2 (5.8)	72.3 (8.7)	73.6 (9.6)	71 (7.9)	72.9 (8.6)	77.6 (9.1)	68.5 (5.4)
Bicep circumference, cm	13.7 (1.3)	13.9 (1.3)	13.6 (1.2)	13.7 (1.2)	13.5 (1.3)	13.8 (1.1)	13.6 (1.0)	13.7 (1.0)	13.5 (1.1)
Hip circumference, cm	47.8 (3.0)	47.8 (2.3)	47.9 (3.0)	48 (2.7)	48.2 (2.1)	47.9 (3.3)	47.8 (3.1)	48 (2.3)	47.7 (3.8)
Thigh circumference, cm	23 (1.8)	22.9 (2.2)	23.6 (1.3)	22.6* (1.8)	22.1 (2.3)	23 (1.4)	22.3* (1.4)	22.2 (1.6)	22.5 (1.4)
Waist circumference, cm	40.5 (3.4)	39.1 (3.6)	41.7 (2.9)	40.9 (3.7)	39.7 (3.7)	42 (3.5)	40.9 (3.9)	39.3 (3.9)	42.3 (3.4)
HEALTH BEHAVIOR									
PA, # days/week	6 (.8)	6 (.8)	6 (.8)	5* (1.8)	5 (1.6)	4 (2.0)	5* (1.8)	5 (1.7)	5 (2.0)
PA, # min/week	283 (64.9)	273 (64.8)	297 (66.7)	207* (114.5)	171 (112.8)	252 (106.6)	167* (116.2)	118 (97.5)	229 (112.7)
Muscle-strengthening exercises, # days per week	2 (.9)	2.5 (1.1)	2 (.7)	2* (1.2)	2 (1.3)	2 (1.2)	1* (1.2)	1 (1.2)	1 (1.2)
Stretching exercises # days per week	3 (1.6)	2 (1.6)	3 (1.8)	2 (1.9)	2.5 (2.0)	2 (1.8)	2 (2.1)	2 (2.7)	2 (1.7)
Fruits and vegetables cups per day	4.5 (1.9)	5 (1.9)	4 (2.0)	4.5 (2.1)	4 (2.0)	5 (2.1)	5 (2.1)	5 (2.2)	4 (2.0)
Sugar-sweetened beverages, fl. oz per day	11 (17.6)	12 (22.1)	10 (15.9)	10 (15.8)	13 (18.2)	9 (15.0)	13 (19.3)	13 (25.3)	13 (16.6)
Sugar-sweetened beverages, Kcal per day	94 (251.2)	128 (306.9)	73 (224.1)	83 (218.0)	118 (264.6)	62 (195.9)	80 (137.2)	37 (60.2)	105 (164.3)
Water, fl. oz per day	36 (17.1)	30 (16.0)	41 (17.1)	36 (19.3)	36 (18.1)	36 (20.9)	31 (18.2)	29 (17.8)	32 (19.2)

Notes. STAN= Standard Maintenance Program, SDM- Choice-Shared Decision-Making, * $p \leq .10$,

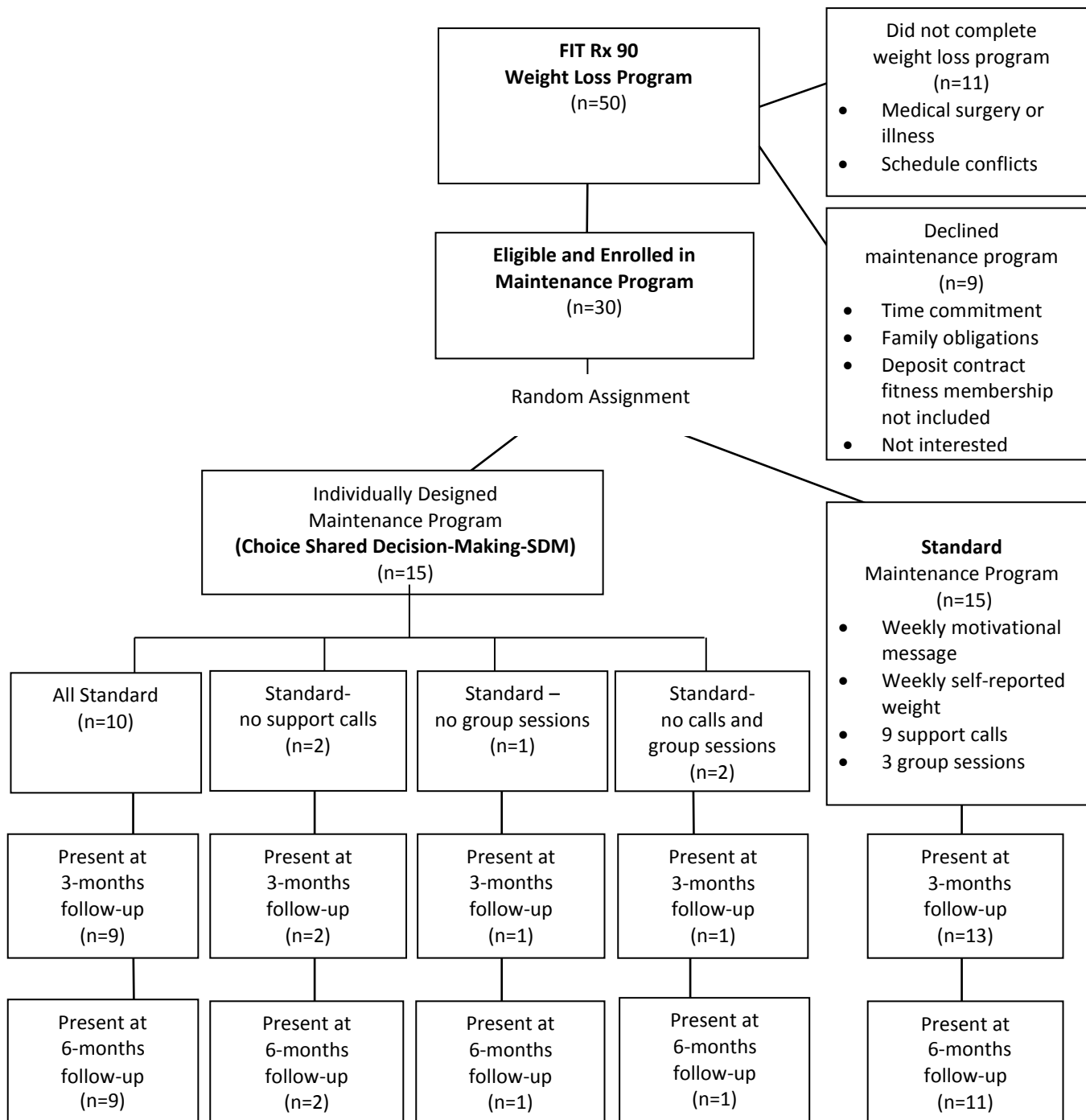
Table 4. Maintenance effects, quality of life and confidence at baseline, 3-months, and 6-months maintenance

Outcome	Completion of Weight Loss Program			3-Months Maintenance			6-Months Maintenance		
	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)	Total Mean (SD)	STAN Mean (SD)	SDM Mean (SD)
QUALITY OF LIFE									
Overall health rating (1-Poor, 5-Excellent)	3.5 (.9)	3.3 (.8)	3.6 (1.0)	3.7 (.9)	3.7 (.5)	3.6 (1.2)	3.8 (.7)	3.7 (.5)	3.8 (.8)
Composite feeling score ¹ (1-Very Low, 5-Very High)	3.9 (.4)	3.7 (.4)	4 (.3)	3.5 (.5)	3.5 (.6)	3.5 (.5)	3.3 (.5)	3.3 (.5)	3.5 (.5)
CONFIDENCE LEVEL									
Maintaining weight (1-Not at all, 5-Extremely)	3.4 (.8)	3.5 (1.0)	3.3 (.6)	3.5 (.8)	3.5 (1.0)	3.5 (.7)	3.5 (.9)	3.3 (.9)	3.7 (.9)
Maintaining PA (1-Not at all, 5-Extremely)	3.5 (.7)	3.4 (.8)	3.6 (.7)	3.8 (.8)	3.8 (1.0)	3.8 (.7)	3.5 (1.0)	3.3 (.9)	3.7 (1.0)
Maintaining healthy eating (1-Not at all, 5-Extremely)	3.4 (.9)	3.5 (1.1)	3.4 (.7)	3.6 (1.0)	4.0 (1.0)	3.3 (1.0)	3.5 (.8)	3.5 (.9)	3.5 (.8)

Notes. STAN, Standard Maintenance Program; SDM, Choice-Shared Decision-Making; *Overall effect, $p < .10$

¹Indicate how you feel today for each item: Optimistic, Stressed, Strong, Disciplined, Healthy, Confident and Energetic

Figure 1. Flowchart of enrollment, randomization, and follow-up



Chapter 5: Integrating Behavioral Strategies

Trial: *FIT Rx 90-2.0*

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Abstract

Background: Although evidence-based behavioral strategies exist to support clinically meaningful weight loss (i.e., $\geq 3\text{-}5\%$ initial body weight), little is known on the effectiveness of integrating strategies into weight loss programs delivered in real-world settings. FIT Rx 90 is a 90-day medically supervised and fitness-based weight loss program developed by practitioners to address the growing concern of obesity among healthcare employees. The program included a fitness assessment, 6 one-to-one personal training sessions, 5 group nutrition sessions, and a deposit contract for a 3-month fitness membership. The purpose of this study was to report on an integrated research-practice partnership that was formed at the completion of the initial FIT Rx 90 program to improve the program by adding evidence-based behavioral strategies tested in the Diabetes Prevention Program (DPP) Lifestyle Intervention.

Methods: During the initial FIT Rx 90 delivery, employees (90% female; mean age= 46.4 ± 9.8 ; mean BMI= 38.4 ± 4.7 ; n=50) lost, on average, $-2.9\pm 3.3\%$ of initial body weight (retention=81%). Subsequently, evidence-based behavioral strategies were integrated into FIT Rx 90 and tested within a quasi-experimental, comparative effectiveness design where participants received the standard FIT Rx 90 (n=24) or FIT Rx 90 Plus (n=44)-delivered by existing program delivery staff trained to implement behavioral strategies (i.e., an interdisciplinary team composed of

wellness managers (n=2), an RD, personal trainers (n=9), and a health educator). Implementation resources for the 12-week behavioral component included an action plan, target weight chart, healthy lifestyle workbook, online tracking survey with teach-back questions, weekly email prompts, and progress reports. The RE-AIM framework guided evaluation of outcomes. Overall effects and between group differences were assessed by Chi-Square or ANOVA. Analyses were present at follow-up and intent-to-treat, ($p < .10$ due to the pilot, exploratory nature of the study). Delivery feasibility, adherence, and costs were monitored.

Results: Participants in FIT Rx 90 Plus lost a significantly higher percentage of initial body weight ($-4.6 \pm 3.6\%$) when compared to FIT Rx 90 participants ($-2.6 \pm 3.5\%$, $p < .10$) at 3-months. FIT Rx 90 Plus participants engaged in more than 4 weeks of self-monitoring using the online tracking tool lost $-6.2 \pm 3.7\%$ compared to $-2.4 \pm 1.8\%$ initial body weight for those that did not, $p < .05$. The implementation of behavioral strategies added approximately one additional hour of staff time and \$27 per participant across the program and was deemed feasible by the practice delivery. Employee adherence and mechanisms for staff feedback were challenges.

Conclusions: This study provides practice-based evidence for the feasibility and effectiveness of integrating behavioral weight loss strategies in existing clinical weight-loss programs, and demonstrates the value of research-practice partnerships for quality improvement. Future efforts will focus on improving engagement, incorporating additional technologies to reduce staff hours, and designing a scalable, team-based model to reach more employees with evidence-based weight loss support.

Introduction

As U.S. healthcare systems are challenged to treat obesity ($BMI \geq 30 \text{kg/m}^2$) among patients (Frood, Johnston, Matteson, & Finegood, 2013; Dietz et al., 2015), the excess weight of healthcare employees simultaneously poses a critical problem impacting productivity, quality of care, credibility, and costs (Bilger, Finkelstein, Kruger, Tate, & Linnan, 2013; Miller, Alpert, & Cross, 2008; Bleich, Bandara, Bennett, Cooper, & Gudzone, 2015). Ranked in the top five U.S. occupational fields for obesity (Luckhaupt, Cohen, Li, & Calvert, 2014), healthcare employees have a higher than average prevalence (~34-47%). Reports of physical inactivity, unhealthy eating patterns, and stress are also common (Lee et al., 2012; Miller et al., 2008; Zapka, Lemon, Magner, & Hale, 2009). In the context of population health management, a majority of employees working in healthcare settings may be stratified into an at-risk population group needing effective behavioral intervention (Blackstone, 2016). Healthcare systems, as one of the fastest growing and largest employment sectors in the country, have a critical need and competitive interest for broad-reaching, cost-effective, evidence-based strategies to support employee weight loss (American Hospital Association-AHA, 2011; Gamble, 2012).

Aware of the consequences of obesity and need for treatment, healthcare systems have increased weight loss support within employee wellness initiatives (Estabrook, Zapka, & Lemon, 2012; Taylor & Bithoney, 2012). For instance, the American Hospital Association (2011) reports approximately 73% of hospitals regularly offer weight loss programs for employees. With access to internal medical fitness facilities and dietetic professionals, healthcare systems frequently design and deliver their own weight loss programs (Health Research Educational Trust-HRET, 2014; Taylor & Bithoney, 2012). Typically, these practitioner-developed programs offer

practical, informational, or participatory support to employees, such as discounted fitness center memberships, personal training, dietary consultation, or weight loss competitions (Ashton, 2014; HRET, 2014). However, programs rarely report incorporating an evidence-based, intensive behavioral component- a combination of dietary, physical activity, and behavioral strategies (i.e., goal-setting, self-monitoring, problem-solving, and relapse prevention) for weight loss (Cawley, 2014; Jensen, et al., 2014). Overall, the impact and sustainability of existing, practitioner-developed healthcare employee weight loss programs are also unclear (Akers, Estabrooks, & Davy, 2010; Lewis, Knanna, & Montrose, 2015). Rigorous program evaluation capturing variability in outcomes, attrition, adherence, and costs of delivery is limited (Akers et al., 2010; Cawley, 2014; Lewis et al., 2015).

Including diet, physical activity, and behavior modification, the sentinel Diabetes Prevention Program (DPP) clinical trial demonstrated the efficacy of structured lifestyle interventions for achieving a modest weight loss (i.e., $\geq 5\%$ initial body weight) and reduction of diabetes incidence and cardiovascular risks (DPP Group, 2002). Over the past decade, the behavioral strategies delivered in this highly intensive, and heavily resourced clinical trial have been applied and tested in a variety of real-world settings to benefit different populations using adapted delivery outlets and formats (Ali, Echouffo-Tcheugui, & Williamson, 2012; Mudaliar, et al., 2016; Whittemore, 2011). For instance, the Centers for Disease Control and Prevention sponsored the national DPP and trains facilitators from the YMCA for group delivery (Ackermann, 2015). Other trials have investigated translational adaptations for delivery by phone, Internet, and DVD with and without interactive voice response (IVR) for at-risk primary care patients (Ali et al., 2012; Almeida et al., 2014; Almeida et al., 2015; Pagoto, Kantor,

Bodenlos, Gitkind, & Ma, 2008). Translations mainly involve an overarching goal of preventing type 2 diabetes (Mudaliar et al, 2016). However, focused solely on weight loss, the Veterans Health Administration incorporated the research-tested DPP strategies when developing its highly disseminated MOVE! weight management program (Damschroder & Lowery, 2013). Each of these translational efforts initiated new organizational initiatives with extensive external support and report wide variation in reach, effectiveness, and sustainability (Ali et al., 2012; Damschroder & Lowery, 2013). The degree to which behavioral strategies adapted from the DPP are feasible to integrate into an existing employee weight loss program using resources readily available to healthcare system practitioners and the impact on weight outcomes is unknown (Ackermann, 2015; Akers et al., 2010; Whittemore, 2011).

Overall, the purpose of the pragmatic, pilot trial was to determine the degree to which FIT Rx 90, a locally-developed, clinical weight loss intervention, achieved a clinically meaningful weight loss (i.e., $\geq 3\%$ initial body weight) when compared to an adapted program integrated with behavioral strategies (FIT Rx 90 Plus). Secondary objectives were to monitor FIT Rx 90 Plus delivery feasibility, employee adherence to behavioral components, and costs. It was hypothesized that adding an evidence-based behavioral component adapted from principles of the DPP to FIT Rx 90 would improve the amount of clinically significant weight lost by employees, be feasible for delivery, and have modest costs for the healthcare system. The level of employee adherence was hypothesized to be comparable to the standard FIT Rx 90 components, but employee preference for the delivery format of behavioral strategies was unknown.

Methods

Design

An integrated research-practice partnership, including interdisciplinary obesity researchers, healthcare administrators, and practice delivery staff, used a participatory process (Estabrooks & Glasgow, 2006) to design this pragmatic, quasi-experimental, comparative effectiveness trial testing the standard FIT Rx 90 versus FIT Rx 90 Plus program (Glasgow et al., 2013). The non-equivalent control group design used randomized program site location for intervention allocation. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework guided planning and evaluation (Glasgow, Vogt, & Boles, 1999) to assess both individual (healthcare employee) and organizational (setting and staff) outcomes. The trial was submitted to the Carilion Clinic Institutional Review Board and deemed quality improvement with informed consent exempted. In addition, senior management and a Human Resources compliance officer reviewed all trial components and provided protocol approval.

Setting

Carilion Clinic is a private, non-profit healthcare delivery system headquartered in Roanoke, Virginia that serves over one million patients in 18 rural counties and six cities. As the largest employer in the region, Carilion has more than 11,700 employees working in a variety of positions to serve its operations of seven hospitals and 220 practices, including clinics, labs, aeromedical, and multi-specialty practices. The workforce is predominantly female (76%). As part of its community wellness initiatives, Carilion operates medical fitness facilities with a full array of services, including personal training, group exercise classes, free childcare,

indoor/outdoor pools, a gymnasium, track, and racquetball courts. Three fitness sites within its main service region were selected for intervention delivery.

Participants

Individual

Carilion Clinic employees working within the healthcare system's main service region were the target population. All department and employment positions were eligible, e.g., full-time, part-time, or flex-time. Specific inclusion criteria included: employees with a BMI ≥ 35 kg/m² or BMI ≥ 30 kg/m² with hypertension, pre-diabetes and/or diabetes, and the physical ability to participate in aerobic and strength-training activities. A physician referral with exercise prescription was required for participation. Exclusion criteria included previous participation in a FIT Rx 90 program, being pregnant, and/or a lack of willingness to participate in baseline and follow-up assessments. A recruitment sample size of 25 employees for FIT Rx 90 and 50 employees for FIT Rx 90 Plus was determined based on staff capacity for delivery. Employees were made aware of the program through Carilion's Intranet system email notifications. Referring Carilion primary care physicians were made aware through an email letter sent by the program's Medical Director describing the program including inclusion criteria and referral process within the electronic health record (EHR). Further information was provided to interested individuals through an in-person, 90 minute group kick-off meeting.

Staff

A core interdisciplinary, FIT Rx 90 practice delivery team, led by a Medical Director, Vice President of Wellness, and Director of Wellness Development, were trained by the research

team to deliver all intervention components. The delivery team for the behavioral component included two fitness managers, a registered dietitian (RD), nine personal trainers, and a health educator. The levels of expertise of these auxiliary support staff included bachelor degrees in dietetics and health promotion, and master degrees in exercise physiology. Technical assistance on behavioral strategy implementation was provided to the team during monthly research-practice support team meetings using recommended strategies and lesson learned from DPP translational trials (Alie et al., 2012; Carroll et al., 2015; Damschroder et al., 2013).

Interventions

Initial practitioner-developed program: *FIT Rx 90*

The healthcare system's sixty-day exercise prescription program for patients (FIT Rx 60) was adapted by practitioners to be FIT Rx 90, a ninety-day, fitness-based weight loss program for its healthcare employees. During initial delivery of FIT Rx 90, employees (90% female; mean age=46±9.8; mean BMI=38±4.7; n=50) lost, on average, -2.9±3.3% of initial body weight (retention=81%). Emphasizing physical activity and dietary change over a 90-day period, the FIT Rx 90 program, overseen by a Medical Director, included: a pre-post fitness consultation, one-to-one personal training sessions (6 for one hour or 12 for 30 minutes), five group nutrition sessions with a RD, 1 group session on stress management with a health educator, a deposit contract, 3-month fitness facility membership (\$36 per month, \$3 return per visit up to 12 visits per month), and a post-physician feedback report.

Program with strategy adaptation: *FIT Rx 90 Plus*

Based on critical elements of the DPP (Knowles et al., 2002), the 5As framework (*Assess, Advise, Agree, Assist, and Arrange*), and exercise and obesity guidelines (Donnelly et al., 2009; Jensen et al., 2014), the behavioral component added the following to standard care: an action plan, target weight chart (i.e., 5-10% initial body weight loss), 12 session healthy lifestyle workbook, a 12 week online tracking survey with teach-back questions, 12 weekly support emails from the fitness manager, and 45-and 90-day progress reports. The online survey prompted weekly self-monitoring, including tracking of weight, physical activity, dietary intake (i.e., fruits and vegetables, high-fat foods, sugar-sweetened beverages, and calories). Teach-back questions aimed to reinforce the weekly behavioral topic, including goal setting, problem solving, self-monitoring, time management, stress reduction, and relapse prevention (Porter et al., 2015). Table 1 provides a summary of FIT Rx 90 Plus weekly sessions, activities, and teach-back questions and identifies the adapted DPP session topic and designated practice delivery staff (i.e., fitness manager, personal trainer, RD, or health educator) responsible for providing employee feedback. Appendix 5.1 includes a sample of program materials.

Data collection and measures

RE-AIM framework

Each dimension of the RE-AIM framework was pragmatically operationalized for condition comparison (Glasgow et al., 1999). Table 2 displays the operational definition, level, focus, and source of data for each RE-AIM dimension. At the individual, healthcare employee-level, reach was a descriptive indicator and effectiveness was an intervening indicator targeted for change. Effectiveness' primary outcomes included mean percent initial body weight loss and percent of enrolled employees achieving ≥ 3 -5% at 3-months; core phase completion of the FIT

Rx 90 program. Weight was measured using a calibrated digital scale (Healthometer ProPlus™, Pelstar, McCook, IL) with the employee wearing light, indoor clothes without shoes. At the organizational level, adoption, implementation, and maintenance were assessed as descriptive indicators of the setting and staff. Sources of data included a FIT Rx 90 fitness assessment and administrative reports shared by the practice team that included session delivery checklists and a costs spreadsheet to inventory staff hours, materials, and labor costs based on U.S. Bureau of Labor Statistics, Occupational Employment and Wages. Team field notes from research-practice meetings provided insights on contextual factors influencing implementation outcomes.

Data analysis

Baseline descriptive statistics were calculated for each group and values are reported as mean \pm standard deviation (SD) or as frequency in percentage. Overall effects and between group differences were assessed by Chi-Square or ANOVA using SPSS (version 22 for MAC, SPSS Inc., Chicago, IL). Analyses were present at follow-up and intent-to-treat with baseline weight for missing measures. Field notes were summarized for common implementation barriers and facilitators. As a small pilot trial seeking preliminary evidence, the statistical significance was set at 10% (Leon, Davis, & Kraemer, 2011; Thabane et al., 2010).

Results

Reach

A flowchart of recruitment, enrollment, and allocation in the FIT Rx 90 and FIT Rx 90 Plus conditions are shown in Figure 1. The practice team reached 91% (n=68) of their recruitment goal; FIT Rx 90 (n=24) and FIT Rx 90 Plus (n=44). Baseline demographic

characteristics of participants are shown in Table 3. Retention rate varied with 88% (n=21) for FIT Rx 90 and 75% (n=33) for FIT Rx 90 Plus at 3-months, ($p>.10$). Program non-completers had a higher BMI and worked part-time/flex position, ($p<.10$). Scheduling, family commitments, and physical injuries were reported challenges.

Employee adherence to behavioral components included action planning (97%), personal training session completion (68%), group session completion (36%), and online survey with teach-back engagement (57%). Participants averaged 84% ($SD=25.7$) on answering teach-back questions correctly. Dietary questions posed the most difficulty. Mean number of fitness facilities averaged 6 ($SD=4.8$) per month. Employees paid a mean \$19 ($SD=12.2$) toward their fitness facility membership with the deposit contract incentive.

Effectiveness

For the primary outcome, participants enrolled in the FIT Rx 90 Plus behavioral condition lost a significantly greater amount of weight ($p<.10$) at program completion. For present at follow-up analysis, on average, FIT Rx 90=-2.6% ($SD= 3.5$) and FIT Rx 90 Plus=-4.6% ($SD=3.6$) initial body weight at 3-months, ($p<.10$). As displayed in Figure 2, the proportion of employees achieving a clinically meaningful weight loss also differed significantly, FIT Rx 90=35% and 25%, and FIT Rx 90 Plus=57% and 40% for $\geq 3\%$ initial body weight loss and $\geq 5\%$ initial body weight loss, respectively, ($p<.10$). For intent-to-treat analysis, on average, FIT Rx 90=-2.3% ($SD=3.5$) and FIT Rx 90 Plus=-3.5% ($SD=3.2$) initial body weight loss at 3-months, ($p<.10$). For proportion of employees achieving a clinically meaningful weight loss, FIT Rx 90=30% and 22%, and FIT Rx 90 Plus=44% and 31% for $\geq 3\%$ initial body weight loss and $\geq 5\%$ initial body weight loss, respectively, ($p<.10$). Adverse outcomes of program participation

included exacerbation of pre-existing conditions, including plantar fasciitis flare-up and musculoskeletal pain (n=7). There were no differences in outcome by baseline characteristics, personal training or group session completion, or mean number of monthly medical fitness facility visits.

As shown in Figure 3, within the FIT Rx 90 Plus condition, there were significant differences in the weight change by participant engagement with the behavioral component of self-monitoring and teach-back. Participants engaged with self-monitoring using the on-line tracking tool with teach-back questions for less than 4 weeks achieved a mean -2.4% ($SD=1.8$) initial body weight loss and those engaged more than 4 weeks achieved a mean -6.2% ($SD=3.7\%$) initial body weight loss at 3-months, ($p<.05$).

Adoption

At the setting level, 100% (n=2) of fitness facilities approached for the behavioral component initiated the FIT Rx 90 Plus program. At the staff level, 100% (n=13) of fitness professionals [e.g., fitness managers (n=2), RD (n=1), health educator (n=1), and personal trainers (n=9)] initiated the Plus behavioral component activities during their assigned program delivery components. Senior administrative buy-in, cost-center sharing, research-practice monthly delivery team support meetings, and a package of adapted employee education materials ready for delivery facilitated uptake.

Implementation

Overall, 93% of FIT Rx 90 and 94% of FIT Rx 90 Plus core program activities were implemented as intended. Personal training and group sessions were challenged by scheduling.

Feedback to employees on weekly workbook and tracking activities lacked consistency among care team. FIT Rx 90 team delivery included 15.5 hours or \$119 per employee, while FIT Rx 90 Plus delivery included 16.5 hours or \$146 per employee. Action plans and progress reports were the most time-consuming activities for the delivery team beyond standard care. Functioning of the online tracking tool challenged the seamlessness of providing feedback.

Maintenance

At the individual-level, 39% (n=9) of FIT Rx 90 and 42% (n=18) of FIT Rx 90 Plus participants converted to a full-time medical fitness facility membership plan. In addition, 71% (n=39) of employees completing the trial formally enrolled in a next iteration FIT Rx 90 post-core maintenance program. As an individually designed, 9-month program, employees selected the following maintenance support options: 92% motivational messages (n=36), 77% weekly self-reported weight (n= 30), 67% telephone support calls (n=26), and 82% small group classes (n=32). At the organizational-level, the healthcare system continued to offer the FIT Rx 90 program with the integrated behavioral strategies beyond the research projection timeline. In addition, the system changed its membership policy for FIT Rx 90 participants to include a waiver of the \$25 initiation fee and a 40% monthly discount.

Discussion

This study reported on how the Carilion integrated research-practice partnership was able to successfully add evidence-based behavioral strategies adapted from principles of the DPP lifestyle intervention to its practitioner-developed, FIT Rx 90 employee weight loss program. For the primary outcome, study hypotheses were supported and demonstrated improved clinically meaningful weight loss outcomes (i.e., $\geq 3\text{-}5\%$ initial body weight loss) for employees allocated

to the FIT Rx 90 Plus condition. Implementation strategies developed by the partnership for delivering the behavioral component were feasible using existing practice resources and added only minimal costs to the healthcare system. However, employee adherence to behavioral components, staff feedback mechanisms, and the functionality of online tools in the FIT Rx 90 Plus condition posed challenges to practice and limited scalability potential.

Although the FIT Rx 90 Plus condition was significantly less intensive and resourced than the original DPP lifestyle intervention and research-delivered translations (DPP, 2002; Ali et al., 2012), 44% of enrolled healthcare employees were able to achieve a positive, clinically meaningful weight loss, exceeding standard care. Mean percent initial body weight loss was comparable to the outcomes (~4% initial body weight) reported in systematic reviews and a meta-analysis of DPP translational studies (Ali et al., 2012; Mudaliar et al., 2016). However, the FIT Rx 90 Plus population was slightly younger, significantly heavier, included more women, and not required to have impaired fasting or elevated post-load glucose (Mudaliar et al., 2016). Similar to other translational studies (Ali et al., 2012; Venditti & Kramer, 2013) and weight loss trials (Burke, Wang, & Sevick, 2011), employee engagement with critical behavioral strategies (e.g., self-monitoring) was shown to have a significant relationship with improved weight loss (i.e., $\geq 5\%$ initial body weight).

However, several FIT Rx 90 Plus employees were challenged with completing weekly tracking and using the online survey tool for participant self-monitoring. Reported barriers included required entry with a study ID rather than employee username, password, manual activity entry, and lack of accessibility among most frequently used technology platforms- all common implementation challenges reported in the literature (Carroll et al., 2015). The burden

of the extra weekly task and prompts regarding incompleteness may have led to slightly higher attrition in the FIT Rx 90 Plus versus the standard condition (Rothberg et al., 2015). Employees would prefer the weekly self-monitoring survey be embedded within their employee Intranet or accessible within a mobile phone application. In addition, an interactive discussion board for peer and provider dialogue, video summaries of group session topics, and a platform integration feature for data transfer from wearable fitness trackers or dietary fitness apps (i.e., MyFitnessPal) were suggested for future program iterations. Improving the accessibility and functionality of online tools would likely mend challenges with employee adherence to behavioral strategies and offers promise for increasing the amount of weight loss (Payne, Kantor, Bodenlos, Gitkind, & Ma, 2015).

Overall, integration of the behavioral component to FIT Rx 90 was feasible for delivery at a minimal cost for the practice team. The ready-to-deliver action plan, target weight chart, workbook materials, and weekly email messaging prompts were user-friendly and provided valuable structure for standardizing the delivery of evidence-based behavioral strategies. In addition, the healthcare system's already existing infrastructure accelerated start-up, i.e., cost-center sharing for staff time from multiple departments (i.e., Nutrition and Dietetics, Community Outreach) and access to an internal marketing department for personalization of materials with the FIT Rx 90 logo and low-cost printing. Having turn-key resources that offer program structure, align with stakeholder needs and values, and fit within the existing delivery system has been shown in other translational trials to be instrumental for program adoption and ensuring successful implementation and sustainability of activities (Estabrooks et al., 2011; Harden, Johnson, Almeida, & Estabrooks, 2016; Johnson, Harden, & Estabrooks, 2015).

For challenges experienced during the trial, the tested technological tools and team-based care plan for offering employee feedback were priority concerns. Manually producing and distributing employee progress reports at 45- and 90-days from entries submitted to the online tracking survey was reported as timely and burdensome to staff. In addition, the weekly feedback from designated staff on workbook activities was not consistent if employees missed training or group sessions. In addition, feedback was fragmented week-to-week with multiple providers interacting with employees. As observed in other trials, mechanisms to improve these communication challenges and provide seamless team-based care are needed (Carroll et al., 2015). Documentation of intervention activities in the EHR, an online administrative dashboard offering team members a real-time summary of employee action plans and progress, and automated technologies may offer a promising, scalable solution (Almeida et al., 2014). Additional staff training on how to provide employee-centered feedback and elicit shared collaborative decision-making on nutrition, physical activity, and behavioral goals for weight loss and weight loss maintenance were also suggested by the practice team.

There are strengths and limitations to this study to consider in interpretation and future partnership plans. To begin, this study was delivered using a healthcare system's existing staff and resources offering strong external validity and practice-based evidence to support implementation and sustainability in real-world settings (Ammerman, Smith, & Calancie, 2014). The participant eligibility criteria were broad and included representatives from a diverse set of healthcare workforce positions. Findings are highly relevant and actionable to improve existing programs in practice and may be transferable to similar healthcare settings that are planning and implementing employee weight loss programs or interested in delivering principles of the DPP

lifestyle intervention (AHA, 2011; Glasgow & Chambers, 2012). Unlike many studies, implementation costs and contextual factors were reported that may speed the translation of research to practice (Kessler & Glasgow, 2011). Related to limitations, the study design involved a small pilot sample size, includes predominantly female, Caucasian employees, does not include objective measures of change in behavior or cardiometabolic risk, and does not report on long-term weight loss maintenance outcomes. Future research-practice partnership efforts will focus on extending the integration of behavioral strategies into the FIT Rx 90 post-core maintenance phase, incorporating user-friendly technologies to improve employee engagement and reduce staff burden, and providing additional staff training to enhance feedback and delivery of team-based care.

Conclusions

In conclusion, this study provides much needed practice-based evidence for demonstrating the feasibility and effectiveness of integrating behavioral weight loss strategies into an already existing, healthcare employee weight loss program. The integrated research-practice partnership approach showed value for quality improvement by generating the capacity and resources to advance the translation of evidence-based lifestyle obesity treatment. Additional staff training and use of automated technology would optimize feedback mechanisms and support development of a scalable, team-based obesity treatment model to reach more employees with intensive behavioral therapy.

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Table 1. Summary of FIT Rx 90 Plus weekly sessions, activities, sample teach-back question, and designated staff for feedback

Week	Adapted DPP Session Topic	Behavioral Strategies	Weekly Workbook and Tracking Activities	Sample Teach-Back Question	Staff Designated to Provide Participant Feedback
0	Welcome & Action Plan	<ul style="list-style-type: none"> • Weight-loss goal • Self-monitoring • 5As framework 	<p>Worksheets:</p> <ul style="list-style-type: none"> • Action Plan for Physical Activity and Healthy Eating • Obstacles and Strategies <p>Tracking:</p> <ul style="list-style-type: none"> • Weight 	<p>For weight loss, health experts agree that you should do:</p> <ul style="list-style-type: none"> ○ 30 min. of aerobic activities on 5 days per week ○ 45 min. of aerobic activities on 5 days per week ○ 60 min. of aerobic activities on 5 days per week 	Fitness Manager
1	Move those Muscles	<ul style="list-style-type: none"> • PA goal • Self-monitoring • Time management 	<p>Worksheets:</p> <ul style="list-style-type: none"> • How Active Am I? • Make a Plan to Be Active <p>Tracking:</p> <ul style="list-style-type: none"> • Weight • Physical activity • Fruits and vegetables 	<p>What are the things you should think about when setting a goal for physical activity?</p> <ul style="list-style-type: none"> ○ It should be realistic ○ It should be time-based ○ It should be specific ○ It should be realistic, time-based, and specific 	Personal Trainers
2	Be Active a Way of Life	<ul style="list-style-type: none"> • Exercise safety • Lifestyle activity • Self-monitoring 	<p>Worksheets:</p> <ul style="list-style-type: none"> • Overcoming Barriers • Find Time to Be Active • Lifestyle Activity <p>Tracking:</p> <p>Physical activity Fruits and vegetables</p>	<p>When doing moderate intensity activities, about how hard should you be working?</p> <ul style="list-style-type: none"> ○ Working hard enough to be able to easily sing a song ○ Working hard enough that you are unable to sing a song, but could still carry on a conversation ○ Working hard enough that you are out of breath and unable to carry on a conversation 	Personal Trainers
3	Healthy Eating with MyPlate	<ul style="list-style-type: none"> • Dietary goal • Regular eating pattern • MyPlate recommendations • Self-monitoring 	<p>Worksheets:</p> <p>What's on Your Plate? Build Your Own Healthy Meal Rate Your Plate</p> <p>Tracking:</p> <p>Weight Physical Activity Fruits and Vegetables</p>	<p>When following the MyPlate guidelines, how much of your plate should include fruits & vegetables?</p> <ul style="list-style-type: none"> ○ Make one quarter of your plate fruits and vegetables ○ Make one third of your plate fruits and vegetables ○ Make half of your plate fruits and vegetables ○ Make your entire plate fruits and vegetables 	Registered Dietician

Week	Adapted DPP Session Topic	Behavioral Strategies	Weekly Workbook and Tracking Activities	Sample Teach-Back Question	Staff Designated to Provide Participant Feedback
4	Be a Fat Detective	<ul style="list-style-type: none"> • Dietary goal • Food substitutions • Nutrition label reading • Portion control • Self-monitoring 	Worksheets: Practicing to Be a Fat Detective Ways to Eat Less Fat Reading Your Labels Tracking: Physical Activity Fruits and Vegetables High-Fat Foods	Most of the fats we eat are hidden. <input type="radio"/> True <input type="radio"/> False	Registered Dietician
5	Sugar	<ul style="list-style-type: none"> • Dietary goal • Self-monitoring 	Worksheets: Rethink Your Drink Find the Added Sugars Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages	Which of the following strategies will help you cut out the added sugars in your diet? <input type="radio"/> Reading the nutrition facts label on packaged foods and drinks <input type="radio"/> Choosing plain water or unsweetened flavored soda water instead of colas <input type="radio"/> Tracking your sugary drinks <input type="radio"/> All of the above are good strategies	Registered Dietician
6	Calories	<ul style="list-style-type: none"> • Dietary goal • Self-monitoring 	Worksheets: Guess the Calories Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	If you want to lose weight, which of the following do you need to do? <input type="radio"/> Eat the same amount of calories as you use everyday <input type="radio"/> Eat the same amount of calories as you use everyday <input type="radio"/> Eat more calories than you use everyday	Registered Dietician
7	Taking Charge of What's Around You	<ul style="list-style-type: none"> • Self-monitoring • Stimulus control 	Worksheets: Thinking About Activity Cues Tracking: Weight Physical Activity	Which of the following choices are red light triggers for eating healthy and being active? <input type="radio"/> Wanting to watch a favorite TV show instead of being active <input type="radio"/> Having no time	Personal Trainers

Week	Adapted DPP Session Topic	Behavioral Strategies	Weekly Workbook and Tracking Activities	Sample Teach-Back Question	Staff Designated to Provide Participant Feedback
			Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	<ul style="list-style-type: none"> ○ Going out to eat at a buffet ○ All of the above 	
8	Problem-Solve	<ul style="list-style-type: none"> ● Problem-solving ● Self-monitoring 	Worksheets: Problem-Solving Practice Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	Breaking up your physical activity into shorter sessions is just as beneficial as doing it all at once as long as the sessions are at least ten minutes long. <ul style="list-style-type: none"> ○ True ○ False 	Personal Trainers
9	Eating Out	<ul style="list-style-type: none"> ● Self-monitoring 	Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	Which of the following strategies can you use to help keep portion sizes under control? <ul style="list-style-type: none"> ○ Sharing a main dish with a friend ○ Order an appetizer-size portion ○ Ask the waiter to box half your entrée before it ever gets to the table ○ All of the above strategies are helpful 	Registered Dietician
10	Talk Back to Negative Thoughts	<ul style="list-style-type: none"> ● Negative thinking ● Self-monitoring 	Worksheet: Practice Talking Back Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	Which of the following strategies could you use to get past negative thinking? <ul style="list-style-type: none"> ○ Replace negative thoughts with positive ones to stay on track with your goals ○ Use imagery to help you see the benefits of sticking with your goals ○ There is really not much you can do about negative thoughts ○ Use both positive thinking and imagery to help you get past negative thoughts and stay on track with your goals 	Health Educator

11	Slippery Slope of Lifestyle Change	<ul style="list-style-type: none"> • Relapse prevention • Self-monitoring 	Worksheets: Slips from Healthy Eating Slips from Physical Activity Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	Which of the following is true when you have a slip? <ul style="list-style-type: none"> ○ It means you aren't trying hard enough ○ It means you won't be successful with your changes ○ Slips are normal and nothing to feel bad about 	Personal Trainers – Slips for Activity Registered Dietician – Slips for Healthy Eating
12	Jump Start Your Activity Plan	<ul style="list-style-type: none"> • Exercise safely • Self-monitoring • Target level – F.I.T.T. 	Worksheets: Preventing Boredom Tracking: Weight Physical Activity Fruits and Vegetables High-Fat Foods Sugar-Sweetened Beverages Calories	If someone is bored with their physical activity routine, what would you suggest they try? <ul style="list-style-type: none"> ○ Continue with the same activity ○ Wait until the boredom passes ○ Add variety to their routine ○ Spend more time with family 	Fitness Manager

Table 2. Operational definition, level, focus, and source of data for each RE-AIM dimension

RE-AIM Dimension	Operational Definition	Level	Focus	Source of Data
Reach	<ul style="list-style-type: none"> Number, proportion, and representativeness of healthcare employees enrolled and retained in FIT Rx 90 program 	Individual; Patient	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report
Effectiveness	<ul style="list-style-type: none"> Mean % initial body weight loss achieved at 3-months; completion of core phase of FIT Rx 90 program % of enrolled healthcare employees achieving ≥3-5% initial body weight at 3-months 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Fitness assessment reports; calibrated digital scale
Adoption	<ul style="list-style-type: none"> Number, proportion, and representativeness of settings and staff willing to initiate the behavioral component of the FIT Rx 90 program 	Organizational; Setting Staff	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report
Implementation	<ul style="list-style-type: none"> Degree to which behavioral components of intervention sessions were delivered as intended Costs of intervention delivery (i.e., staff time and materials needed to carry out intervention steps) Contextual factors influencing outcomes 	Organizational; Staff	Descriptive assessment	<ul style="list-style-type: none"> Session delivery checklist Costs spreadsheet Team field notes
Maintenance _i	<ul style="list-style-type: none"> Proportion of employees continuing fitness membership beyond core phase of FIT Rx 90 program Intention of employee engagement to engage in post-core behavioral strategies 	Individual; Patient	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report
Maintenance _o	<ul style="list-style-type: none"> Intention of sustained delivery of behavioral strategies within practice 	Organizational; Practice	Descriptive assessment	<ul style="list-style-type: none"> FIT Rx 90 administrative report

Notes. i-individual, o-organizational

Table 3. Baseline characteristics and weight status of FIT Rx 90 pilot trial participants

Characteristics	FIT Rx 90 n=24	FIT Rx 90 Plus n=44	p-value
<i>Demographic</i>			
Age, mean years, SD	44 (9.2)	47 (11)	0.411
Gender, %			
• Female	83%	91	0.354
Race, %			0.181
• White/Caucasian	83%	96%	
• Black	17%	4%	
Employment Status, %			0.377
• Full-time	92%	80%	
• Part-time	8%	20%	
Position, %			0.455
• Health Practitioner	25%	36%	
• Health Technician	33%	20%	
• Healthcare Support Staff	25%	20%	
• Medical Manager	4%	13%	
• Other	13%	11%	
Years of Service, mean years, SD	10 (8.2)	10 (8.3)	0.734
<i>Weight Status</i>			
Weight, kg, mean, SD	112 (35.5)	116 (72.6)	0.711
Body Mass Index (BMI), kg/m ² , mean, SD	40 (5.6)	39 (6.4)	0.501
BMI Category, kg/m ²			0.247
• Obese Class I, BMI=30-34.9	13%	32%	
• Obese Class II, BMI=35-39.9	42%	32%	
• Obese Class III, BMI≥40	46%	36%	

Figure 1. Flowchart of participant recruitment, enrollment, allocation, follow-up and analysis

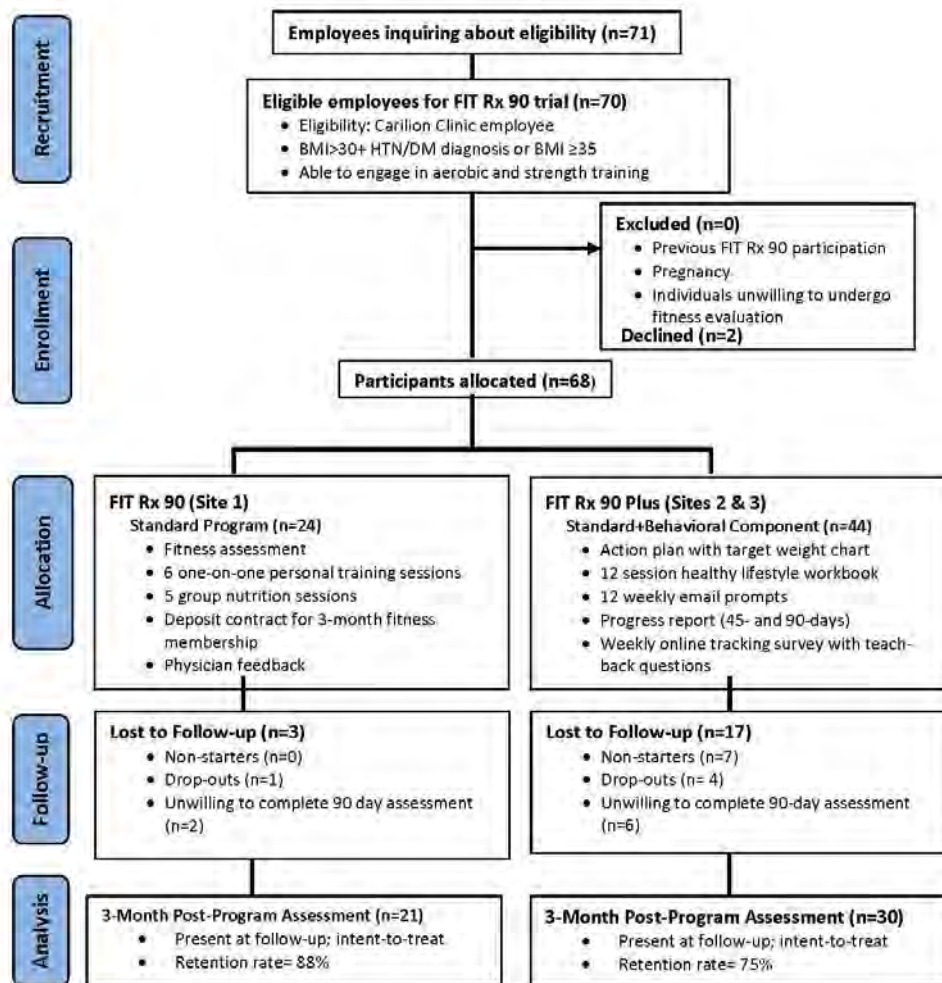
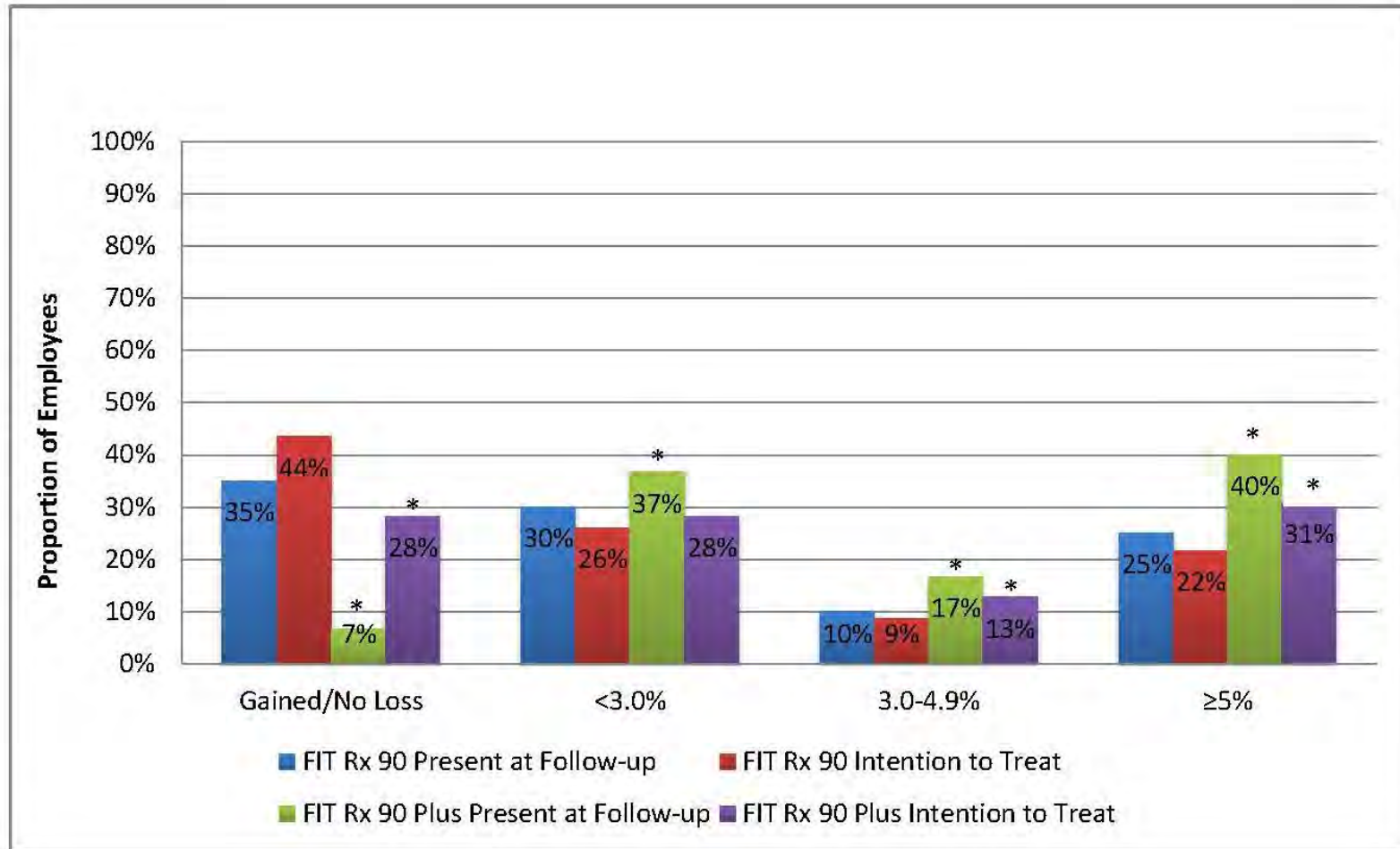
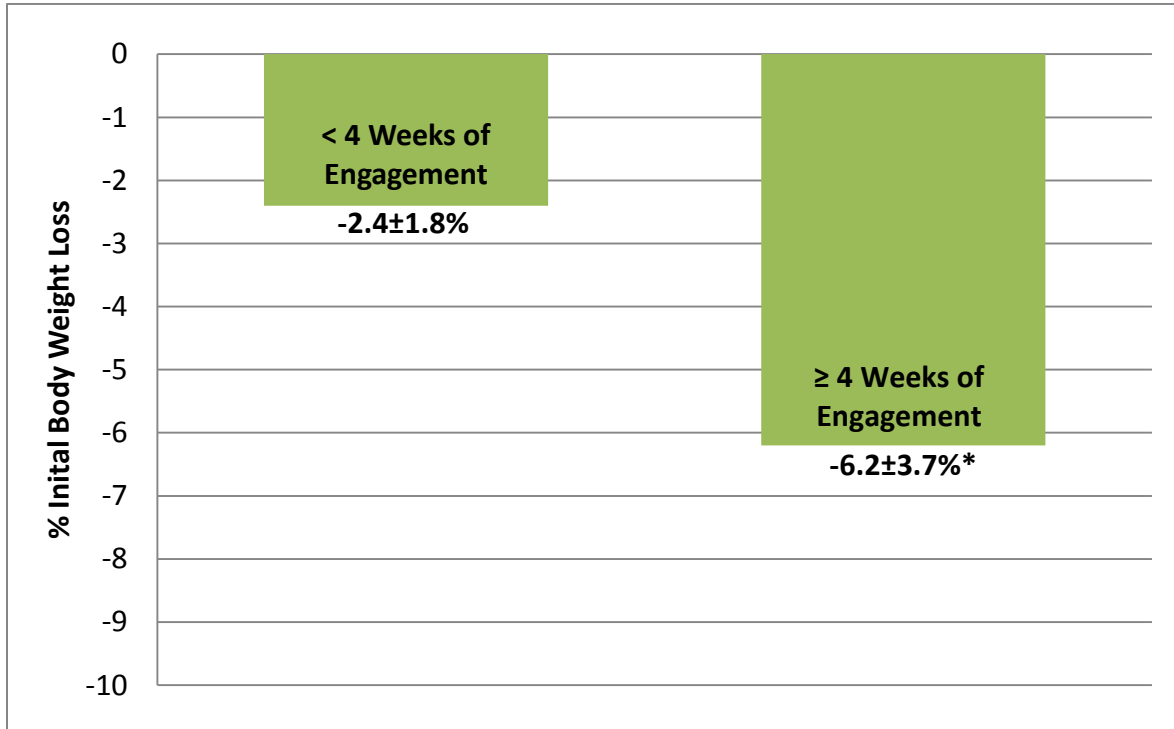


Figure 2. FIT Rx 90 versus FIT Rx 90 Plus, proportion of employees achieving clinically meaningful weight loss a 3-months



Notes. * p<.05; ≥3% initial body weight loss is defined as clinical meaningful weight loss with observed improvements in cardiovascular and metabolic risks

Figure 3. FIT Rx 90 Plus, weight change by level of engagement with online tracking survey and teach-back questions



Notes. * $p < .05$; Engagement involved FIT Rx 90 Plus participants self-monitoring weight, dietary, and physical activity behaviors, and tracking progress and completed workbook activities through 12 weekly online surveys. Each survey concluded with 2-3 'teach-back' questions on the weekly behavior change topic

Chapter 6: Integrating Consultation and Action Planning

Trial: *Carilion Healthy Lifestyles-Nurse Care Coordinators*

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Abstract

Background: Nurse care coordinators provide services to patients with a variety of chronic conditions, many of which include healthful eating, physical activity, and weight control self-management needs. However, evidence on how to support routine nurse care coordinator implementation of treatment and the impact on patient weight loss is lacking.

Methods: An integrated research-practice partnership adapted an evidence-based behavioral weight loss program (i.e., clinical intervention) for delivery by nurse care coordinators. A pragmatic effectiveness-implementation hybrid type 3 trial with a formative evaluation was conducted to: 1) assess whether a CME or CME Plus research-tested implementation strategy accelerated program uptake, and 2) evaluate the clinical intervention's impact on patients' achieving and maintaining a clinically meaningful weight loss (i.e., 3-5% initial body weight). The CME included a 2.5-hour training workshop and a package of ready-to-deliver resources for the 12-month, 20-session clinical weight loss intervention. The CME Plus included the CME plus ongoing consultation at 1-3-6, and 12-months post-workshop. Consultation included instruction on intervention implementation, case review, self-reflection, and feedback embedded within an action plan using the 5As (Assess, Advise, Agree, Assist, and Arrange) to increase clinical intervention reach. The RE-AIM framework guided intervention planning and a mixed

methods evaluation including patient chart review. Chi Square and ANOVA tested for overall effects and between group differences, $p < .05$.

Results: For the implementation strategy, all 45 nurse care coordinators in the system engaged in either the CME (n=31) or CME Plus (n=14) condition. On average, coordinators enrolled 17 ± 25.3 patients per a nurse care coordinator over 12 months with no difference between conditions (CME= 14 ± 21.9 ; CME Plus= 24 ± 31.4). Similarly, implementation of the clinical intervention did not differ by condition with approximately $84 \pm 0.1\%$ of the clinical intervention being delivered as intended across sessions, though differences did exist in some elements of the clinical intervention. Across the RE-AIM framework, the clinical intervention reached 748 patients (48 ± 14.3 years, 81% female, 89% White, 47% BMI ≥ 40) with 77% completing more than one session (n=579). The effectiveness of the clinical intervention did not differ by condition on average percent weight loss ($-2.1 \pm 4.7\%$ at 6 months; $-2.3 \pm 6.1\%$ at 12 months) or the proportion of patients who had achieved a 5% weight loss (56%, n=320 at 6 months; 39% at 12 months). At the clinic level, adoption (70% CME; 86% CME Plus, $p > .05$) and maintenance at 12 months (CME=70%, CME Plus=86%, $p > .05$) were not significantly different. However, a significantly higher proportion of nurse coordinators in the CME Plus condition adopted (100% vs. 61%, $p < .01$) and sustained implementation past 12 months (79% vs. 55%, $p < 0.05$). Total cost of delivery per patient averaged \$557.

Conclusions: Trial findings demonstrate that consultation and action planning may accelerate uptake and sustainability of evidence-based care compared to usual implementation strategies. Contextual factors and patient-centered adaptations to improve program implementation, retention, and weight loss outcomes for nurse care coordinator delivery were identified through the research-practice partnership.

Introduction

Obesity is one of the most prevalent and challenging chronic conditions to manage in ambulatory, primary care settings, with more than one-third of adult patients classified as obese ($BMI \geq 30 \text{ kg/m}^2$) (Dietz et al., 2015; Ogden, Carroll, Fryar, & Flegal, 2015; Rao et al., 2011). To manage obesity, it is recommended primary care providers (PCP) systematically assess weight status and offer patients intensive behavioral therapy to improve diet, increase physical activity, and build skills for lasting lifestyle change (Jensen et al., 2014). The 5As (Assess, Advise, Agree, Assist, and Arrange) of health behavior counseling (Estabrooks & Glasgow, 2006; Moyer, 2012; Schlair, 2012) and a high-intensity, non-pharmaceutical, lifestyle modification intervention exemplified in the National Diabetes Prevention Program (Knowler et al., 2002) offer a structure for therapy. Although evidence-based clinical guidelines and research-developed interventions exist (Jensen et al., 2014), delivery barriers (i.e., lack of time, high cost) limit PCP uptake (Carvajal, Wadden, Tsai, Peck, & Moran, 2013; Wadden, Webb, Moran, & Bailer, 2012). Engaging auxiliary health providers, such as nurse care coordinators who play a central role in the patient-centered medical home (Biernacki, Champagne, Peng, Maizel, & Turner, 2015), is a promising strategy to overcome research-to-practice gaps (Wadden et al., 2012). However, evidence on how to support routine nurse care coordinator implementation of lifestyle obesity treatment and the impact on patient weight loss is lacking (Fitzpatrick et al., 2015; Rao et al., 2011).

Employing nurse care coordinators in a collaborative, team-based approach, the patient-centered medical home has become a widely accepted model for how to transform and improve the delivery of chronic disease management in a complex and fragmented health system (Arend,

Tsang-Quinn, Levine, & Thomas, 2012; Nielsen, Buelt, Patel, & Nichols, 2016) In medical homes, physician-led teams often utilize nurses in the role of care coordinators to partner with high-risk patients to address chronic health concerns and prevent complications (Biernacki et al., 2015). Nurse care coordinators have been successfully activated to reduce hospital readmissions, reduce morbidity and mortality from non-communicable diseases (i.e., asthma, cardiovascular disease, chronic obstructive pulmonary disorder, and diabetes), and improve patient satisfaction with care (Carver & Jessie, 2011; Henderson, Princell, & Martin, 2012; Kisokanth, Indrakumar, & Joseph, 2015). They are trained to recognize and respond to the complex needs of their patients (Vanderboom, Thackeray, & Rhudy, 2015). With the goal of developing an on-going relationship, nurse care coordinators proactively help patients design personalized care plans, understand and monitor prescribed medications, follow their physicians' advice, and connect with support to control and manage their conditions (Biernacki et al., 2015; Smolowitz et al., 2015). Furthermore, nurse care coordinators frequently engage patients with obesity-related co-morbidities; i.e., type 2 diabetes, hypertension, and lipid disorders (Biernacki et al., 2015; Henderson et al., 2012). Due to these chronic conditions, patients are seen regularly for follow-up in the medical home providing an ideal opportunity for intervention (Phillips, Wood, & Kinnersley, 2014).

Although nurse care coordinators appear to be well-placed for implementing obesity treatment (Phillips et al., 2014) and evidence supports the effectiveness of lifestyle interventions delivered by nurses in primary care (Carvajal et al., 2013; Sargent, Forrest, & Parker, 2012), challenges exist for uptake, widespread use, and sustainability (Asselin, Osunlana, Ogunleye, Sharma, & Campbell-Scherer, 2016; Phillips et al., 2014). Nurse care coordinators often lack the

knowledge, skills, and confidence to address weight loss (Phillips et al., 2014). There is a lack of clarity on evidence-based dietary and physical activity advice for obesity management and availability of packaged resources to support implementation (Damschroder & Lowery, 2013). Nurses also express concerns about stigmatization and sensitivity with their own weight that may jeopardize patient encounters (Gunther, Guo, Sinfield, Rogers, & Baker, 2012) and patients' motivation and preferences for obesity treatment within primary care setting are uncertain (Carvajal et al., 2013). In addition, the feasibility of integrating an intensive weight loss program into the daily workflow of a nurse care coordinator is unknown (Thabault, Burke, & Ades, 2016). Capabilities for referral, documentation, billing, and ongoing patient monitoring with clinical information technologies have not been activated in most systems to support the implementation of obesity care that is distinct from co-morbid conditions (Steglitz, Sommers, Talen, Thornton, & Spring, 2015).

To overcome uptake barriers of evidence-based care, implementation facilitation strategies are recognized as a promising mechanism to change practice (Edmunds, Beidas, & Kendall, 2013; Lau et al., 2015; Powell et al., 2012). Implementation strategies facilitate the translation process by identifying how practices and their clinicians will adopt and sustain interventions within the realities of their own settings (Kitson & Harvey, 2016; Powell et al., 2012). The most commonly practiced method of facilitation includes providing a didactic training, often in the form of continuing medical education, on an intervention with specific protocols and tools for delivery (Beidas, Edmunds, Marcus, & Kendall, 2012; Edmunds, Kendall, et al., 2013). This strategy is low-intensity with infrequent feedback, and appears to be insufficient to lead to broad adoption of new clinical strategies (Herschell, Kolko, Baumann, &

Davis, 2010; Lau et al., 2015). A number of studies have focused on combining didactic approaches with ongoing consultation and have shown promising results (Beidas et al., 2012; Edmunds, Beidas, et al., 2013; Herschell et al., 2010; Nadeem, Gleacher, & Beidas, 2013). For example, Edmunds and colleagues developed a consultee-centered approach and demonstrated that didactic training followed by case reviews, self-evaluation by providers, and ongoing feedback was effective in changing provider behavior (Edmunds, Kendall, et al., 2013).

While these approaches are encouraging for changing provider behavior and enhancing the implementation quality of health services, there is limited information on how these strategies may lead to broad adoption of new clinical skills or high reach into the patient population. To address provider adoption and patient reach, action planning that includes a focus on the scale-up of an intervention may provide a model for healthcare settings (Estabrooks & Glasgow, 2006; Hagger & Luszczynska, 2014). Action planning is a strategy that involves setting goals, identifying obstacles, and strategizing to overcome obstacles, is a technique frequently used in behavioral interventions and public health practice to guide and monitor progress, and has demonstrated positive results for promoting accountability for delivery (Estabrooks & Glasgow, 2006; Hagger & Luszczynska, 2014). When considered within a consultee-centered training approach (Edmunds et al., 2013), action planning could be used to operationalize and provide additional structure for feedback sessions.

The purpose of this study was to determine if, when compared to a CME, an implementation strategy that included a consultee-centered approach and action planning (CME Plus) could improve the reach and effectiveness of an adapted evidence-based clinical weight loss intervention at the patient level and the adoption, implementation, and maintenance of

delivery at the clinical and nurse coordinator level. It was hypothesized that the CME Plus implementation strategy, when compared to the CME, would lead to (1) higher rates of patient enrollment per care coordinator, (2) a higher proportion of patients achieving and maintaining a clinically meaningful weight loss (3-5% of initial body weight), (3) a larger proportion of clinical and nurse coordinator adoption of the clinical weight loss intervention, (4) improved implementation quality, and (5) a higher rate of sustained delivery across clinics and care coordinators 12 months post initial CME training.

Methods

Design

An integrated research-practice partnership (Estabrooks & Glasgow, 2006) formed to develop locally relevant resources for nurse care coordinators to deliver evidence-based obesity treatment services in the medical home. Following the integrated research-practice partnerships participatory model (Estabrooks & Glasgow, 2006; Glasgow & Chambers, 2012), the partnership involved a collaborative agreement to advance evidence-based behavioral interventions using an approach that balanced scientific and practice-based evidence, while simultaneously considering available delivery resources, costs, and context of delivery. Study findings were expected to provide empirical evidence to support future decision-making on training methodologies and how best to support the integration of evidence-based behavioral weight loss strategies into routine nurse care coordinator practice. The integrated research-practice partnership included investigators with expertise in implementation science and adaptation of evidence-based weight management interventions for Research team members included two principal investigators with content expertise and two doctoral-level graduate research students concentrating in translational obesity research and implementation science. Practice team members included organizational

decision-makers (e.g., medical director and senior director of ambulatory care) as well as four senior care coordinators from the health system's department of family and community medicine.

The design of this pilot study is a mixed-methods, type 3 hybrid effectiveness-implementation trial (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) with a formative evaluation (Geonnotti, Peikes, Wang, & Smith, 2013; Stetler et al., 2006). As a multi-level, type 3 trial, the study primarily focused on the impact of the implementation facilitation strategy at the setting and staff-level (medical home practices and nurse care coordinators), and secondarily focused on the clinical intervention's impact on individual-level, patient weight loss. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework guided planning and evaluation outcomes (Glasgow, Vogt, & Boles, 1999). The study's operational definitions, level, focus, and source of data for each RE-AIM dimension for the implementation strategy are displayed in Table 1 and for the clinical weight loss intervention in Table 2.

The four stages of a formative evaluation (development, implementation-focused, progress-focused, and interpretative) provided a structure for the research-practice team's evaluation throughout the pilot trial (Stetler et al., 2006). During the three month, pre-implementation development stage, the team conducted bi-weekly, 60-minute research-practice meetings to share stakeholder perspectives on program needs. Nurse care coordinator training and availability of packaged resources to support implementation of evidence-based weight loss support were identified priorities. The research team worked with the senior care coordinators to develop a training strategy and adapt clinical intervention materials. During the 12-month implementation phase, the team conducted trainings, practice profiles, nurse care coordinator surveys on sessions, and regular reviews of action plans. With implementation of the program,

quarterly practice and care coordinator reach reports and a review of care coordinator- reported patient outcomes were conducted by senior care coordinators. Finally, the team assessed overall effectiveness and maintenance at the patient level based on weight changes over time. In addition, future adaptations and sustainability needs were discussed.

Setting

Carilion Clinic is a private, not-for-profit, integrated healthcare delivery system based in Roanoke, Virginia. Carilion owns and operates seven hospitals with 1,026 beds and has more than 685 physicians in 240 practice sites, including primary care clinics, residency and fellowship programs, medical fitness facilities, laboratories, and multi-specialty physician services. The health system serves close to one million people in a unique blend of 18 predominantly rural counties and six cities throughout western Virginia (Carilion Clinic, 2015). The prevalence of obesity ($BMI \geq 30$ kg/m²) ranges from 28-36% in counties and cities throughout the system (County Health Rankings Virginia, 2015). Within Carilion's Department of Family and Community Medicine, the system is divided into three service regions for primary care, administrative purposes. The primary care practices began transformation to the medical home model with nurse care coordinators serving as a member of the care team in 2009. The system, including its hospitals, primary care, and specialty practices, has fully integrated an electronic health record (EHR) and MyChart patient portal (Carver & Jessie, 2011) (Epic, Verona, Wisconsin; www.epic.com) as part of its transparency in reporting and population health management efforts.

Participants

Implementation strategy

Nurse care coordinators (n=45) across 37 medical homes within the three service regions were offered Standard Continuing Medical Education (CME) during their regularly scheduled, professional development meeting (Region A, n=14 clinics; Region B, n=9 clinics) or CME Plus (Region C, n=14 clinics). Fourteen nurse care coordinators from Region C received the CME Plus training (31% of the total number of coordinators). Senior care coordinators who facilitate quality improvement initiatives collaboratively developed the protocol and agreed to the complete the proposed training strategy assigned to their region.

Clinical intervention

At the individual, *patient-level*, the target population was adult primary care patients, aged 18 years or older, seen in medical homes for wellness and chronic disease management. Inclusion criteria included being a current patient within the Carilion system, an overweight or obese classification ($BMI \geq 25\text{kg/m}^2$), and physician referral. Program exclusion criteria were comprised of currently pregnant women and non-English speaking patients. It was anticipated nurse care coordinators would identify patients through practice providers' referrals and high-risk registries. More than 300,000 patients were reported to be empaneled within Carilion's medical home practices with a total demographic profile consisting of 54% female, 90% White, 7% Black-African-American, 1% Hispanic, mean age 56 ($SD=8.8$) years, and mean BMI=29 ($SD=.91$). Overall, demographics are similar to census data for the system's service regions (Juday, Lombard, & Sen, 2014). The area is generally more likely to be white, older, and from lower SES status when compared to the state; 13-20% of the area population falls below the poverty line. Among localities, the poverty rate ranges from 6-35% (US Census Bureau, 2012).

At the organizational, *setting level*, medical homes were identified by senior care coordinators as the primary location to deliver the clinical weight loss intervention. Offering pediatric to geriatric services, the types of medical home practices within the Carilion system included family medicine (n=30, 81%), internal medicine (n=4, 11%), and medical education residency (n=3, 8%). The mean total number of patients for practices was 8,137 ($SD=4,870$) and mean weighted panel size of practices was 7,317 ($SD=4,691$) patients. The percentage payor mix included Medicaid eligible 8.3% ($SD=8.3$) and Medicare eligible 48% ($SD=14.8$). Practice staffing included a mean 1.3 ($SD=.58$) nurse care coordinators. Seventy-eight of practices (n=29) had medical office associates (MOA) on staff to support nurse care coordinators. The associates helped with managing high-risk and disease specific registries, scheduling, reminder calls and letters, and pre-visit preparation. Urgent care centers and practices that had not completed transformation to a patient-centered medical home model were excluded from delivering the intervention during the pilot phase.

At the organizational, *staff-level*, nurse care coordinators were the target delivery agents for the clinical weight loss intervention. All nurse care coordinators were eligible. Level of nursing licensure for the staff included licensed practice nurses (LPN, n=12, 27%) and registered nurses (RN, n=33, 73%). Seventy-one percent of nurse care coordinators (n=32) had over 10 years of experience in nursing. Eight-seven percent of nurse care coordinators (n=39) were employed full-time. A requirement for the position was obtainment of a chronic care certification (PentaHealth Institute), which included a day-long training, 4 on-line modules on evidence-based self-management (heart failure, diabetes, COPD, and depression), and an examination. The integrated chronic care certification covered principles of adult education, health literacy,

problem-solving, facilitation of behavior change, motivational interviewing, goal-setting, and theory-based tele-health.

Intervention

Implementation strategy: CME

Each of the components (workshop, package of materials, and behavioral rehearsal, i.e., role-playing) planned for inclusion in the CME is outlined in Table 3 and a fuller description is provided in Appendix 6.1. An instructive, training workshop of two and one-half hours, led by research partners, was conducted as part of nurse care coordinators' quarterly professional development. The training included an overview of the healthy lifestyle weight loss program, distribution of nurse care coordinator facilitator and patient materials, a feedback session, and an evaluation assessing delivery confidence. An active learning component of the workshop included time for behavioral rehearsal of initial patient sessions (Edmunds, Kendall, et al., 2013). The clinical recommendations for nutrition, physical activity, and intensive behavioral therapy for weight management were emphasized (Donnelly et al., 2009; Jensen et al., 2014).

For nurse care coordinators, a package of facilitator materials following the 5As framework was distributed electronically to assist with delivering the program either in-person or by phone (Estabrooks & Glasgow, 2006; Fitzpatrick et al., 2015). The package included lesson plans, guided scripts, and a program evaluation form for twenty sessions (Almeida et al., 2014). Teach-back questions were developed to assess patient understanding of each session's material (Porter et al., 2015). SmartPhrases (also known as "dot phrases") were created to provide nurse care coordinators with a standard electronic template for documenting implementation of each session's components and patient progress in the EHR (Esper & Walker, 2015; Thaker et al.,

2015). The template was modifiable and included a section for free text. Program smartphrases for each session are included in Appendix 6.2.

Implementation strategy: CME Plus

In addition to components included in CME, the enhanced CME Plus strategy included ongoing consultation and action planning (Edmunds, Beidas, et al., 2013; Estabrooks & Glasgow, 2006). The planned components are outlined in Table 3 and a fuller description is provided in Appendix 6.1. Occurring at one, three, six, and 12 months post-initial training, the four 90-minute consultations, led by research partners, included goal-setting (Pearson, 2012), additional behavioral rehearsal (Edmunds, Kendall, et al., 2013), reflection and feedback through case discussion (Beidas et al., 2012), and ongoing technical assistance support (e.g., questions and answers) at regularly scheduled team meetings. The consultations focused on improving reach and implementation quality using an adapted 5As approach (Glasgow, Emont, & Miller, 2006), 1) assessed nurse care coordinators' motivation and progress with engaging patients in the clinical weight loss intervention, 2) advised on practice implementation strategies, 3) facilitated an agreement on reach goals, 4) assisted with identifying support for overcoming delivery obstacles, and 5) arranged for ongoing review and follow-up on goals. At the one-month consultation, nurse care coordinators completed action plans to identify personal reach goals for 3-6-and 12-months post-initial training session. Principal investigators then facilitated a discussion session wherein personal goals, obstacles, and strategies were compiled into a regional action plan. Sample personal and regional action plans are shown in Figure 1.

Subsequent consultations reviewed progress on reach goals and provided interactive opportunities for nurse care coordinators to share their patient experiences. At the 3-months

consultation, two case study reviews and a participatory demonstration of muscle-strengthening and flexibility exercises were conducted. At the 6-months consultation, a post-core role session and a case review panel discussion with high-engaged nurse care coordinators took place. Both the thirty-minute case studies and panel discussion addressed patient context, recruitment strategy, method of delivery, session progress, changes made to sessions, level of patient engagement, patient behaviors, and weight change. Participating nurse care coordinators were asked to discuss their documentation processes, challenges, and recommendations for program improvement. Finally, at the 12-month consultation, final reach results were shared, adaptations were summarized, and ideas were discussed for future programming and action planning.

Clinical intervention: Healthy Lifestyles Weight Loss Program

Referred to as Carilion's Healthy Lifestyles program, the structure, topics, and content of the adapted clinic weight loss and weight loss maintenance intervention are displayed in Appendix 6.3. Guided by the 5As model (Whitlock, Orleans, Pender, & Allan, 2002), the intervention included patient assessment, weight loss and behavioral advice, collaborative agreement on weight loss and behavioral goals, assistance in the identification and resolution of barriers, and arranging for follow-up. This approach was embedded across all intervention sessions and included the development of an initial and dynamic, patient action plan (P. A. Estabrooks & Glasgow, 2006). The intervention for lifestyle treatment was based on clinical guidelines for obesity management (Force, 2012; Jensen et al., 2014) (AHA/ACA/TOS Obesity Management, 2013 and USPSTF Behavioral Counseling Guidelines, 2012) and adapted from the Diabetes Prevention Project Lifestyle Intervention (Almeida et al., 2014; Aziz et al., 2015; DPP Group, 2002).

The structure of the intervention was modeled after the Centers for Medicare and Medicaid Services (CMS) coverage of intensive behavioral therapy for obesity (Services, 2012), which included 20 sessions over a 12-month period (four weekly, ten bi-weekly, and six monthly), with a goal for patients to achieve at least a 3-kilogram (kg) weight loss by six months. The first six months of the intervention offered a core phase focused on initiating an action plan to achieve recommended levels of physical activity (i.e., at least 300 minutes of moderate-vigorous physical activity a week and two days of at least 15 minutes of strength-training a week), meet healthy eating MyPlate dietary guidelines (i.e., at least five servings of fruits and vegetables a day; reduced consumption of dietary fats, sugars, and empty calories; and increased consumption of whole grains, lean protein, and water) (McGuire, 2011), and a target weight goal (i.e., at least three kg/five percent initial body weight loss). The next six months of the program offered a post-core phase emphasizing maintenance strategies such stress management, cognitive restructuring, relapse prevention, and ongoing physical activity.

For patients, the adapted materials included a 20 session healthy lifestyle workbook (300 pages), action plan, commitment contract, tracking logs, and appendix materials including muscle-strengthening exercises and strategies to overcome obstacles for each goal area. Nurse care coordinators received all materials in an electronic format via an internal organization shared-drive to print or send to patients by session.

Data collection and measures

RE-AIM measurement

For the implementation facilitation strategy reach and implementation of the CME and CME plus strategies were evaluated. Reach was assessed as the number, proportion, and

representativeness of nurse care coordinators trained. Characteristics for representativeness included gender, nursing licensure (LPN/RN), and employment status (% full-time). Implementation was assessed as the number of training sessions and degree to which components were delivered as planned. Effectiveness of the implementation strategies was captured by evaluating the clinical intervention using RE-AIM. Adoption and organizational-level maintenance of the CME-plus implementation strategy were beyond the scope of the pilot study.

For the clinical weight loss intervention, reach, effectiveness, and maintenance were measured at the patient-level. Reach was assessed as the number, proportion, and representativeness of patients enrolled and retained. Characteristics of representativeness included age, gender, race, ethnicity, and weight status (kg., BMI, and BMI classification). Using standard reporting practice, height was measured using a wall-mounted stadiometer, and weight was measured using a digital scale in the medical home practice; unless noted as a patient self-report by phone or email. Effectiveness was assessed as the mean percentage initial body weight loss at 6-months as a primary outcome. Other weight loss outcomes included the number and percentage of patients achieving a reduction of 3 kg., and at least a 3% and 5% initial body weight loss at 6-months. Maintenance was assessed as the mean percentage initial body weight loss at 12-months, along with the number and percentage of patients achieving a reduction of three kg, and at least a 3% and 5% initial body weight loss at 12-months.

Adoption, implementation, and maintenance were measured at the organizational level (setting-practice, staff-nurse care coordinator) for the clinical weight loss intervention. Adoption was assessed as the number, proportion, and representativeness of practices and nurse care coordinators that initiated delivery of the clinical intervention. Practice characteristics of

representativeness included size, payor mix, practice type, regional location, and staffing of nurse care coordinators and medical office associates as part of the care team. Staff characteristics of representativeness included gender, licensure, chronic care certification, and employment status. Implementation was assessed as the implementation quality of clinical intervention based on addressing the 5As across sessions. Organizational maintenance was assessed as sustained delivery of the clinical intervention into a second year.

All RE-AIM measures were assessed based on definitions and suggested reporting criteria at www.re-aim.org (Glasgow et al., 1999). Effectiveness of the implementation facilitation strategy and implementation of the clinical intervention, along with nurse care coordinator characteristics, overlap in the hybrid evaluation. To ease confusion in reporting, the implementation data was provided in the results of the implementation facilitation strategy rather than within the clinical intervention testing. The source of data for each RE-AIM dimension is noted in Table 1 for the implementation facilitation strategy and Table 2 for the clinical weight loss intervention. The integrated research-practice partnership worked together to collect data for the formative evaluation using 7 quantitative and qualitative sources. Triangulation of data sources informed RE-AIM dimension measures for both the implementation facilitation strategy and clinical weight loss intervention.

Instruments and processes

Several data collection instruments and processes involving both the research and practice teams were used in the trial:

- 1) Training evaluation- A two-page, post-training survey was administered to all nurse care coordinators by the research team immediately following the CME. The survey displayed in

Appendix 6.4 quantitatively assessed nurse care coordinators' overall training satisfaction, along with perceptions of their ability to apply knowledge learned about lifestyle obesity treatment, their confidence to implement the lifestyle program, and their confidence to reach a large number of patients.

2) Training fidelity checklist- A graduate research assistant tracked the planned and completed components of the CME and CME Plus, including the content, frequency, and duration of each activity. Agendas and meeting notes from the senior care coordinator team confirmed training activity.

3) Administrative records- The senior care coordinator team tracked nurse care coordinators' attendance at training and consultation sessions. Nurse care coordinators electronically reported the medical record number of patients participating in at least one program session during the pilot phase, along with the date of the patient's initial program session, to a senior nurse care coordinator. Materials, staff costs (mean hourly rate for personnel delivery time), and patient co-payments were tracked to provide an estimated cost description of the implementation strategy and clinical intervention.

4) Session program evaluation- Twenty program evaluations were created by the research team to assess fidelity and obtain feedback from nurse care coordinators on each clinical intervention session. The evaluations included: an assessment of delivery format, a rating for met learning objectives, a checklist of lesson plan, workbook sections, and activities completed, a section for noting additional activities, props, and materials used, a level of patient engagement, and an open-ended section seeking comments on what worked best, and suggestions for future session adaptations. CME Plus participants were asked to complete the evaluations and send to

the research team after each completed session via inter-office mail, email, or fax. A sample is included in Appendix 6.5.

5) Patient chart review for weight change- A retrospective, manual, EHR review of patient charts was conducted for all patients enrolled in at least one session of the program. The chart review team included an administrative director, a senior care coordinator, and a graduate research assistant. Each member was trained on the chart extraction tool and the data dictionary for coding. Each chart review extracted: patient demographics (age, gender, race, ethnicity), anthropometric data (weight, height, and BMI at baseline, 1-month, 3-months, 6-months, 12-months, and 18-months post-initial session), and the number of sessions in which the patient participated to date. Each chart review took approximately 5 minutes. Double-key entry occurred for 30% of patients

6) Patient chart review for implementation quality – A retrospective, manual, EHR review of smartphrases was conducted for 100 randomly selected patients to assess the implementation quality of session activities. Patient selection was based on a computer-based, random number generator. Extraction forms were created for each smartphrase aligned with the 5As of each session (sample in Appendix 6.6). For each 5As' area, reviewers noted if the section was fully addressed, partially addressed, or not addressed and if the nurse care coordinator delivered each session component. When relevant, reviewers noted patient-reported outcomes, along with any additional comments or session adaptations noted in the smartphrases' free text sections. Each review took approximately 20 minutes. All three reviewers extracted the first 10 patients together, review pairs double-key entered 10 additional patients, and the remaining were double-key entered by a graduate research assistant. All discrepancies were discussed among the review team, with principal investigators contacted for clarification when needed.

7) Focus group discussions – At the end of the pilot phase, two separate focus group discussions were conducted with high engaged and low engaged nurse care coordinators. High engagers were identified as nurse care coordinators that were able to successfully reach a large number of patients ($n > 20$) during the pilot phase. Low engagers were identified as nurse care coordinators that had not started the program in their practice or were struggling to enroll patients ($n < 3$). A semi-structured discussion guide was used to explore motivations, barriers, and strategies for patient engagement. A list of discussion guide questions is included in Appendix 6.7 (High Engagers) and Appendix 6.8 (Low Engagers). Each focus group, lasting 50 ($SD = 7.1$) minutes, was moderated by a principal investigator, and probed by the senior care coordinator team. After obtaining participants' verbal consent, discussions were recorded and transcribed verbatim.

Data analysis

Descriptive, parametric, and non-parametric status frequencies, overall effects, and between group effects between CME and CME Plus training were used for analysis. Values were reported as mean \pm standard deviation (SD) or as frequency in percentage. Chi-square tests of association (categorical variables) and ANOVA tests (continuous variables) were used to compare demographics, characteristics, and weight change between conditions. For implementation quality, a percentage was computed for the 5As addressed across clinical intervention sessions. An inter-rater reliability analysis using the Pearson correlation was performed to determine consistency in chart extraction. Within each training condition, between group effects considered participants and nonparticipants for reach, patient engagement level for effectiveness and individual-level maintenance, and uptake status during the 12-month pilot

phase for adoption and organizational-level maintenance. All statistical tests were two-sided and the significance level was set at $p < 0.05$. SPSS statistical analysis software (version 23.0, SPSS Inc, Chicago, IL) was used for all quantitative analyses.

Focus group discussion transcripts and nurse care coordinators' notes extracted from patient charts were independently reviewed for common themes and categories with sample meaning units by three separate research assistants and the chart review team. Member checking occurred with the senior care coordinator team to review findings (Creswell, 2000). Dedoose (version 6.1.18, SocioCultural Research Consultants, LLC, www.dedoose.com) was used to organize the qualitative data. Findings were displayed in a tabular form representing common themes, categories, and illustrative quotes.

Results

Implementation strategy

Reach

Table 4 displays the reach of the training strategy and characteristics of nurse care coordinators that received the CME or CME Plus condition. A total of 45 nurse care coordinators (100%) received the training (CME=31, 100%; CME Plus=14, 100%). Training participants were 100% female, 27% LPNs, 73% RNs, 100% certified in chronic care, and 87% full-time employment status. No statistically significant differences existed between training conditions in gender, nursing licensure, certification, or employment.

The post-training evaluation results found a mean 4 ($SD=.71$) out of 5 for overall training rating. At baseline, CME Plus participants reported significant less agreement in their ability to apply the knowledge learned from the initial CME workshop ($p=.004$), less confidence to implement the clinical intervention ($p=.012$), and less confidence to reach a large number of

patients ($p=.005$) during the pilot phase than CME participants. At the 12-month consultation, CME Plus participants increased their mean level of confidence for implementing the weight loss intervention from 5.9 ($SD=2.1$) to 7.5 ($SD=2.1$) on a 10-point scale.

Implementation

The number of training sessions (CME=1, CME Plus=5) were completed by the research team as planned in the delivery protocol. The degree to which each component of the trainings was completed as planned for CME (100%) and CME Plus (100%) are noted in Table 3. One variation reported in both training conditions was a higher level of feedback on implementation strategies provided by senior care coordinators to practice-based nurse care coordinators during regional staff meetings or one-to-one interactions. Feedback frequently included tips from nurse care coordinators' peers with high engagement and patient weight loss success stories. The training costs included approximately 20 staff hours for preparation and delivery for CME, and an additional 40 staff hours for CME Plus, excluding the research team's time for adapting the workbook, lesson plans, and phone scripts. Total training costs including materials and hourly target rate were \$37 per LPN and \$51 per RN in CME condition and \$169 per LPN and \$237 per RN in CME Plus condition.

Clinical intervention

Reach

A mean of 17 ($SD=25.3$) patients per a nurse care coordinator were enrolled in the Healthy Lifestyle weight loss program; CME=14 ($SD=21.9$), CME Plus=24 ($SD=31.4$). The mean number of patients enrolled per nurse care coordinator during one to 3-months post-training was 1 ($SD=3.4$), from three to 6-months post-training was 3 ($SD=4.8$), and six to 12-

months post-training was 8 ($SD=13.1$). There were no statistically significant differences between training conditions on patient enrollment. Based on completed action plans shown in Figure 1, CME Plus goals for total patient enrollment were exceeded regionally by 115% (goal=157 patients, actual=337 patients) and personally by 71% (goal mean=14 patients, actual mean=24 patients).

A total of 780 patients were enrolled in the Healthy Lifestyles clinical weight loss intervention (CME=443, CME Plus=337). Patient characteristics and weight status by training condition and participation status are displayed in Table 6. Participants ($N=748$) were defined as patients meeting program evaluation inclusion criteria. Non-participants ($N=32$) were child/adolescents ($n=11$), deceased ($n=3$), pregnancy ($n=7$), initial normal BMI ($n=6$), reporting bariatric surgical procedure ($n=4$), and reporting chemotherapy/radiation treatment with extreme weight cycling ($n=1$) during the pilot phase. Patients preparing for a bariatric surgical candidacy application or identified as post-bariatric at baseline were included. The total patient population was a mean age 48 years ($SD=14.3$), 81% female, 89% White, 10% Black, and 1% Hispanic. Patients' BMI classifications included 8% overweight, 21% Class I obesity, 22% Class II obesity, 31% Class III obesity, and 16% Class IV obesity. Statistically significant differences were found in a younger age, Hispanic ethnicity, lower body weight, and lower mean BMI between participants and nonparticipants regardless of implementation strategy condition.

Program retention results revealed 77% ($n=579$) of patients completed more than one session, 30% ($n=224$) completed 3 months of sessions, 14% ($n=105$) completed the 6-months core phase of 14 sessions, and 4% ($n=27$) of eligible patients completed the 12-months program including the post-core phase of 20 sessions. At the time of evaluation, 2% ($n=13$) of patients were still proceeding in the post-core program phase. The only statistical significant difference in

retention was participants classified as overweight and not obese were more likely to only participate in one session ($p=.02$)

Effectiveness

Table 7 displays weight change by training condition and participant engagement level at 1-3-and 6-months. The EHR had a measurement of weight on file in 81%, 75%, and 76% of patients at 1-3-and 6-months respectively. The primary outcome of patient initial percent body weight loss was -2.1% ($SD=4.7$) at 6-months; CME=-1.8% ($SD=4.7$), CME Plus=-2.5% ($SD=4.7$). No statistically significant differences in outcomes were observed between CME or CME Plus training conditions. However, weight loss outcomes were significantly greater with increasing program intensity at 6-months ($p=.000$). Patients engaged in more than one session compared to patients engaged in only one session achieved -2.7% ($SD=4.8$); patients completing the core phase achieved -5.6% ($SD=5.2$); and patients completing the post-core phase achieved -7.5% ($SD=4.7$). One patient was not included in effectiveness results due to no weight chart data.

Adoption

At the setting-level, 76% ($n=28$) of medical home practices initiated the Healthy Lifestyles clinical weight loss intervention during the first 12-months; CME=70% ($n=16$), CME Plus=86% ($n=12$). Practices with a greater number of patients and weighted panel size were statistically more likely to adopt the intervention ($p=.004$, $p=.010$, respectively). CME Plus practices that adopted the intervention were more likely to have a medical office associate on staff to assist nurse care coordinators ($p=.017$). At the staff-level, 73% ($n=33$) of nurse care coordinators initiated at least one Healthy Lifestyles patient session; CME=61% ($n=19$), CME Plus=100% ($n=14$). CME Plus were statistically more likely to adopt than CME ($p=.007$), with

no differences by staff characteristics. Table 8 displays setting-level adoption outcomes by practice and Table 9 shows staff-level adoption outcomes by nurse care coordinator.

Implementation

Nurse care coordinators addressed the overall 5As a mean 84% ($SD=.10$) across sessions in the 100 randomly selected patient charts. As specific implementation components, the 5As were addressed in the review as: *Assess* 81% ($SD=.13$), *Advise* 79% ($SD=.14$), *Agree* 73% ($SD=.14$), and *Assist/Arrange* 95% ($SD=.08$). Significant differences were found with *Assess* (CME 86% ($SD=.07$), CME Plus 69% ($SD=.30$); $p=.011$) and *Advise* (CME 82% ($SD=.08$), CME Plus 67% ($SD=.28$); $p=.015$). On average, patients completed 6 ($SD=5.7$) program sessions with a nurse care coordinator. The mean duration of sessions was 38 ($SD=18.4$) minutes and the length of program engagement was 88 ($SD=112.5$) days. There were no statistically significant implementation differences between groups in mean enrollment number, duration, length of program session engagement, or nurse care coordinator level of licensure (LPN/RN). Inter-rater reliability was over 80% for the coding team.

In session program evaluations ($n=92$), nurse care coordinators self-reported a mean 9 out of 10 for meeting session learning objectives and a mean 8.2 out of 10 for patient engagement level. Total mean costs for delivering the Healthy Lifestyles program per patient was estimated at \$559 (\$467 for LPNs and \$642 for RNs). Program materials in the initial package averaged \$4.25 per patient for the healthcare system. Supplemental materials commonly reported as adaptations, including a calorie counting book and healthy portion plate learning aid, averaged \$8 per patient. Staff hours averaged 12.5 hours for the total 12-month program per patient. Direct patient costs, based on insurer-required visit co-payments estimated at \$25 each, was \$500 for the total program.

Maintenance

Table 7 displays patient-level maintenance by training condition and participant engagement level at 12-months. The EHR had a measurement of weight on file in 67% of patients. Patient initial percent body weight loss was -2.3% ($SD=6.1$) at 12-months; CME=-2.1% ($SD=5.9$), CME Plus=-2.4% ($SD=6.5$). No statistically significant differences occurred between CME or CME Plus. However, weight loss maintenance outcomes were significantly greater with increasing program intensity at 12-months ($p=.000$). Patients engaged in more than one session maintained -2.8% ($SD=6.3$); patients completing the core phase maintained -6.0% ($SD=6.2$); and patients completing the post-core phase maintained -6.6% ($SD=5.9$). Since only 21% ($n=157$) of patients reached the 18-months follow-up or had a weight on file at the time of chart review, results were not reported for this timeframe in study tables. The mean initial body weight loss, -2.6% ($SD=7.1$), showed potential trends in this small patient sample toward long-term maintenance.

At the organizational level, the clinical intervention has continued to be offered beyond the 12-month implementation strategy. During the post-pilot evaluation, as shown in Table 8, 76 percent of practices continued to enroll patients beyond the 12-month pilot phase, CME =70% ($n=16$), CME Plus=86% ($n=12$). As shown in Table 9, sixty percent ($n=27$) of nurse care coordinators enrolled patients beyond the pilot phase; CME=55% ($n=16$), CME Plus=79% ($n=11$).

Qualitative inquiry

Focus groups

Focus group participants included high program engagers (n=4 [Region A=2, Region C=2], mean 3 (*SD*=1.2) years of service as a nurse care coordinator) and low program engagers (n=5 [Region A=3, Region B=1, Region C=1], mean 3 (*SD*=1.1) years of service as a nurse care coordinator). Seven topical themes emerged from the two discussions: 1) Experience helping patients with weight loss, 2) Motivation to offer program, 3) Barriers to offer program, 4) Patient recruitment and referrals, 5) Program delivery, 6) Patient retention, and 7) Needed program resources. Table 10 outlines the categories and illustrative quotes for each theme, along with summarized similarities and differences between levels of engagement. Although all care coordinators reported an overwhelming need to offer patients weight loss support, high engagers were more likely to use a patient-centered approach to successfully recruit and encourage long-term engagement. Major recommendations include instituting better integration with chronic disease management, developing a payment system to assist with program costs, and incorporating additional resources to provide more personalized levels of support for patients with severe obesity, low-incomes, and physical challenges.

Patient chart notes

Review of nurse care coordinator's comments documented in the 100 randomly selected patient charts revealed six common themes: 1) Program processes, 2) Motivation for weight loss, 3) Barriers, 4) Facilitators, 5) Patient outcomes, and 6) Program adaptations. Table 11 outlines the categories and provides an illustrative quote. The chart notes revealed the ease of program scheduling with most initial Healthy Lifestyles sessions occurring on the same day directly after a PCP appointment, yet difficulty occurred with patient follow-up and ongoing engagement. Patients were motivated for weight loss to improve functional status, chronic care management, quality of life, and to meet bariatric or orthopedic, surgical pre-requisites. Wide variability

existed in reports of weight loss, dietary, and physical activity change. Self-monitoring, fitness trackers, and social support were facilitators. Finances, caregiving, life stresses, complicated grief, and existing poor health were barriers. In a few charts, pharmacological use for weight loss was reported with mixed results. Common program adaptations included changing the program structure by combining sessions, extending time between follow-up, and adding brief, weight check-ins at the clinic or through phone/MyChart patient self-reports.

Discussion

Overcoming research to practice gaps, this hybrid effectiveness-implementation trial demonstrated the utility of adding consultation and action planning to support the training of nurse care coordinators to deliver lifestyle obesity treatment in medical home practices. The findings show modest support in confirming the hypotheses for greater uptake among the enhanced implementation strategy and the effectiveness of the clinical intervention for patients achieving and maintaining a three to five percent initial body weight loss. Consultation and action planning accelerated adoption and improved reach compared to the CME of a one-time workshop, particularly in the early pilot months. However, strong leadership, ongoing facilitator feedback, and peer-sharing from highly engaged care coordinators in Region B, the largest, main service area in the Carilion system, positively influenced uptake over time to enhance reach outcomes in the CME condition. Providing a package of ready-to-deliver resources, a majority of nurse care coordinators in both training conditions were able to initiate evidence-based obesity care within their practices, but widespread use, implementation quality, and program effectiveness varied. Heterogeneity in practices, adaptations to delivery structure that minimized

levels of patient engagement and follow-up, along with patient-reported barriers appear to have impacted the proportion of patients achieving and maintaining clinically meaningful weight loss.

Implementation strategy

Findings from the formative evaluation of the implementation strategy revealed a strong reach, overall effectiveness, training quality, and individual-level maintenance of interventions. Full reach of all active nurse care coordinators in both the CME and CME Plus conditions resulted from leadership buy-in, an existing infrastructure for facilitation support, and convenient integration into required staff meetings that guaranteed attendance. Research and practice partners co-designing training components promoted fit within the system's existing scheduling and facilitation processes. These organizational influences and facilitation strategies have similarly been reported in other studies to be instrumental for successful uptake and representation (Damschroder, Goodrich, Robinson, Fletcher, & Lowery, 2011; Lopez-Patton et al., 2015; Wandersman et al., 2008). With certification in chronic care management and experience in health behavior change, nurse care coordinators were receptive to facilitating lifestyle management and had access to a large pool of eligible patients. However, time, PCP support, and patient commitment were major concerns. As expected and reported in the literature (Carvajal et al., 2013; Dietz et al., 2015a; Phillips et al., 2014), baseline confidence in engaging patients specifically for weight loss was low among a majority of nurses. This characteristic was most prevalent, but improved during the pilot in the CME Plus condition, a region outside the main service area that was reported to have less experience with obesity-related, quality improvement initiatives.

The CME Plus implementation strategy was able to be fully delivered as intended, and was deemed a viable and effective approach by the partnership to support nurse care coordinators in delivering lifestyle obesity treatment. The structured consultation offered at 1, 3, 6, and 12-months after the initial training workshop reinforced administrator support for program uptake and provided an outlet for nurse care coordinators to share their implementation strategies and problem-solve challenges with experts from the research team. For instance, nurse care coordinators reported adjusting their eligibility criteria to target patients with a BMI \geq 40 to adhere to their practice's high-risk population health management strategy (Haas et al., 2013), but were overwhelmed with the weight loss needs and physical limitations of de-conditioned patients with severe obesity. Highly relevant case review discussions with the research team generated alternative strategies for safe and appropriate delivery, such as initiating activity goals with a series of chair-based, muscle-strengthening exercises. As shown in other studies in education, mental health, and substance abuse, consultation and additional contact with trainees provides greater uptake of an evidence-based intervention than a single training (Beidas et al., 2012; Kleinpell, Faut-Callahan, Carlson, Llewellyn, & Dreher, 2015; Nadeem et al., 2013).

However, interestingly, based on the existing infrastructure and facilitation practice within Carilion's medical homes, the senior nursing team appears to have moderated the strength of the relationship between consultation and uptake in this pilot trial. As part of their typical role in providing guidance and assistance for integrating population health management tools into practice (Haas et al, 2013), the senior care team monitored Healthy Lifestyles implementation and provided feedback to all nurse care coordinators following the initial CME workshop. As a reported deviation from the CME plan (Table 3), the team's feedback on how highly engaged nurse care coordinators were able to initiate the program with patients, along with reports of

significant weight loss, improved health risk factors, and quality of life outcomes created implementation momentum and peer-pressure for uptake. An exception to this observance occurred within Region C where the senior care coordinator was on maternity leave during parts of the pilot, limiting the level of feedback and reach. As medical home networks with teams of peer-practice facilitators grow across the U.S.(Jackson et al., 2013), this contextual finding offers insights into a potentially un-tapped strategic partner for improving obesity care and advancing dissemination and implementation science efforts.

Developing and consistently reviewing the regional and personal action plans during consultations provided an opportunity for realistic goal-setting, context-specific, problem-solving, and progress monitoring. Over time, nurse care coordinators adjusted their personal reach goals based on the degree to which the program was meeting their population's needs and the context of their specific practice. Compared to the CME, clear expectations for patient enrollment and an accountability system emerged during the consultation sessions. Initiating the program became a priority for the CME Plus region and reach goals were exceeded. The primary challenge with the action planning component involved the burden of obtaining reach totals from nurse care coordinators and a lack of a formalized process for reporting. As a pilot trial, the healthcare system was unable to invest time and resources in configuring an EHR report to identify enrollment by region or nurse care coordinator. Furthermore, the Smartphrase set produced for the program did not contain discreet fields with report functionality, a common major barrier for real-time measurement and evaluation in medical home practices (Krist et al., 2014; Thaker et al., 2015).

Assessing implementation quality of the 5As across total sessions (1-20), both CME and CME Plus conditions were able to deliver the Healthy Lifestyles program with strong fidelity;

>80%. Separate evaluation of each component of the 5As framework revealed significant differences between conditions, with less quality for CME Plus delivery of the *Assess* and *Advise* components of sessions. This finding may be an unintended consequence of focusing solely on reach during goal-setting and action planning sessions. Using a patient-centered approach, CME Plus nurse care coordinators reported: 1) conducting sessions in less than 15 minutes, 2) arranging on-site weight checks with distribution of session handouts, 3) integrating session materials with a PCP visit, and 4) combining sessions to reduce or eliminate patient charges, scheduling burdens, and promote efficiency. These strategies often supported increased patient recruitment and on-going engagement, but minimized the degree to which patients received intensive behavioral therapy (Jensen et al., 2014). Specifically, brief sessions taking place by phone and MyChart kept patients engaged with weight self-monitoring, but often did not systematically include the more time-intensive, full assessments of dietary and physical activity behaviors or complete advice on behavioral strategies. Furthermore, balancing the potential revenue generating service with patients' ability or willingness to pay may have constricted time available to fully implement sessions. Balancing revenue-generating services, care coordination priorities, and patient volume is a continuous challenge for optimizing care delivery in the medical home (Wagner, Sandhu, Coleman, Phillips, & Sugarman, 2014).

Clinical intervention

Formative evaluation of the Healthy Lifestyles clinical intervention demonstrated a modest effect on weight loss, with strong reach, adoption, and maintenance. Overall implementation quality was satisfactory based on addressing the 5As, but several adaptations were made to the program to meet patient needs and the burden of direct patient costs. The mean

-2% initial body weight loss achieved at 6 months and 12-months was less than reported in efficacy and other DPP translational or intensive behavioral weight loss trials ((Aziz et al., 2015; Pagoto, Kantor, Bodenlos, Gitkind, & Ma, 2008; Thabault et al., 2016). However, weight loss was favorable to results from other large-scale DPP translations targeting patients in the Veteran Affairs, patients with low-income, and patients seen briefly during primary care visits (Aziz et al., 2015; Carroll et al., 2015; Garvin, Marion, Narsavage, & Finnegan, 2015). Positively, on average, patients were able to maintain their weight loss achieved during program participation, and a comparative percentage of program participants achieved at least a 3-5% initial body weight loss(Aziz et al., 2015). The proportion of patients (77%) completing more than one session was relatively high for a translational trial (Ackermann, 2015), but the proportion of patients completing the program's core (14%) and post-core phases were extremely low (4%).

As shown in systematic reviews of real-world DPP adapted programs (Ali et al., 2012; Aziz et al., 2015; Mudaliar et al., 2016), intensity predicted weight loss outcomes. At least a mean 5-7% initial body weight was able to be achieved and maintained for patient populations engaged throughout the core and post-core phases. Ongoing engagement and program retention was needed to produce clinically meaningful weight loss. However, with low intensity intervention (1-4 sessions), some amount of weight loss and change in dietary and physical activity behaviors was able to be achieved, which from a systems' population health perspective may still have positive impact in chronic disease prevention and management (Aziz et al., 2015).

Total patient enrollment during the pilot exceeded expectations. Nurse care coordinators in the CME Plus overwhelmingly surpassed both their regional and personal goals for patient engagement set at the first consultation session dispelling initial staff concern in the ability to implement the intervention. However, across conditions, highly engaged nurse care coordinators

disproportionately contributed to the overall patient volume versus less engaged nurse care coordinators, with some high engagers initiating the Healthy Lifestyles program with over 85 patients. Physician referrals, high-risk registries, and reviews of appointment schedules for eligible patients were deemed effective recruitment strategies. Nurse care coordinators also strategically placed program fliers near practice scales and waiting areas.

The recruited patient population had a wide range of BMIs. Patients classified as overweight (BMI=25-29.9) were more likely to drop-out, a finding similar to other DPP-adapted trials (Azar, Xiao, & Ma, .2013). This supports the assumption that the program may potentially have been too intensive, physician-dictated, or not worth the costs for their needs or expectations. By employing a population health management recruitment strategy focused on patients with the highest-risk, this trial included a larger percentage of patients with a BMI \geq 40 than is typical in research-based or most DDP-adaptation studies (Aziz et al., 2015). Reach findings also revealed a practice need and interest in offering obesity treatment for youth, families, and elective orthopedic and pre-surgical bariatric candidates; areas for future partnership exploration.

At both the setting and staff level, the positive rates of adoption revealed that a majority of practices and nurse care coordinators were able to initiate the program within 12-months of initial training. A potential mechanism for higher rates of adoption among CME Plus includes increased nurse care coordinator confidence developed from consultation sessions that focused on identifying recruitment strategies and problem-solving program obstacles. For both training conditions, having a package of ready-to-deliver program resources was consistently identified as a facilitator for uptake. The value of a delivery package, along with higher rates of adoption among larger practices and those with additional support staff, is similar to findings in other

studies (Damschroder & Lowery, 2013; Lau et al., 2015). Strategies suggested locally and in the literature to improve adoption include involving more key stakeholders, such as practice medical directors, managers, and referring physicians (Wandersman et al., 2008). Preparing a recruitment kit with a one-page program summary, a brief slide presentation targeting all practice stakeholders, practice fliers, and an EHR Smartset that includes referral and follow-up may be useful tools to include in a future resource package. Identifying a physician champion that fully understands program components and who supports the program being delivered by nurse care coordinators would also be advantageous for uptake.

The role of the nurse care coordinator is still evolving and being defined in medical home practices (Biernacki et al., 2015). The competing priorities of the role, including hospital discharge follow-up, transition care management, care of complex patients with uncontrolled diabetes or hypertension, and being a supportive member of the practice team were evidenced in this trial and likely influenced overall level of uptake and implementation. The LPN or RN nursing licensure impacted the degree a nurse care coordinator may intervene with patient care (S. Haas, Swan, & Haynes, 2013). For instance, LPN work is deemed limited to patient intake and only a RN may extend assessment to the formulation of a care plan (Smolowitz et al., 2015). However, except for delivery costs, there were no differences in adoption or effectiveness between LPNs or RNs in this study. When MOAs worked with a nurse care coordinator on scheduling and patient follow-up, uptake and patient engagement increased suggesting practices may benefit by designating office staff roles in obesity care workflows. Adoption of evidence-based obesity care practices is expected to increase throughout primary care when members of the care team are better defined and expanded (Fitzpatrick et al., 2015). Addressing

reimbursement and staffing models for nurse care coordinators' delivery will be critical for sustainability within the healthcare system (Haas, Vlasses, & Havey, 2016).

Modeling the clinical intervention on CMS's structure (20 sessions; four weekly, ten bi-weekly, and six monthly) received mixed reviews when implemented in practice. For some patients, the initial weekly sessions were too costly and burdensome to schedule. For others, the monthly sessions were reported to not offer enough support and contribute to a drop-off in engagement. This finding brings attention to a need for greater flexibility and patient-centeredness in the delivery of intensive behavior therapy. If strictly following the CMS service eligibility goal for patients to achieve at least a 3 kg. weight loss by 6-months, only 38% of enrolled patients would have met criteria to continue. Although not applied in this trial, nurse care coordinators expressed concerns on how this policy would have been enforced considering a majority of their patient populations had a poor treatment response based on CMS criteria. Protocols on messaging and alternative options for non-responders would be needed. Suggestions for patients wanting to continue treatment included: 1) referring patients to a community, group-based or commercial program, 2) referring patients to a more-intensive medically supervised weight loss programs with very low calorie diets and meal replacements, 3) offering combination lifestyle and pharmacological therapy, or 4) exploring surgical treatment options.

Strengths and limitations

There are several strengths to this trial that contribute to the field. First, this highly, pragmatic, pilot trial is believed to be a forerunner in testing system-wide strategies for increasing delivery of obesity care by nurse care coordinators within the medical home. Previous trials have focused on chronic care management (Jackson et al., 2013), but have not inclusively

targeted obesity as an intervening, high risk factor or disease state. Second, this type 3 hybrid effectiveness-implementation trial expanded beyond a sole assessment of weight loss effectiveness typical in trials to primarily focus on testing implementation strategies to increase uptake of lifestyle obesity treatment (Curran et al, 2012). There is a paucity of type 3 trials published in the literature that focus on this key to successful translation of research to practice, while simultaneously still providing a measure of impact, with none known to specifically focus on obesity care in the clinical setting (Estabrooks, 2016).

Third, the trial demonstrated the feasibility of implementing and sustaining both the implementation strategy and clinical intervention using the system's existing infrastructure and available resources. The thoroughly described training strategies conveniently reached all nurse care coordinators through regional meetings, a generalizable approach that other large health systems with a medical home network may replicate. Without dependence on external funding for delivery, training activities and the Healthy Lifestyle program were quickly initiated and able to demonstrate sustainability potential for institutionalization within the system. Fourth, this trial included a cost description of implementation answering the demand for undertaking economic evaluation in health services research (Lau, R et al., 2015; Hoomans & Severns, 2014).

Consultation and action planning was a low-cost, training strategy and the adapted, package of clinical intervention delivery resources was affordable for the research-practice partnership to develop. Finally, the EHR chart review provided a large percentage of patient weights for each of the 1-,3-,6-, and 12-months' time points and the focus group discussions with both high- and low-engaged nurse care coordinators offered informative, in-depth, and context-specific implementation insights. Overall, this multi-level, mixed methods approach generated relevant

and actionable findings in which the team could respond as part of its ongoing, quality improvement process.

This trial includes a few limitations to consider when interpreting findings. First, the implementation strategy was assessed using a quasi-experimental design and in a system where the senior care coordinator leadership team involved across all phases of the trial were interested in improving the uptake, reach, and effectiveness of weight management strategies within their respective regions. As a result the nurses in regions that received only the CME condition, also received informal feedback on their activities relative to those in the CME Plus condition. To reduce the impact of this potential confound we explicitly assigned the large central region, where pilots are typically rolled out, to the CME only condition. Future work would ideally randomly assign nurse coordinators to different implementation strategies.

Second, potential mediators and moderators were not fully assessed due to privacy concerns and study timing. For nurse care coordinators, mediators, such as obesity attitudes, personal weight, or past experiences with patient weight loss, and moderators, such as their amount of leadership feedback or PCP support, may have created a potential bias in uptake. For patients, mediators, such as their health literacy, financial status, and self-efficacy, and moderators, such as their use of pharmaceuticals or community-based, fitness facilities, may have biased their weight loss outcomes.

Third, evaluation of the clinical weight loss intervention was limited to a pre-post, quasi-experimental design instead of an originally, planned matched-cohort. Assigning a program modifier required for generating EHR reports and the pull time needed for the matched sample exceeded the capacity of the health system's analytics team. Likewise, building a pilot trial reporting function was not a system priority over regulatory and funded projects assigned to the

overburdened technology support group, a common challenge facing health services research (Krist et al., 2014). This unforeseen barrier required the team to shift to manual chart extraction focused solely on primary outcomes. Comparisons to standard care and secondary outcomes, such as changes in patients' blood pressure, lipid profile, hemoglobin A1C3, physical activity, and dietary consumption, will be explored in future studies. In addition, evaluation of the patient experience is needed.

Fourth, the patient sample was predominantly female and White, limiting the clinical intervention's generalizability across diverse patient populations. Fifth, the economic evaluation was limited and did not include opportunity costs to providers and patients partaking in the implementation activities. A full cost-effectiveness or cost-benefit analysis would better inform future decision-making. Finally, the assessment of implementation quality of the 5As was based on review of what nurse care coordinators reported in the Smartphrase template. The modification of templates to accurately reflect actual care and follow-up delivered has been reported as an ongoing concern in primary care (Gabert, Thomson, Gakidou, & Roth, 2016; Gaffey, 2009; Krist et al., 2014).

Implications for clinical practice

The implementation strategies and clinical weight loss intervention tested in this pilot trial offers valuable "how to" guidance for primary care to initiate the delivery of lifestyle obesity treatment. Conducting consultations that problem-solve and offer feedback on implementation, either in formal sessions led by experts or informal sessions with practice facilitators, seems to positively impact staff uptake beyond basic training and distribution of materials. Action planning based on the 5As was shown to be an effective tool that not only is

useful for facilitating patient behavior change, but also for guiding staff in initiating and sustaining a new patient service. To optimize the impact of action planning in the future, comprehensive goal-setting that not only includes process-based goals for enrolling patients, but also includes a measure of retention and program effectiveness deserves exploration. This outcome-based addition aligns with the current shift in healthcare from pay-for-service to pay-for-performance and performance evaluations for nurse care coordinators in the medical home ((Henderson et al., 2012). Other adaptations to action planning may be to expand the strategy to involve the enhanced chronic care, interdisciplinary team and its system processes, including measuring referral sources and levels of support from a practice's behavioral health, social work, and pharmacy providers (Dietz et al., 2015b).

A key revelation from this trial is that the severity of obesity that primary care is observing among patients requires high levels of ongoing support and additional services to address a complex array of physical, psychological, social, and financial needs. Nurse care coordinators' work would benefit from stronger linkages to other clinical and community resources, especially those supporting low-income patients (i.e., affordable healthy food outlets or subsidized fitness memberships at the YMCA). Aligned with clinical guidelines (Jensen et al., 2014), protocols for future programming will need to support the continuum of obesity care where lifestyle management is continually offered along with pharmaceutical and/or surgical intervention (Dietz et al., 2015b).

Patients are seen regularly in the medical home and often interact at other points within the health system that are systematically documented in the EHR providing longitudinal opportunities for patient follow-up, relapse prevention, and data monitoring across the lifespan. For the EHR and MyChart patient portal to not only track weight reports at each visit, but

provide a % initial body weight change overtime would be a more helpful and actionable standard for providers and patients to acknowledge clinically, meaningful weight loss. Standardization of weight tracking and incorporation of target outcomes into practice benchmarks and scorecards for performance may support the integration of offering obesity treatment in routine care. Developing functions within the EHR to glean weight and obesity-related services data without labor intensive, manual chart review is critical for advancement (Krist et al., 2014; Steglitz et al., 2015).

Ultimately to advance nurse care coordinators in delivering lifestyle obesity treatment, clinical practice will need to create the business case for this expanded role. Billing payment models, standardization of coding, and the revenue-generating potential of services are areas in need of more development and thorough investigation. Recent release of Medicare's physician fee schedule for 2017 including proposed coverage of DPP services under Medicare Part B is a potential, promising mechanism to support obesity care (CMS News, 2016).

Implications for research

This trial revealed the complexity of applying the RE-AIM framework to a hybrid-effectiveness design. It was easy to become confused in operationalizing dimensions. For instance, implementation for the clinical intervention was the same measure as effectiveness for the implementation strategy. Individual-level maintenance for the implementation strategy was the same measure as organizational-level maintenance for the clinical intervention. Reach for the implementation strategy was the same measure as staff-level adoption for the clinical intervention. Future possibilities for clarifying the application of the RE-AIM framework include an expansion of hybrid trials to a 1) a reach-effectiveness hybrid, 2) an effectiveness-maintenance, or 3) an adoption-implementation hybrid (Estabrooks, 2016).

Empirical evidence was generated within this trial supporting the use of the integrated research-practice partnership approach. The partnership provided mutually-beneficial value to both research and practice members. For researchers, a very brief, three-month start-up time, access to a system's practices, staff, and EHR, and insights into contextual factors influencing processes and outcomes were observable advantages over the traditional research approach. The sustainability of the program and partnership beyond the pilot trial provided ongoing projects for future research and practice-based, training opportunities for students. Partnering with practice facilitation teams and quality improvement initiatives taking place within primary care's medical home transformation are a natural fit for implementation science researchers.

Conclusions

In summary, this trial 1) confirmed nurse care coordinators are well-placed to implement lifestyle obesity treatment, 2) provided actionable evidence to support future training components, and 3) offered tangible ways to integrate behavioral weight loss strategies into a sustainable system of obesity care for primary care practice. Trial findings demonstrate that consultation and action planning led by an integrated research-practice partnership may accelerate uptake and improve reach of evidence-based care compared to usual implementation strategies. Incorporating an on-going, goal-setting, problem-solving, and feedback system using the 5As model is a promising implementation strategy to overcome practice-based, translational challenges and identify patient-centered adaptations for medical home interventions. Future trials focusing on strategies for nurse care coordinators to increase patient engagement and program retention rates may improve the robustness of weight loss outcomes.

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Table 1. Operational definition, level, focus, and source of data for each RE-AIM dimension in implementation strategy evaluation

RE-AIM Dimension	Operational Definition	Level	Focus	Source of Data
Reach	<ul style="list-style-type: none"> Number, proportion, and representativeness of nurse care coordinators trained 	Individual; Nurse care coordinator	Descriptive assessment	<ul style="list-style-type: none"> Administrative records Training evaluation
Effectiveness*	<ul style="list-style-type: none"> Number of mean patients enrolled by nurse care coordinators at 3, 6- and 12-months post-training Implementation quality of clinical intervention based on addressing 5As (Assess, Advise, Agree, Assist/Arrange) across sessions 	Individual; Nurse care coordinator	Targeted change	<ul style="list-style-type: none"> Administrative records with patient chart confirmation Retrospective review of a random selection of 100 patient charts
Adoption	<ul style="list-style-type: none"> Number, proportion, and representativeness of practice regions that agreed to receive the training strategy 	Organizational; Practice region	Beyond scope of pilot phase	<ul style="list-style-type: none"> N/A
Implementation	<ul style="list-style-type: none"> Number of training sessions and degree to which components were delivered as planned 	Organizational; Training staff	Descriptive assessment	<ul style="list-style-type: none"> Training fidelity checklist
Maintenance _i	<ul style="list-style-type: none"> Number of mean patients enrolled by nurse care coordinators at 18-months post-training 	Individual; Nurse care coordinator	Descriptive assessment	<ul style="list-style-type: none"> Administrative records with patient chart confirmation
Maintenance _o	<ul style="list-style-type: none"> Sustained delivery of training strategy across multiple years 	Organizational; Practice region	Beyond scope of pilot phase	<ul style="list-style-type: none"> N/A

Notes. *Effectiveness of the implementation strategy and implementation of the clinical intervention overlap; i=individual; o=organizational

Table 2. Operational definition, level, focus, and source of data for each RE-AIM dimension in Healthy Lifestyles clinical weight loss intervention evaluation

RE-AIM Dimension	Operational Definition	Level	Focus	Source of Data
Reach	<ul style="list-style-type: none"> Number, proportion, and representativeness of patients enrolled and retained 	Individual; Patient	Descriptive assessment	<ul style="list-style-type: none"> Patient charts
Effectiveness	<ul style="list-style-type: none"> Mean % initial body weight loss at 6-months % of enrolled patients achieving at least a 3kg. at 6-months % of enrolled patients achieving $\geq 3\%$-5% initial body weight loss at 6-months 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Patient charts
Adoption	<ul style="list-style-type: none"> Number, proportion, and representativeness of practices and nurse care coordinators that initiated delivery of clinical intervention clinical 	Organizational; Practice, Nurse care coordinator	Targeted change	<ul style="list-style-type: none"> Administrative records with patient chart confirmation
Implementation*	<ul style="list-style-type: none"> Implementation quality of clinical intervention based on addressing 5As (Assess, Advise, Agree, Assist/Arrange) across sessions Costs of intervention delivery 	Organizational; Nurse care coordinator	Targeted change as a result of implementation strategy	<ul style="list-style-type: none"> Retrospective review of a random selection of 100 patient charts
Maintenance _i	<ul style="list-style-type: none"> Mean % initial body weight loss at 12-months % of enrolled patients maintaining at least a 3kg. at 12-months % of enrolled patients maintaining $\geq 3\%$-5% initial body weight loss at 12-months 	Individual; Patient	Targeted change	<ul style="list-style-type: none"> Patient charts
Maintenance _o	<ul style="list-style-type: none"> Sustained delivery of clinical intervention across multiple years 	Organizational; Practice, Nurse care coordinator	Descriptive assessment	<ul style="list-style-type: none"> Administrative records with patient chart verification

Notes. *Effectiveness of the implementation strategy and implementation of the clinical intervention overlap; i=individual; o=organizational

Table 3. Components of CME and CME Plus training planned and completed during pilot phase

Training Components	Description	CME Training		CME Plus Training	
		Planned	Completed	Planned	Completed
Workshop	<ul style="list-style-type: none"> • A 2 ½ hours training session providing an overview of the intervention and recommendations for weight management 	√	√	√	√
Facilitator materials for nurse care coordinators	<ul style="list-style-type: none"> • Twenty lesson plans and guided scripts • Teach-back questions to assess patient understanding • Electronic health record smart-phrases templates • Program evaluation forms 	√ √ √ √	√ √ √ √	√ √ √ √	√ √ √ √
Patient education materials	<ul style="list-style-type: none"> • Twenty session healthy lifestyle workbook • Patient action plan form • Target weight chart • Commitment contract • Tracking logs • Appendix materials including exercises and strategies 	√ √ √ √ √ √	√ √ √ √ √ √	√ √ √ √ √ √	√ √ √ √ √ √
Behavioral rehearsal	<ul style="list-style-type: none"> • Role-playing of initial core program sessions • Role-playing of post-core program sessions 	√	√	√ √	√ √
Consultation	<ul style="list-style-type: none"> • Four 90-minute consultee-centered sessions at 1-3-6 and 12-months post-workshop • Additional technical assistance to support the implementation of the clinical weight loss intervention 			√ √	√ √
Action planning	<ul style="list-style-type: none"> • Personal action plan for nurse care coordinators to identify reach goals at 1-3-6 and 12-months post-workshop • Regional action plan for nurse care coordinators to identify composite reach goals at 1-3-6 and 12-months post-workshop 			√ √	√ √
Case review	<ul style="list-style-type: none"> • Thirty minute panel discussions at 3 and 6-months consultations to reflect and provide feedback on a patient case (n=4) 			√	√
Feedback	<ul style="list-style-type: none"> • Reports to nurse care coordinators of implementation strategies found to be successful in practices and patient success stories 		√	√	√

Legend: √-Yes, documentation of implementation by integrated research-practice partnership

Table 4. Training intervention reach; characteristics of coordinators that received the CME or CME Plus implementation strategy

RE-AIM Outcome REACH	Care Coordinator Population	CME	CME Plus	Significance (p-value)
Nurse care coordinators participating, no., % offered that received training	45/45 100%	31/31 100%	14/14 100%	n/a
Gender, female, no., %	45 100%	45 100%	45 100%	n/a
Licensed practical nurse (LPN), no., %	12 27%	9 29%	3 21%	0.59
Licensed registered nurse (RN), no., %	33 73%	22 71%	11 79%	
Chronic care certification, no., %	45 100%	45 100%	45 100%	n/a
Employment status, full-time, no., %	39 87%	25 81%	14 100%	0.08
Able to apply information (1-strongly disagree; 5-strongly agree), (SD) ¹	4 (.72)	4.2 (.62)	3.6 (.76)	.004*
Implementation confidence (0-not at all; 10-very confident), (SD) ¹	7 (2.0)	7.5 (1.7)	5.9 (2.1)	.012*
Reach confidence (0-not at all; 10-very confident), (SD) ¹	3.3 (2.1)	3.9 (2.1)	2 (1.5)	.005*

Notes. ¹All assessed at the end of the standard training session with a focus on care coordinator perceptions of their ability to apply the knowledge learned, their confidence to implement the specific program, and their confidence to reach a large number of patients; * $p < .05$

Table 5. Effectiveness of training operationalized as mean patient enrollment per nurse care coordinator and session implementation quality based on addressing the 5As

RE-AIM Outcome EFFECTIVENESS	Total N=100	CME N=53	CME Plus N=47	Significance (p-value)
Patient enrollment (i.e., initiating at least one session) per nurse care coordinator	17.3 (25.3)	14.3 (21.9)	23.9 (31.4)	.241
• Enrollment per nurse care coordinator 3 months post-training	1.4 (3.4)	1 (3.3)	2.3 (3.5)	.189
• Enrollment per nurse care coordinator 3-6 months post-training	2.7 (4.8)	2.3 (4.6)	3.6 (5.1)	.384
• Enrollment per nurse care coordinator 6-12 months post-training	8.1 (13.1)	6.7 (11.8)	11.1 (15.7)	.310
• Enrollment per nurse care coordinator 12-18 months post-training	4.4 (6.6)	3.9 (5.9)	5.4 (8.0)	.497
5As addressed by nurse care coordinator across sessions (1-20) delivered mean %, (SD)	84% (.10)	86% (.09)	81% (.18)	.162
• <i>Assess</i> addressed by nurse care coordinator across sessions (1-20) delivered mean %, (SD)	81% (.13)	86% (.07)	69% (.30)	.011*
• <i>Advise</i> addressed by nurse care coordinator across sessions (1-20) delivered mean %, (SD)	79% (.14)	82% (.08)	67% (.28)	.015*
• <i>Agree</i> addressed by nurse care coordinators across sessions (1, 2, 5, 14, & 20) delivered, mean %, (SD)	73% (.14)	82% (.09)	55% (.31)	.085
• <i>Assist/Arrange</i> addressed by nurse care coordinators across sessions (1-20) delivered, mean %, (SD)	95% (.08)	97% (.05)	91% (.24)	.299
Program sessions completed, mean no., (SD)	6 (5.7)	7 (6.2)	5 (4.9)	.131
Duration of program sessions, mean minutes, (SD)	38 (18.4)	39 (14.4)	35 (24.1)	.477
Length of program engagement, mean days, (SD)	88 (112.5)	98 (122.8)	76 (99.6)	.332

Notes. * $p < .05$

Table 6. Reach of the Healthy Lifestyles clinical weight loss intervention

Individual-Patient Level RE-AIM Outcome	Total All N=780	CME			CME Plus			Test p-value			
		All [1] N=443	Participants [2] N=426	Non- Participants [3] N=17	All [4] N=337	Participants [5] N=322	Non- Participants [6] N=15	[1]- [4] N=780	[2]-[5] N=748	[3]-[6] N=32	[2+5]- [3+6] N=780
Patient Characteristics											
Age, mean years, (SD)	48 (14.3)	49 (14.4)	50 (13.8)	33 (19.7)	47 (14.1)	48 (13.6)	37 (21)	.076	.050*	.609	.000*
Gender, % female	631 81%	366 83%	351 82%	15 88%	265 79%	253 79%	12 80%	.161	.189	.522	.609
Race, no., %								.151	.103	.153	.393
• % Black or African-American	78 10%	54 12%	54 13%	0 0%	21 6%	19 6%	2 13%				
• % White	694 89%	381 86%	364 85%	17 100%	311 92%	299 93%	12 80%				
Ethnicity, no., %	6	4	4	0	2	0	2	.624	.081	.120	.000*
• Hispanic	.8%	.9%	100%	0%	.6%	0%	100%				
Weight Status	n=779	n=443	n=426	n=17	n=336	n=321	n=15	n=779	n=747	n=32	n=779
Body weight, kg	115 (29.5)	115 (29.9)	115 (29.7)	92 (25.6)	116 (29)	116 (28.7)	99.7 (31)	.640	.698	.454	.000*
BMI, mean kg./m ² , (SD)	41 (9.9)	41 (9.7)	41 (9.6)	35 (9.5)	41 (9.1)	41 (9.0)	37 (10.7)	.791	.752	.673	.001*
BMI Classifications								.645	.369	.932	.645
Normal Weight, BMI=18-24.9, no., %	6 .4%	3 .7%	N/A	3 18%	3 .9%	N/A	3 20%				
Overweight, BMI=25-29.9 no., %	59 8%	39 5%	37 9%	2 12%	20 3%	19 6%	1 7%				
Obesity or Obese Class I, BMI=30-34.9, no., %	162 21%	86 11%	85 20%	1 6%	76 10%	75 23%	1 7%				
Severe Obesity or Obese Class II, BMI=35-39.9, no., %	170 22%	100 13%	100 24%	0 0%	70 9%	69 22%	1 7%				
Morbid Obesity or Obese Class III, BMI=40-49.9, no., %	243 31%	132 17%	129 30%	3 18%	111 14%	108 34%	3 20%				

Individual-Patient Level RE-AIM Outcome	Total All N=780	CME			CME Plus			Test p-value			
		All [1] N=443	Participants [2] N=426	Non- Participants [3] N=17	All [4] N=337	Participants [5] N=322	Non- Participants [6] N=15	[1]- [4] N=780	[2]-[5] N=748	[3]-[6] N=32	[2+5]- [3+6] N=780
Super Obesity or Obese Class IV, BMI≥50, no., %	128 16%	77 10%	75 18%	2 12%	51 7%	50 16%	1 7%				
At the 97 th percentile, youth, age-gender specific, no., %	1 .1%	0 0%	N/A	0 0%	1 .1%	N/A	1 7%				
At the 98 th percentile, youth, age-gender specific, no., %	3 .4%	2 .3%	N/A	2 12%	1 .1%	N/A	1 7%				
At the 99 th percentile, youth, age-gender specific, no., %	7 .9%	4 .5%	N/A	4 24%	3 .4%	N/A	3 20%				

Note. * $p < .05$

Table 7. Individual-patient level effectiveness and maintenance of the Healthy Lifestyles clinical weight loss intervention

Individual-Patient Level RE-AIM Outcomes	Total All N=747	CME			CME Plus			Test p-value			
		All [1] N=426	Participants Engaged More than One Session [2] N=335	Participants Engaged Only One Session [3] N=91	All [4] N=321	Participants Engaged More than One Session [5] N=244	Participants Engaged Only One Session [6] N=77	[1]- [4] N=747	[2]-[5] N=579	[3]-[6] N=168	[2+5]- [3+6] N=747
EFFECTIVENESS											
Initial weight, kg., (SD)	116 (29.3)	115 (29.7)	115 (30)	117 (30)	116 (28.7)	117 (28)	116 (32)	.698	.561	.813	.852
<i>1 Month</i>	n=603	n= 351	n=312	n=39	n=252	n=227	n=25	n=603	n=539	n=64	n=603
% initial body weight loss at 1 month, mean %, (SD)	-1.1% (2)	-1.1% (2)	-1.2% (2)	-.20 (1.7)	-1.1% (1.9)	-1.3% (1.8)	.40 (1.9)	.927	.835	.195	.000*
Patients that achieved ≥ 3kg. weight loss at 1 month, no., %	115 15%	72 17%	68 20%	4 4%	43 13%	43 18%	0 0%	.288	.419	.098	.006
Patients that achieved 3-4.99% initial body weight loss at 1 month, no., %	93 12%	55 13%	51 15%	4 4%	38 12%	38 16%	0 0%	.843	.903	.098	.032*
Patients that achieved ≥ 5% initial body weight loss at 1 month, no., %	20 3%	11 3%	11 3%	0 0%	9 3%	9 4%	0 0%	.767	.790	N/A	.117
<i>3 Months</i>	n=557	n=319	n=271	n=48	n=238	n=202	n=36	n=557	n=473	n=84	n=557
% initial body weight loss at 3 months, mean %, (SD)	-1.9% (3.3)	-1.9% (3.3)	-2.1 (3.4)	-.68 (2.2)	-2.0% (3.2)	-2.3% (3.2)	-.18% (2.4)	.881	.653	.331	.000*
Patients that achieved ≥ 3kg. weight loss at 3 months, no., %	202 27%	112 26%	103 31%	9 10%	90 28%	87 36%	3 4%	.511	.267	.177	.000*
Patients that achieved 3-4.99% initial body weight loss at 3 months, no., %	184 25%	102 24%	95 28%	7 8%	82 26%	80 33%	2 3%	.538	.311	.186	.000*
Patients that achieved ≥ 5% initial body weight loss at 3 months, no., %	91 12%	52 12%	50 15%	2 2%	39 12%	38 16%	1 1%	.978	.920	.734	.001*

Individual-Patient Level RE-AIM Outcomes	Total All N=747	CME			CME Plus			Test p-value			
		All [1] N=426	Participants Engaged More than One Session [2] N=335	Participants Engaged Only One Session [3] N=91	All [4] N=321	Participants Engaged More than One Session [5] N=244	Participants Engaged Only One Session [6] N=77	[1]- [4] N=747	[2]-[5] N=579	[3]-[6] N=168	[2+5]- [3+6] N=747
EFFECTIVENESS											
<i>6 Months</i>	n=566	n=322	n=266	n=56	n=244	n=198	n=46	n=566	n=464	n=102	n=566
% initial body weight loss at 6 months, mean %, (SD)	-2.1% (4.7)	-1.8% (4.7)	-2.3% (4.9)	.81% (3.0)	-2.5% (4.7)	-3.2% (4.6)	.7% (3.6)	.088	.051	.865	.000*
Patients that achieved ≥ 3kg. weight loss at 6 months, no., %	213 29%	112 27%	110 33%	2 2%	101 32%	95 39%	6 8%	.108	.155	.077	.000*
Patients that achieved 3-4.99% initial body weight loss at 6 months, no., %	200 27%	108 25%	105 31%	3 3%	92 29%	88 36%	4 5%	.305	.283	.507	.000*
Patients that achieved ≥ 5% initial body weight loss at 6 months, no., %	120 16%	59 14%	59 18%	0 0%	61 19%	59 24%	2 3%	.054	.062	.115	.000*
MAINTENANCE <small>Individual</small>											
<i>12 Months</i>	n=466	n=271	n=229	n=42	n=195	n=160	n=35	n=466	n=389	n=77	n=466
% initial body weight loss at 12 months, mean %, (SD)	-2.3% (6.1)	-2.1% (5.9)	-2.7% (5.9)	.99% (4.3)	-2.4% (6.5)	-3.0% (6.8)	.36% (3.9)	.635	.637	.506	.000*
Patients that achieved ≥ 3kg. weight loss at 12 months, no., %	193 26%	109 26%	104 31%	5 5%	84 26%	75 31%	9 12%	.537	.776	.118	.000*
Patients that achieved 3-4.99% initial body weight loss at 12 months, no., %	178 24%	99 23%	93 28%	6 7%	79 25%	73 30%	6 8%	.383	.325	.731	.000*
Patients that achieved ≥ 5% initial body weight loss at 12 months, no., %	111 15%	61 14%	59 18%	2 1%	50 16%	48 20%	2 3%	.434	.357	.851	.000*

Note. * $p < .05$

Table 8. Setting-level adoption and maintenance of the Healthy Lifestyles clinical weight loss intervention

Organization Level RE-AIM Outcomes	Total All N=37	CME			CME Plus			Test p-value			
		All [1] N=23	Adopters [2] N=16	Non- Adopters [3] N=7	All [4] N=14	Adopters [5] N=12	Non- Adopters [6] N=2	[1]-[4] N=37	[2]-[5] N=28	[3]-[6] N=9	[2+5]- [3+6] N=37
<i>Setting</i> ADOPTION											
Number and proportion of practices, no., %	37 100%	23 62%	16 70%	7 30%	14 38%	12 86%	2 14%	.267	n/a	n/a	.002*
Practice Characteristics											
Total patients, mean no., (SD)	8137 (4870)	7759 (4869)	9433 (4821)	3935 (2070)	8757 (4989)	9357 (5163)	5158 (51.6)	.553	.747	.452	.004*
Weighted panel size, mean no., (SD)	7317 (4691)	7151 (4884)	8684 (4971)	3647 (2251)	7591 (4522)	8046 (4752)	4862 (68)	.786	.641	.491	.010*
Payor Mix											
• Medicaid eligible, % (SD)	8.3% (8.3)	7.6% (8.7)	9.9% (9.7)	2.6% (1.1)	9.3% (7.6)	9.3% (7.8)	9.4% (8.4)	.560	.308	.038*	.081
• Medicare eligible, % (SD)	48% (14.8)	49.5% (14.2)	45.6% (14.2)	58.3% (18.8)	45.5% (16.1)	47.1% (16.7)	35.9% (8.7)	.442	.069	.159	.218
Practice Type											
• Family medicine, no., %	30 81%	18 60%	13 81%	5 71.4%	12 40%	10 83%	2 100%				
• Internal medicine, no., %	4 11%	2 50%	0 0%	2 29%	2 50%	2 17%	0 0%				
• Medical education residency, no., %	3 8%	3 100%	3 19%	0 0%	0 0%	0 0%	0 0%				
Location											
• Region A	14 38%	14 61%	13 81%	1 14%	0 0%	0 0%	0 0%				
• Region B	9 24%	9 39%	3 19%	6 86%	0 0%	0 0%	0 0%				
• Region C	14 38%	0 0%	0 0%	0 0%	14 100%	12 100%	2 100%				

Organization Level RE-AIM Outcomes	Total All N=37	CME			CME Plus			Test p-value			
		All [1] N=23	Adopters [2] N=16	Non- Adopters [3] N=7	All [4] N=14	Adopters [5] N=12	Non- Adopters [6] N=2	[1]-[4] N=37	[2]-[5] N=28	[3]-[6] N=9	[2+5]- [3+6] N=37
ADOPTION											
Practice Staffing											
• Number of nurse care coordinators, mean (SD)	1.3 (.58)	1.3 (.65)	1.5 (.73)	1 (.00)	1.3 (.47)	1.3 (.49)	1 (.00)	.757	.502	n/a	.052
• Full-time nurse care coordinator, no., %	26 70%	18 78%	14 88%	4 57%	8 57%	8 67%	0 0%	.173	.184	.151	.051
• Medical Office Associate, no., %	29 78%	16 70%	10 63%	6 86%	13 93%	12 100%	1 50%	.095	.017*	.284	.960
MAINTENANCE											
Practices reaching patients post-12 months during pilot phase, no., %	28 76%	16 70%	15 94%	1 14%	12 86%	12 100%	0 0%	.087	n/a	n/a	.002*

Note. * $p < .05$

Table 9. Staff -level adoption and maintenance of the Healthy Lifestyles clinical weight loss intervention

Organization Level RE-AIM Outcomes	Total	CME			CME Plus			Test p-value				
		All [1] N=31	Adopters [2] N=19	Non- Adopters [3] N=12	All [4] N=14	Adopters [5] N=14	Non- Adopters [6] N=0	[1]-[4] N=45	[2]-[5] N=23	[3]-[6] N=12	[2+5]- [3+6] N=31	
<i>Staff Level</i> ADOPTION												
Number and proportion of nurse care coordinators, no., %	45 100%	31 69%	19 61%	12 39%	14 31%	14 100%	0 0%	.430	.007*	n/a	.007*	
Staff Characteristics												
Licensure								.593	.746	n/a	.442	
Licensed practical nurse (LPN), no., %	12 27%	9 29%	5 27%	3 21%	3 21%	3 21%	0 0%					
Licensed registered nurse (RN), no., %	33 73%	22 71%	8 67%	11 79%	11 79%	11 0%	0 0%					
Gender, female, no., %	45 100%	31 69%	19 61%	12 39%	14 31%	14 100%	0 0%	n/a	n/a	n/a	n/a	
Chronic care certification, no., %	45 100%	31 69%	19 61%	12 39%	14 31%	14 100%	0 0%	n/a	n/a	n/a	n/a	
Full-time employment, no., %	39 87%	25 81%	15 79%	10 83%	14 31%	14 100%	0 0%	.692	.067	n/a	n/a	
MAINTENANCE <small>Organization</small>												
Nurse care coordinators reaching patients post-12 months during pilot phase, no., %	27 60%	16 52%	16 55%	0 0%	11 79%	11 79%	0 0%	.087	.087	n/a	n/a	

Note. * $p < .05$

Table 10. Common themes, categories, and sample meanings units from nurse care coordinators with high and low program engagement with noted similarities and differences

Themes	Categories	Nurse Care Coordinators with High Program Engagement	Nurse Care Coordinators with Low Program Engagement
Experience Helping Patients with Weight Loss	Role	"My part is to get them motivated, and tell them how much better they are going to feel, and just to keep them pumped up"	"In a lot of ways, we are coaching and encouraging them as we go along"
	Support	"We have to accommodate patients' schedules...if we are more flexible with them, they are more apt to continue"	"Teaching them healthy options, and how to read labels, and things like that"
	<ul style="list-style-type: none"> • Similarities: Identified role as a coach for healthy lifestyle promotion; Stressed a need for patient commitment and motivation • Differences: High engagers emphasized using a patient-centered approach; High engagers discussed instrumental support strategies to keep patients motivated rather than simply providing informational material 		
Motivation to Offer Program	Intention to Deliver	"We have a greater number of obese people in our community. It was exciting that we had something to help guide them"	"My plan was not to use it right away"
	Program Characteristics	"It was all basically right there for you. All you had to do was go and present it to the patient, and go from there"	"I found that it was very overwhelming" "Some parts of it were a little bit difficult for patients to grasp"
	<ul style="list-style-type: none"> • Similarities: Most intended to deliver the program post-training; Need for offering weight loss support was recognized • Differences: High engagers were more likely to value having a structured program; Low engagers were more likely to perceive given program structure and content as a delivery obstacle, and less likely to adapt program to meet patient needs 		
Barriers to Offer Program	Patient	"I do offer to combine session 1 and 2 and session 3 and 4 to help them [patient-financial challenges]"	"Unfortunately, for a lot of my population, they don't even have the monthly funds to get through the month"
	Care Coordinator	"I feel like I have lost other visits, because I have had so many"	"Trying to find enough time to also target this program- there are just a lot of different things that we do"
	<ul style="list-style-type: none"> • Similarities: Reported patients' lack of finances as a significant barrier; Lack of patient readiness was a common roadblock for offering the program • Differences: Low engagers identified the program as overwhelming for patient populations; Low engagers stated difficulty with incorporating the program into their current job duties 		
Recruitment and Referrals	Methods	"My doctors have actually been a great help in referring patients to me"	"I identify through the daily huddle sheet. I've added in BMIs to it. I usually will highlight for the doctors"

Themes	Categories	Nurse Care Coordinators with High Program Engagement	Nurse Care Coordinators with Low Program Engagement
Recruitment and Referrals, cont.	Key Messages	"One thing that I try to promote is that it is teaching them how to eat healthy for the rest of their life"	"I try to stay away from the word diet. I definitely emphasize that it is a healthy lifestyle"
	<ul style="list-style-type: none"> Similarities: A common theme for key recruitment messaging involved an emphasis on lifestyle rather than diet; Daily huddle sheets were an effective recruitment method Differences: High engagers were more likely to advertise the program in their clinics; High engagers performed regular chart reviews and alerted physicians of patients meeting criteria 		
Program Delivery	Format	"I do mostly face-to-face, and occasionally I'll have to do a phone if the patient can't get in the office"	"I have not gotten to the point of feeling comfortable using it yet. But, I've only had limited experience"
	Structure	"I'm following the program"	"Well, I find the duration is way too long to keep people interested and motivated"
	Adaptations	"My Fitness Pal is my favorite for logging food. It is great. It has everything in it"	"We did a group...hard to get them all in the same needs. They were able to give each other some suggestions"
	<ul style="list-style-type: none"> Similarities: Most delivery took place in-person rather than over the phone; Delivery was attempted for couples or small groups Differences: High engagers were more likely to adapt the format and structure to meet patient needs, including promoting My Fitness Pal for mobile-friendly tracking by smartphone users; Level of comfort with the program and its materials impacted delivery for low engagers 		
Patient Retention	Interactions	"I would say that probably a good 75% of my patients keep returning"	"I think there is a huge fall-out. They maybe go up to session 3, some 4 or 5. But after that, they either stop coming"
	Strategies	"We will continue to work with them, as long as they are willing to come in, we will do everything we can to help them"	"Spend a lot of time on the phone calling them"
	<ul style="list-style-type: none"> Similarities: Drop-out was experienced by both high and low engagers; Phone calls were the most common form of patient contact Differences: High-engagers report long-term interaction and have had patients complete program in entirety; High engagers use multiple strategies (i.e., phone, letter, MyChart, rewards) for retention 		
Needed Resources	Technology	"I wish we had an app that would work, that we could just develop a Healthy Lifestyles app"	N/A
	Supplementary Aids	"Portion plates-I have a lot of patients that say, I do not want to measure that, weight that, or think about that"	"I would suggest recipes, something simple, maybe two or three ingredients, that would give them an idea of things that they could eat"

Themes	Categories	Nurse Care Coordinators with High Program Engagement	Nurse Care Coordinators with Low Program Engagement
Needed Resources, cont.	Training	"It's very difficult to be in the room with them..[some strategies for those who are doing couple sessions to try to help diffuse any type of negative talk between the two]"	"I had a lapse from the training to when I started, so maybe just a little refresher or quick course or something"
		<ul style="list-style-type: none"> • Similarities: Additional resources and tools were identified to support recruitment and program delivery • Differences: Needed resources identified by high engagers related to more personalized levels of support; Low engagers requested resources that high engagers had already taken the initiative to incorporate into the program (i.e., clinic fliers, and recipes) 	

Table 11. Common themes, categories, and illustrative quotes from nurse care coordinators' patient chart notes

Themes	Categories	Nurse Care Coordinators' Patient Chart Notes
Program Processes	Referral	<ul style="list-style-type: none"> Met with patient per request of Dr.-could benefit from healthy lifestyle counseling. He is morbidly obese with HTN, DM, & cholesterol.
	Scheduling	<ul style="list-style-type: none"> Call placed to patient. I explained what Healthy Lifestyle program consists of. Patient would like to try it and has scheduled an appt. Met patient right at the end of his office visit.
	Structure	<ul style="list-style-type: none"> Completed the 20 sessions of the Healthy Lifestyle program. Patient was given all healthy lifestyle session hand-outs and will call with questions or concerns.
	Format	<ul style="list-style-type: none"> Plan to meet in-person, daughter may join. She has been following the program over the phone with me for several months as it is difficult for her to come into the office due to how far she lives from the clinic.
	Follow-up	<ul style="list-style-type: none"> Tried to reach patient again to follow up on Healthy Lifestyle session no show. Left voice mail message. Patient will call/send MyChart message to make next appointment to discuss progress towards goals and to continue education. Patient did not show for last sessions, but reconnected at 3-month physician follow up.
Motivation for Weight Loss	Overall Health	<ul style="list-style-type: none"> Patient states she is the heaviest she has ever been and would just like to be healthier and feel better. Patient wants to feel better, breathe better, sleep better, and have more energy for her grandchildren.
	Chronic Disease Management	<ul style="list-style-type: none"> He has HTN, pre-diabetes, and high cholesterol and knows that losing weight will help to manage these conditions. Patient had 2 stents placed 2 weeks ago. Her cardiologist would like her to lose 20 lbs. in the next 6 months. She is an insulin dependent diabetic and is followed by endocrinology--she would like to use less medications for her treatment.
	Pain Reduction	<ul style="list-style-type: none"> States she has a lot of pain from arthritis and knows that her weight contributes to this pain.
	Appearance	<ul style="list-style-type: none"> Patient states she just wants to look better. She feels very self-conscious of herself since gaining weight over the past few years.
	Surgical	<ul style="list-style-type: none"> She is considering bariatric surgery to help with her obesity and states that her insurance requires a 1 year medically supervised weight loss plan before they will approve. Patient reports she needs to lose 25 pounds to get her knee fixed.
Barriers Barriers, cont.	Financial	<ul style="list-style-type: none"> Patient voiced concern about the inability to pay. She cannot afford a gym membership, and is concerned about the cost of healthy foods.

Themes	Categories	Nurse Care Coordinators' Patient Chart Notes
	Expectations	<ul style="list-style-type: none"> This patient feels overwhelmed with the amount of weight she feels she needs to lose. The scale is not showing a weight loss and patient is frustrated with progress.
	Family	<ul style="list-style-type: none"> Husband's diet is unhealthy and she struggles to follow a different diet than him. She states there continues to be "drama" in her home which is making it difficult to follow the Healthy Lifestyle program.
	Stress	<ul style="list-style-type: none"> Patient reports significant stress in her life currently. She is the sole provider for the household, she is finishing school and trying to find a new job, she is the main caretaker of the home, has a young son to raise and a husband who is not in the greatest of health.
	Emotional Eating	<ul style="list-style-type: none"> She is very discouraged with herself at this time and states struggles with emotional eating which is generally related to her current weight.
	Physical or Mental Health	<ul style="list-style-type: none"> She tried to go walking at the mall recently, but it caused foot pain. Patient is struggling with anxiety and depression.
Facilitators	Dietary Change	<ul style="list-style-type: none"> She is doing very well, diet is being well controlled with smaller portion sizes and limits on regular soda.
	Self-Monitoring	<ul style="list-style-type: none"> She is reporting her weight through MyChart each week. She tracks her food and pays close attention to calories.
	Activity	<ul style="list-style-type: none"> Weight is down - she has continued to exercise almost everyday (usually 6 days a week) on her treadmill for at least 1 hour.
	Support	<ul style="list-style-type: none"> She is with her husband today and her with this program by doing it with her as he needs to lose weight as well.
	Pharmacological	<ul style="list-style-type: none"> She is taking Wellbutrin and feels like this is also helping to curb her appetite. Patient recently saw PCP and was provided Rx for Qysemia. The Phentermine has decreased her cravings considerably. No known side effects from med.
	Weight Loss	<ul style="list-style-type: none"> She has lost 14 lbs. and is wearing clothes that she has not been able to. She is energized and excited about her progress and future! She continues to follow diet as instructed and has lost 40 lbs. since beginning the program. She is very positive with the results. Total weight loss through today is 19 pounds! Per patient, PCP has stopped one of her blood pressure medications.
	Dietary Change	<ul style="list-style-type: none"> She is stating that she has reduced her intake, smaller portions and cut out Kool Aid. She is reading food labels consistently, drinking more water, making conscious food choices taking into account calorie, fat, and sugars.

Themes	Categories	Nurse Care Coordinators' Patient Chart Notes
Patient Outcomes	Physical Activity	<ul style="list-style-type: none"> • Patient recently joined the YMCA. She tries to exercise 3 times a week including cardio and resistance training. She also swims. • Patient has been walking two miles per day.
	Maintenance	<ul style="list-style-type: none"> • Patient is slowly gaining the weight she had previously lost. At one time, she was down almost 18 lbs.; currently she is down 7.4 lbs. since starting the program 5 months ago. • Patient and I discussed how patient plans to maintain the diet and exercise plan as this is just not for weight loss but for long-term lifestyle. Patient reports; "I am going to keep doing it because I feel better and I will stick with it".
Program Adaptations	Structure	<ul style="list-style-type: none"> • Session 1 and 2 conducted together. • Changed follow-up from 1 to 2 weeks.
	Weight Checks	<ul style="list-style-type: none"> • Patient in for weight check for healthy lifestyle program. She already has all of the sessions printed and in a notebook. • She will follow the sessions and call me as the sessions are due and come in for weight checks. • Patient does not have scale at home, but is going to come in the office to weigh.
	Resources	<ul style="list-style-type: none"> • Discussed calorie counting today and discussed some ways to keep track such as My Fitness Pal app and patient is also considering a Fit Bit • Patient admits to having some hip pain and asked for at-home exercises to perform. With using the teach back method she performed a lower body exercise that can strengthen her hips. • Provided patient with healthy recipes.

Figure 1. Sample regional action plan from CME Plus training

Regional Nurse Care Coordinator Action Plan to Support Patient Weight Loss

Why do we think it is important to help our patients lose weight?

- *To improve the health of our patients and the community*
- *To help prevent and manage chronic diseases, such as diabetes.*
- *To improve patients' quality of life and happiness*
- *To improve patients' self-confidence*
- *To provide motivation and accountability for patients to help them reach their health goals*

Our plan to engage patients in the Healthy Lifestyle program will be:

- *Recruit 13 patients over the next month*
- *Recruit 40 patients over the next 3 months*
- *Recruit 79 patients over the next 6 months*
- *Recruit 157 patients over the next 12 months*

What are our 3 biggest obstacles that could get in the way of achieving our goal?

1. *Time—both content to fit in 30-45 minute sessions and provider interruptions during sessions*
2. *Provider support*
3. *Patient commitment*

What can we do to get past these obstacles? (Write at least 3 strategies for each obstacle.)

Time:

1. *Schedule sessions during time when providers are not seeing patients (e.g., 7-145)*
2. *Create a block of protected slots on schedule*
3. *Enlist support of medical office associate with scheduling and appointment reminder calls*

Provider Support:

1. *Use Epic to identify patients and send messages to physicians suggesting program referral*
2. *Use Huddle meetings or weekly provider meetings to provide education and share program fliers*
3. *Share weight loss success stories with providers*
4. *Highlight role of changes in weight and related outcomes on score card indicators*

Patient Commitment:

1. *Use program commitment contract*
2. *Write BMI on daily patient schedule*
3. *Send patient a letter if session is missed*
4. *Schedule the sessions when it is convenient for patient*

What tools do we have that can help us meet our goals?

People who will support us: *Other nurse care coordinators, senior nurse care coordinator leadership, weight loss program partners*

Materials that can help: *Workbook, lesson plans, call scripts, program evaluations, recipes, handouts for budget shopping*

Resources that we can use: *Clinic space, appendices from workbook, portion plate*

Figure 2. Sample personal action plan from CME Plus training

My Nurse Care Coordinator Action Plan to Support Patient Weight Loss

Name: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Email: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Why do you think it is important to help our patients lose weight?

- *improve health and chronic disease outcomes for patients*
- *decrease risk for future complications*

How many of your patients have expressed an interest in weight loss before? Many

How many of your patients have you worked with to help lose weight? 5

My plan to engage patients in the Healthy Lifestyle program will be:

- I will recruit 2 patients over the next month.
- I will recruit 3 patients over the next 3 months
- I will recruit 5 patients over the next 6 months.
- I will recruit 10 patients over the next 12 months.

Think about the 2 biggest obstacles that could get in the way of achieving our goal?

1. *Time- these visits take plenty of time and it will be hard to work in too many with the schedule I already have*
2. *Patient follow-through with the program*

What can you do to get past these obstacles? (Write 3 strategies for each obstacle.)

Time:

1. *Don't overbook my schedule*
2. *Target patients at most risk*
3. *Devote specific time on my schedule*

Patient Follow-through:

1. *Call patient between visits*
2. *Help patient keep a positive attitude*
3. *Celebrate small successes*

What tools do you have that can help you meet your goals?

People who will support us: *Medical office associate, physician, senior nurse care coordinator*

Materials that can help: *Healthy lifestyle workbook, lesson plans*

Resources that we can use: *Websites, recipes*

Section 3 – Summary Findings and Recommendations

Chapter 7: Synthesis of Carilion Implementation Trials

The overall purpose of this dissertation was to develop a greater understanding of how an integrated research-practice partnership approach facilitates and sustains evidence-based lifestyle management strategies across a healthcare system to treat obesity among patients and employees. As an exemplar, Carilion's implementation trials demonstrated how the integrated research-practice approach serves as a valuable mechanism for advancing the translation of evidence-based strategies into the practice workflow of a rapidly, transforming healthcare system. Lessons learned from the aims and outcomes of this dissertation support the use of an integrated-research practice partnership approach as a solution for overcoming gaps in lifestyle obesity treatment. In addition, findings from a RE-AIM evaluation of each trial produced highly relevant and actionable evidence to inform the future development of a comprehensive system of evidence-based care for Carilion's patients and employees.

Implementation Context and Processes

Guided systematically by the Integrated Research-Practice Partnership Participatory model (Chapter 1, Figure 2), the Carilion partnership identified the implementation context and processes used for the integration of each evidence-based strategy tested by the trials featured in this dissertation. As a summary tool, Table 1 through Table 5 highlights the specific participatory steps used in each trial, e.g., My Own Health Report (MOHR), FIT Rx 90-1.0, FIT Rx 90-2.0, and Carilion Healthy Lifestyles.

Participatory Steps

Table 1 shows the collaborative, participatory structures, including composition and roles, involved in each research-practice team's processes. All trials involved shared leadership

and included the practice team in delivery of the strategy. Formal partnership meetings ranged from bi-weekly to quarterly encounters. However, informal interactions, either in-person, or by phone, email, or text, occurred more frequently at two-levels: 1) leadership (i.e., Principal Investigators, Medical Director, and healthcare system directors), and 2) delivery team (i.e., study coordinator, research assistants, and frontline practice staff). The interactions provided opportunities for additional planning, monitoring, sharing successes, and trouble-shooting implementation processes as needed. Except for the MOHR trial, all implementation trials were developed, implemented, and evaluated based on the expertise, interests, and existing capacity of local researchers, administrators, and staff.

Table 2 outlines the health problems prioritized in each trial, the selected target population for intervention, and proposed research questions. All trials were framed to inform practice decision-making on strategies to improve lifestyle obesity management for weight loss or weight loss maintenance. Uniquely, the MOHR trial focused heavily on assessment, collaborative goal-setting, and referrals for diet and exercise to support lifestyle change. Target populations across trials were common in their broad inclusion criteria of reaching primary care patients or healthcare employees at risk for overweight and obesity (e.g., $\text{BMI} \geq 25 \text{ kg/m}^2$ or $\text{BMI} \geq 30 \text{ kg/m}^2$). As trial iterations evolved during the partnership, eligibility criteria became slightly more restrictive to focus greater on populations with the highest risk and cost to the system. For instance, criteria changed to $\text{BMI} \geq 30 \text{ kg/m}^2$ with co-morbidities related to a poor metabolic profile, $\text{BMI} \geq 35 \text{ kg/m}^2$, or $\text{BMI} \geq 40 \text{ kg/m}^2$. This evolution in target prioritization aligns with the population health management approach and supports a healthcare system's focus on achieving the triple aim of 1) improving the patient experience of care, 2) improving the

health of populations, and 3) reducing the per capita cost of healthcare (Berwick, Nolan, & Whittington, 2008).

Research questions generated from each team included input from both research and practice stakeholders and were characteristic of a system at the formative stage of systematically treating obesity. All questions were related to the feasibility of integrating evidence-based strategies into workflows and/or already existing programs being delivered by practice staff. In addition, questions aimed to comparatively assess effectiveness of weight loss interventions in clinical practice (Appel et al., 2011). Reflective of the implementation science experts involved in the partnership, questions were multi-level and involved assessment of contextual factors to help identify, understand, operationalize, and evaluate key phenomenon related to the uptake of strategies by providers within the Carilion system (Tabak et al., 2012). The FIT Rx 90-1.0 trial focused on the role of employee preference and shared decision-making in questioning. Whereas, the MOHR and Carilion Healthy Lifestyles trials posed questions eliciting feedback regarding clinicians' experience with implementation. Across trials, research questions echoed emerging themes in healthcare transformation, including a focus on patient-reported outcomes (Estabrooks et al., 2012), patient-centered care (Epstein & Street, 2011), and an expansion of the triple aims to include a quadruple aim focused on provider and staff experience (Bodenheimer & Sinsky, 2014).

Table 3 documents the implementation strategies selected by each trial for integrating an evidence-based principle into practice. All strategies were based on the most recent clinical guidelines for obesity, the 5As (*Assess, Advise, Agree, Assist, and Arrange*) framework, and critical elements adapted from the Diabetes Prevention Program (DPP) lifestyle intervention (Jensen et al., 2014; Knowler et al., 2012; Moyer, 2012). The duration and dose of selected

strategies varied widely, from a brief encounter in the MOHR trial to a 12-month structured lifestyle program with a core and post-core phase in the Carilion Healthy Lifestyles trial. Strong influences for strategy decision-making by practice included costs, practicality, and low staff burden. Research partners placed a greater emphasis on scalability and sustainability potential in selection. Ultimately, being able to fit within the existing capacity of both research and practice teams, along with the infrastructure of the system, was important.

Table 4 outlines how each research-practice team adapted their selected implementation strategies to fit with evidence-based principles, the healthcare system, and target population. Across trials, the implementation strategies were adapted and packaged for delivery based on the capacity and available resources of the research-practice partnership. All strategies involved engagement of an inter-professional delivery team and offered a structure for delivery that involved a variety of formats, including one-to-one or group; in-person, phone, email, or text; and workshops, consultation, or educational materials. Common within the menu of strategies were action planning, goal-setting, and mechanisms for ongoing staff, employee, and patient feedback. The MOHR trial demonstrated the rapid, iterative nature of strategy adaptation based on firsthand experiences within the context of local practice. Appendix 7.1. depicts the adaptations made by the teams with program session schedules across trials in comparison to the original DPP program.

Table 5 details the research designs and level of review from the Carilion Institutional Review Board for each trial. Guided by the RE-AIM framework (Glasgow et al., 1999), all trials were pragmatic, used a mixed-methods approach, and included multi-level assessments of costs and contextual factors. Hypotheses and practical study designs were formulated based on the most relevant information needed to inform decision-making (Tunis, Stryer, & Clancy, 2003).

Designs evolved in complexity from a case study to a randomized, type 3 hybrid effectiveness-implementation trial (Curran et al., 2012). Standard care served as a control condition when feasible to assess. Two trials (e.g., MOHR and FIT Rx 90-1.0) were approved under expedited review for survey methodology designed to develop or contribute to generalizable knowledge and the others were deemed quality improvement focused on informing practice improvements.

Broader Policy, Community, and Cultural

Overall, each trial was set within a broader context of a national transformation in healthcare culture, priorities, and financial support (Schill et al., 2015; Whittington et al., 2015). Due to an aging population, increased prevalence of chronic diseases, and escalating healthcare costs, a major shift was occurring in the U.S. healthcare delivery approach (Schill & Malani, 2015). There was a national call for healthcare systems to fundamentally transform from an acute, sick-care system to a non-acute, system that promotes health and cultivates a *culture of wellness* (Cosgrove, 2013). Increased insurance coverage, new models of healthcare delivery, expanded workforces, and different payment systems were being explored to make the change (O'Donnell et al., 2015; Schill et al., 2015). The Patient Protection and Affordable Care Act (2010) supported efforts with policy mandates and demonstration projects (Shaw et al., 2014). The Chronic Care Model, accountable care organizations, and the patient-centered medical home were advocated as delivery frameworks to improve health outcomes (Arend et al., 2012; Shortell et al., 2008; Wagener et al., 2014).

The Carilion system was active in national change endeavors and locally was giving increased attention to high-risk patient and employee populations, advancements in technologies, and ways to proactively offer preventive care and treatment to address its communities' poorest health outcomes and underlying behaviors (i.e., obesity, poor nutrition,

and a lack of physical activity). Creating a service culture that promoted collaborative, team-based, mutually accountable, and patient-centered care were priorities (Englander et al., 2013; Kirch, 2016). Furthermore, attention to productivity, sustainability, being cost-effective, and examining comparative effectiveness were being promoted to reduce costs (O'Donnell, Anand, Ganser, & Wexler, 2015; Steenkamer, Drewes, Heijink, Baan, & Struijs, 2016). The integrated research-practice partnership approach aligned with the attitudes of this desired, but challenging, cultural change and offered a timely, supportive mechanism for Carilion to engage in rigorously testing delivery models and integrating evidence-based strategies for patient-centered, cost-conscious obesity care (Glasgow et al., 2012; Johnson et al., 2014).

Implementation Outcomes

For assessment of implementation outcomes, the Carilion partnership used the RE-AIM framework as an embedded tool within the Integrated Research-Practice Partnership Participatory model (Chapter 1, Figure 2) to systematically guide its evaluation and decision-making processes for each trial. Evaluation outcomes were summarized and displayed for comparison by dimension, i.e., Table 6 (*Reach*), Table 7 (*Effectiveness*), Table 8 (*Adoption and Implementation*), and Table 9 (*Maintenance*).

RE-AIM Dimensions Summary

Across featured trials, the implementation strategies tested by each research-practice project demonstrated a strong potential to reach a high proportion of at-risk patients and healthcare employees. Each research-practice team was able to meet its pilot trial reach goal, except for the FIT Rx 90-2.0 recruitment effort at its site outside of the main service region (72%). Direct invitation by a provider on the delivery team either face-to-face, by phone, or

email increased participation. Representative of practice panel populations, the healthcare employment sector, and western Virginia demographics, program enrollees were predominantly female, white, and had a mean BMI of at least an obesity Class II classification ($BMI \geq 35 \text{ kg/m}^2$). Overall, participants reported a high number of poor health behaviors and psychosocial issues. Retention varied widely between patient and healthcare employee trials for core and post-core phases. Program non-completers were more likely to report challenges with scheduling, family-work commitments, and medical conditions.

The adapted implementation strategies tested in each trial showed promising potential to effectively support patients and healthcare employees in achieving a modest, clinically significant weight loss ($\geq 3\text{-}5\%$ initial body weight) without unintended negative consequences. Weight loss at program completion was favorable to results from other large-scale DPP translational studies, although wide variation existed (Aziz et al., 2015; Carroll et al., 2015; Garvin, Marion, Narsavage, & Finnegan, 2015). As shown in systematic reviews of real-world DPP adapted programs (Ali et al., 2012; Aziz et al., 2015; Mudaliar et al., 2016), participants' adherence to critical elements of intensive behavioral therapy (i.e., goal-setting, self-monitoring, problem-solving) and level of engagement in intervention components predicted more robust weight loss outcomes. However, even with low intensity intervention (2-4 contacts), some amount of weight loss and change in dietary and physical activity behaviors was able to be achieved, which from a systems' population health perspective may still have positive impact in chronic disease prevention and management (Aziz et al., 2015).

At the organizational-level, each of the implementation strategies tested had reasonable adoption among both settings and staff exposed to intervention components during the pilot trials. Packaged implementation delivery bundles developed by the research-practice team,

including ready-to-deliver patient education materials, lesson plans, and scripts, were noted as positive contributors to uptake. In addition, training and ongoing technical assistance offered by the research team and senior practice leaders were reported to accelerate uptake for all levels of staff within the system (i.e., physicians, residents, registered nurses, licensed practical nurses, fitness managers, personal trainers, registered dietitians, and health educators) to initiate evidence-based, lifestyle obesity treatment. Optimization of technology, including greater integration of implementation strategies into the existing delivery infrastructure of the EHR and patient portal, may facilitate greater adoption and offer improved scalability of strategies across the healthcare system.

The strategies selected and adapted for testing across trials were able to be successfully implemented as intended at a reasonable cost. Except for the MOHR trial which required the engagement of nursing staff from the system's centralized call center, all strategies were able to be delivered with the staff initially selected as delivery agents. Overall, implementation fidelity was strong, with deviations from protocol typically occurring due to tailoring to patient needs, time constraints, and scheduling conflicts. Again, like the adoption dimension, investing in additional technological tools is seen as a potential means to support ongoing consistency of implementation quality, reduce costly staff time burdens, and promote improved scalability.

At the individual and organizational-level, the tested implementation strategies exhibited potential to support maintenance of clinically significant weight loss ($\geq 3\text{-}5\%$ initial body weight) and, except for the MOHR trial, were sustained by the Carilion system. Similar to short-term outcomes, the degree to which weight loss was maintained by strategy varied based on adherence and retention.

Decision-Making and Translational Solution

Based on the RE-AIM evaluation outcomes, Table 10 highlights the partnership's decision-making results and the degree to which each tested implementation strategy was deemed by the partnership as a potential translational solution for delivering evidence-based obesity care to Carilion patients and healthcare employees. Decision-making involved the partnership determining if: 1) a new strategy was needed for the target population, 2) additional adaptations should be made and tested, or 3) the strategy was ready for integration. Choice with shared decision-making, behavioral strategies, action planning and consultation, and delivery of the Carilion Healthy Lifestyles program by nurse care coordinators were ready for integration. Strategies were integrated into existing services and continued beyond their initial pilot trial periods.

Finally, Table 11 provides an overall summary of criteria considered by the research-practice partnership for determining if a strategy had potential to be a translational solution for implementation and sustainability of evidence-based lifestyle obesity management within the system. Each trial's strategy, criteria consideration checklist, and priority perspective for initiation are displayed. Criteria included: 1) feasibility of implementation as designed, 2) maintenance of critical elements of the evidence-based principles of comprehensive lifestyle obesity management (i.e., diet, physical activity, and intensive behavioral therapy), 3) achievement of clinically, meaningful weight loss, and 4) sustainability of strategy within the system. An interesting finding when comparing the criteria checklist versus the perspective initiating the trial was the positive role of a shared priority perspective. All strategies were sustained, except for the assessment, prioritization, and engagement tool that was initiated from a research priority perspective in the MOHR trial.

Future Recommendations

Integrated Research-Practice Partnership

From the series of Carilion implementation trials conducted from 2013-2016, this dissertation generated several areas for future investigation on the integrated research-practice partnership approach. Studying the specific processes involved with the formation and execution of a collaborative agreement, and the degree to which processes align with the best practices of team science, may advance partnership impact. Expanding stakeholder engagement within the partnership to include formal mechanisms for more frontline staff and end-users (i.e., patients and healthcare employees) to participate in the prioritization of health problems, development of research questions, and testing of implementation strategies offers another level for exploring participatory processes. The association between a shared priority perspective and the degree to which translation and sustainability of a strategy occurs with a healthcare system needs further testing. Finally, designing larger, pragmatic, randomized, multi-system trials that empirically test the comparative effectiveness of implementing evidence-based strategies with and without use of the integrated research-practice partnerships would strengthen the science-base for the approach.

Lifestyle Obesity Management

Future areas for research-practice action were identified within this study to inform the development of a Carilion system of obesity care. To begin, recognizing the need to address the full continuum of obesity care from prevention to post-bariatric surgery was evident. Each of the 5As Framework processes could be further leveraged and enhanced by the partnership to accomplish this goal with both patients and healthcare employees. Engaging auxiliary members of the care team and optimizing technology may support more comprehensive assessment, goal-

setting, and follow-up. Integration of obesity care plans into the EHR and MyChart patient portal offer opportunities for improved team-based care delivery, engagement, linkages to community support resources, and ongoing monitoring and evaluation. In accordance with the tenets of population health management, development of a more intensive medical weight loss program for severe obesity that would be delivered by a highly skilled interdisciplinary team (i.e., bariatric physician, psychologist, registered dietician, exercise physiologist, and nurse care coordinator) with greater physician oversight and structured patient interaction is needed. Combining lifestyle intervention with pharmacological therapy may be explored. Developing financial models, including identification of medical billing and coding procedures, are critical to support and sustain the obesity care system.

The evidence-based strategies shown to have promising potential as a translational solution (e.g., choice with shared decision-making, behavioral strategies, and action planning with consultation) in this study need to be more thoroughly evaluated for long-term impact. The degree to which strategies support improved obesity-associated, cardio-metabolic risk factors, i.e., hemoglobin A1c (HbA1c), blood pressure (BP), and lipid profiles, are areas for future research. In addition, outcomes such as quality of life, healthcare utilization costs, productivity, and satisfaction are of partnership interest. In conclusion, engaging interdisciplinary obesity researchers, healthcare system administrators, and practice delivery staff to collaboratively conduct ongoing, rapid learning trials offers promising potential to continue the advancement of delivering evidence-based lifestyle obesity treatment throughout the Carilion system.

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Table 1. Collaborative agreement on participatory structure and roles for Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice Shared Decision-Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
<p>Integrated Research-Practice Partnership</p> <ul style="list-style-type: none"> • Collaborative, participatory structure • Roles 	<p>Structure Research</p> <ul style="list-style-type: none"> • Principal Investigator • Study Coordinator • Undergraduate/ Graduate Research Assistants <p>Practice</p> <ul style="list-style-type: none"> • Medical Director • Practice Manager • Physician Faculty and Residents • Nurses • Medical Office Associates • Call Center Nurse Operators • Clinical Research Coordinator <p>Roles</p> <ul style="list-style-type: none"> • Shared leadership • Practice team led delivery and workflow integration • Research team led evaluation and served as liaison with national team • Biweekly national learning collaborative calls • Formal health system internship for graduate students 	<p>Structure Research</p> <ul style="list-style-type: none"> • Principal Investigator • Behavioral Scientist • Health Economist • Nutrition-RD Researchers • Study Coordinator • Undergraduate/ Graduate Research Assistants <p>Practice</p> <ul style="list-style-type: none"> • Medical Director • Vice President of Wellness • Wellness Development Director • Fitness Managers <p>Roles</p> <ul style="list-style-type: none"> • Shared leadership • Practice staff co-facilitated group sessions • Research team led delivery and evaluation • Formal health system internships for graduate students 	<p>Structure Research</p> <ul style="list-style-type: none"> • Principal Investigator • Behavioral Scientist • Nutrition-RD Researchers • Study Coordinator • Undergraduate/ Graduate Research Assistants • DXA Technologist <p>Practice</p> <ul style="list-style-type: none"> • Medical Director • Vice President of Wellness • Wellness Development Director • Employee Wellness Manager • Fitness Managers • Registered Dietician • Personal Trainers • Phlebotomist <p>Roles</p> <ul style="list-style-type: none"> • Shared leadership • Shared delivery and evaluation • Monthly meetings 	<p>Structure Research</p> <ul style="list-style-type: none"> • Principal Investigator • Behavioral Scientist • Study Coordinator • Graduate Research Assistants <p>Practice</p> <ul style="list-style-type: none"> • Medical Director • Senior Director of Ambulatory Care • Senior Care Coordinators • Nurse Care Coordinators <p>Roles</p> <ul style="list-style-type: none"> • Shared leadership • Practice team led delivery • Research provided training and ongoing technical assistance • Shared evaluation • Biweekly to quarterly meetings

Table 2. Problem prioritization and research questions for Carilion patient and healthcare employee trials

Components	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Problem Prioritization <ul style="list-style-type: none"> • <i>Target population</i> 	<p>Priority problem</p> <ul style="list-style-type: none"> • Obesity; Addressing behavioral and psychosocial patient-reported outcomes in primary care (i.e., BMI, diet, and exercise) <p>Target population</p> <ul style="list-style-type: none"> • Carilion Family Medicine adult patients visiting practice for chronic disease/wellness visit; 18-75 years • Carilion primary care providers 	<p>Priority problem</p> <ul style="list-style-type: none"> • Obesity; Weight loss maintenance <p>Target population</p> <ul style="list-style-type: none"> • Carilion healthcare employees (BMI ≥30) 	<p>Priority problem</p> <ul style="list-style-type: none"> • Obesity; Weight loss and Weight loss maintenance <p>Target population</p> <ul style="list-style-type: none"> • Carilion healthcare employees (BMI ≥30 with co-morbidity, or BMI≥35) 	<p>Priority problem</p> <ul style="list-style-type: none"> • Overweight and obesity; Weight loss and weight loss maintenance <p>Target population</p> <ul style="list-style-type: none"> • Carilion Family Medicine adult patients (BMI≥25) • Carilion nurse care coordinators
Research Question(s)	<ul style="list-style-type: none"> • To what extent is it feasible to integrate the MOHR assessment, prioritization, and engagement tool into primary care practice workflow to support obesity care? • How do patient and provider-reports of 1) screening, 2) collaborative goal-setting, 3) referrals, and 4) perceptions of positive, behavior change related to diet and exercise compare after fielding the tool? 	<ul style="list-style-type: none"> • To what extent did FIT Rx 90 employee participants maintain weight loss? • What maintenance components are feasible, preferred, and effective for supporting weight loss maintenance? • What is the role of choice and shared decision-making (SDM) of program components on the effectiveness of weight loss maintenance support? 	<ul style="list-style-type: none"> • How does the addition of an evidence-based behavioral component increase the effectiveness of the FIT Rx 90 weight loss program? • What is the feasibility of the FIT Rx 90 practice team delivering a behavioral component? 	<ul style="list-style-type: none"> • What is the utility of action planning and consultation as an implementation facilitation strategy for increasing program uptake and patient engagement? • What is the feasibility of nurse care coordinators delivering an intensive, behavioral-based weight loss program within Carilion medical homes? • To what extent do Carilion Healthy Lifestyles patient participants lose and maintain ≥3-5% initial body weight?

Table 3. Strategy selection and decision-making influences for Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Strategy Selection <ul style="list-style-type: none"> <i>Decision-making influences</i> 	<ul style="list-style-type: none"> MOHR tool topics selected by expert consensus panel considering population health management goals, along with USPSTF and National Prevention Strategy recommendations Question selection for MOHR tool required brief, practical, relevant, and actionable measures for practice MOHR structure based on 5As framework <p>Decision-making</p> <ul style="list-style-type: none"> Integration strategies considerate of patient and staff burden Concerns about delivery time Need for integration into existing workflows at Carilion medical residency practice sites 	<ul style="list-style-type: none"> Behavioral-based 6-months maintenance program developed for support after existing, practitioner-developed FIT Rx 90 weight loss program Based on critical elements of the DPP, 5As framework, and behavioral choice theory Incorporated best practices of shared decision-making <p>Decision-making</p> <ul style="list-style-type: none"> Needed to be practical, with scalability and sustainability potential within system 	<ul style="list-style-type: none"> Behavioral component added to standard care 3 months FIT Rx 90 weight loss program Based on critical elements of the DPP, 5As framework, American College of Sports Medicine and AHA/ACC/TOS guidelines for obesity <p>Decision-making</p> <p>Needed to be practical and low-cost for delivery within system</p>	<ul style="list-style-type: none"> One-to-one 12-month lifestyle program for weight loss and weight loss maintenance delivered by nurse care coordinators Based on critical elements of DPP, 5As framework, and CMS reimbursement guidelines for delivery structure <p>Decision-making</p> <ul style="list-style-type: none"> Practice expressed need for patient weight loss support for population health management of chronic disease Program needed to fit within practice settings and existing services offered by nurse care coordinators Tools needed to offer structure and be ready-for-delivery by nurse care coordinators

Notes. 5As (Assess, Advise, Agree, Assist, and Arrange); CMS-Centers for Medicare and Medicaid Services; DPP-Diabetes Prevention Program; MOHR-My Own Health Report; USPSTF-United States Preventive Services Task Force

Table 4. Strategy adaptation for fit within evidence-based principles, system, and target population for Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Strategy Adaptation	<p>Early Site Strategy 1</p> <ul style="list-style-type: none"> • Patients mailed letter to complete MOHR on the web 2 weeks before appointment • MOA offered to complete MOHR on appointment reminder calls • Patients offered to completed MOHR at In-office computer kiosk <p>Strategy 2</p> <ul style="list-style-type: none"> • Carilion Direct nurse operators called patients and asked MOHR questions over the phone 1 week before visit <p>Delayed Site Strategy 1</p> <ul style="list-style-type: none"> • MOA invited patients to visit web or come 15 minutes early to complete MOHR at in-office computer kiosk on appointment reminder calls <p>Strategy 2</p> <ul style="list-style-type: none"> • Carilion Direct called patients and asked MOHR questions over the phone 1 week before visit 	<p>Standard</p> <ul style="list-style-type: none"> • 24 weekly motivational messages by email/text • 24 weekly self-reported weight by email/text • 3 bi-monthly group classes led by fitness managers • 9 phone support sessions (6 bi-weekly, 3 monthly) led by research assistants <p>Standard with Choice-SDM</p> <ul style="list-style-type: none"> • Employees chose preferred, adapted strategies using SDM selection processes 	<p>FIT Rx 90</p> <ul style="list-style-type: none"> • Fitness consultation • 6 one-to-one personal training sessions (1 hour) or 12 sessions (30 min.) • 5 group nutrition sessions • Optional DXA scan for body composition assessment <p>FIT Rx 90 Plus</p> <ul style="list-style-type: none"> • Action plan • Target weight chart • 12 session healthy lifestyle workbook • 12 week online tracking survey with teach-back questions • 12 weekly emails from fitness manager • Progress reports 	<p>Implementation Strategy</p> <p>CME</p> <ul style="list-style-type: none"> • Workshop; 2 ½ hours training session for nurse care coordinators with behavioral rehearsal-session role plays • Facilitator materials; lesson plans and phone scripts, teach-back questions, EHR Smartphrase templates • Patient education materials; workbook, action plan, contract, and tracking logs <p>CME Plus</p> <ul style="list-style-type: none"> • Consultee-centered consultation; four 90 min. sessions at 1-3-6-and 12-months post-training • Action planning; Personal and regional plans for nurse care coordinators to identify patient reach goals at 1-3-6- and 12-months post-workshop • Case review; 30 min. panel discussions at 3-and 6-months consultations • Feedback; reports to nurse care on successful implementation strategies and patient success stories <p>Clinical Weight Loss Intervention</p> <ul style="list-style-type: none"> • 20 one-to-one sessions (in-person or by phone, 4 weekly, 10 bi-weekly, and 6 monthly)

Notes. Carilion Direct-centralized call center; CME-Continuing medical education; DXA-Dual energy X-ray absorptiometry, EHR-Electronic health record; MOHR-My Own Health Report; MOA-Medical office associate

Table 5. Research designs and level of IRB review for Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Integration Trials <ul style="list-style-type: none"> • <i>Design</i> • <i>Conceptual framework</i> • <i>IRB Review</i> 	<p>Design</p> <ul style="list-style-type: none"> • Pragmatic • Case study • Frequencies of • Post patient-provider experience surveys, interviews • Guided by RE-AIM Framework • Mixed methods • Cost description • Surveys, exit interviews <p>IRB Review</p> <ul style="list-style-type: none"> • Exempt research 	<p>Design</p> <ul style="list-style-type: none"> • Pragmatic • Randomized control trial • testing Standard vs. Choice-SDM of support strategies in 6-months employee weight loss maintenance phase • Mixed methods • Baseline, 3-months, 9-months • Cost description • Guided by RE-AIM Framework • Surveys, fitness assessment • <p>IRB Review</p> <ul style="list-style-type: none"> • Exempt research 	<p>Design</p> <ul style="list-style-type: none"> • Pragmatic • Quasi-experimental, comparative effectiveness pilot • Trial testing FIT Rx 90 vs. FIT Rx 90 Plus program with behavioral strategies • Mixed methods • Baseline, 3-months • Cost description • Guided by RE-AIM Framework • Surveys, fitness assessment <p>IRB Review</p> <ul style="list-style-type: none"> • Quality improvement 	<p>Design</p> <ul style="list-style-type: none"> • Pragmatic • Type 3 hybrid effectiveness-implementation trial comparing implementation strategy and pre-post • Guided by RE-AIM Framework • Mixed methods • Chart review, focus groups • Cost description • Baseline, 1, 3, 6, and 12-months <p>IRB Review</p> <ul style="list-style-type: none"> • Quality improvement

Notes. IRB-Institutional Review Board; RE-AIM-Reach, Effectiveness, Adoption, Implementation and Maintenance

Table 6. RE-AIM evaluation (Reach) of patient trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
<p>Reach</p> <ul style="list-style-type: none"> • <i>Demographics</i> • <i>Weight status</i> • <i>Retention</i> • <i>Completers vs. drop-outs</i> 	<p>MOHR Tool Completion</p> <p>Early Site, n=291 Strategy 1^a- 3% of invited Strategy 2^b- 64% of invited</p> <ul style="list-style-type: none"> • Age, category of years 7% 18-25 27% 26-39 21% 40-49 33% 50-64 12% 65-75 • 65% female • 84% White, 13% Black-African American • 79% reported BMI≥25 kg/m² • 57% completed Patient Experience Survey <p>Delayed Site, n=306 Strategy 1^c- 10% of invited Strategy 2^b- 62% of invited</p> <ul style="list-style-type: none"> • Age, category of years 6% 18-25 22% 26-39 23% 40-49 35% 50-64 14% 65-75 • 73% female • 58% White, 39% Black-African American • 82% reported BMI≥25 kg/m² • 71% completed Patient Experience Survey 	<p>Total N=30</p> <ul style="list-style-type: none"> • 47±8.5 years • 90% female • 83% White • BMI=35.7±3.4 • 87% retention at 6-months post-core, 80% at 9-months post-core <p>Standard, n=15</p> <ul style="list-style-type: none"> • 47±6.2 years • 87% female • 74% White • BMI=35.1±3.8 • 87% at 6-months post-core, 73% at 9-months post-core <p>Choice-SDM, n=15</p> <ul style="list-style-type: none"> • 47±8.5 years • 93% female • 100% White • BMI=36.3±2.9 • 87% retention at 6- and 9-months core • Program non-completers had a higher BMI and a smaller % weight loss. Scheduling, family-work commitments, and 	<p>Total N=68</p> <ul style="list-style-type: none"> • 46±10.3 years • 87% female • 91% White • BMI=39±6 • 79% retention at 3-months core; 62% at 9-months post-core <p>FIT Rx 90, n=24</p> <ul style="list-style-type: none"> • 44±9.2 years • 83% female • 83% White • BMI=40±5.6 • 88% retention at 3-months core, 65% at 9-months <p>FIT Rx 90 Plus, n=44</p> <ul style="list-style-type: none"> • 47±11 years • 91% female • 96% White • BMI=39±6.4 • 75% retention at 3-months core, 58% at 9-months post-cost • Program non-completers had a higher BMI and worked part-time/flex position. Scheduling, family commitments, and 	<p>Implementation Strategy</p> <p>Total N=45, 100% received training</p> <ul style="list-style-type: none"> • 100% female; 27% LPN, 73% RN, 87% FT <p>CME, n=31, 100% received training</p> <ul style="list-style-type: none"> • 100% female; 29% LPN, 71% RN, 81% FT <p>CME Plus, n=14, 100% received training</p> <ul style="list-style-type: none"> • 100% female; 21% LPN, 79% RN, 100% FT <p>Clinical Weight Loss Intervention</p> <p>Total N=780</p> <ul style="list-style-type: none"> • 48±14.3 years; 81% female • 89% White, 10% Black-African American • BMI=41±9.9 kg/m² <p>CME n=443</p> <ul style="list-style-type: none"> • 49±14.4 years; 83% female • 86% White, 12% Black-African American • BMI=41±9.7 kg/m² <p>CME Plus n=337</p> <ul style="list-style-type: none"> • 47±14.1 years; 79% female • 92% White, 6% Black-African American • BMI=41±9.1 kg/m² • 77% of patients completed 1 session • Mean number of completed

		medical conditions were reported challenges	physical injuries were reported challenges	sessions=6±5.7 <ul style="list-style-type: none"> • 14% retention at 6-months, 4% retention at 12-months post-core, No difference between conditions • Non-completers had a lower BMI, p<.05.
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Notes. a-mailed invitation with medical office associate administering MOHR during visit reminder call; b-Carilion Direct nurse operators administering MOHR, c-MOHR administered at in-office computer kiosk ; BMI-Body mass index; FT-Full-time; IRB-Institutional Review Board; LPN-Licensed practical nurse; RN-Registered nurse

Table 7. RE-AIM evaluation (Effectiveness) of Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Effectiveness Individual-level <ul style="list-style-type: none"> • % initial body weight • Proportion achieving $\geq 3\text{-}5\%$ initial body weight loss 	Patient and Provider-Reports Elevated BMI most important issue <ul style="list-style-type: none"> • Patient-report- 24% early, 32% delayed; highest ranked issue at both sites Wanted to discuss elevated BMI <ul style="list-style-type: none"> • Patient-report- 13% early, 20% delayed Were ready to make change <ul style="list-style-type: none"> • Patient-report- 15% early, 22% delayed Collaborative goal-setting for diet <ul style="list-style-type: none"> • Patient-report- 52% early, 51% delayed, 44% control • Provider-report- 80% delayed Collaborative goal-setting for PA/exercise <ul style="list-style-type: none"> • Patient-report- 45% early, 48% delayed, 38% control • Provider-report- 80% delayed Positive change with diet <ul style="list-style-type: none"> • Patient-report- 59% early, 58% delayed, 47% control • Provider-report- 95% delayed Positive change with PA/exercise <ul style="list-style-type: none"> • Patient-report- 54% early, 48% delayed, 35% control • Provider-report- 95% delayed 	Present at Follow-Up <ul style="list-style-type: none"> • Standard=$-4.8\pm 3.4\%$ and Choice-SDM=$-3.7\pm 5.4\%$ at 6-months, $p>.10$, present at follow-up • 62% of Standard and 54% of Choice-SDM achieved $\geq 3\%$ • 31% of Standard and 31% of Choice-SDM achieved $\geq 5\%$ Intention to Treat <ul style="list-style-type: none"> • Standard=-4.1 ± 3.4 and Choice-SDM=-3.5 ± 5.4 at 6-months, $p>.10$, present at follow-up • 53% of Standard and 47% of Choice-SDM achieved $\geq 3\%$ • 27% of Standard and 27% of Choice-SDM achieved $\geq 5\%$ No between group differences, $p>.10$	Present at Follow-up <ul style="list-style-type: none"> • FIT Rx 90= $-2.6\pm 3.5\%$ and Plus=$-4.6\pm 3.6\%$ at 3-months, $p<.05$ • 35% of FIT Rx 90 and 57% of Plus achieved $\geq 3\%$ • 25% of FIT Rx 90 and 40% of Plus achieved $\geq 5\%$ Intention to Treat <ul style="list-style-type: none"> • On average, employees lost FIT Rx 90= $-2.3\pm 3.5\%$, Plus= $-3.5\pm 3.2\%$ at 3-months, $p<.05$ • 30% of FIT Rx 90 and 44% of Plus achieved $\geq 3\%$ • 22% of FIT Rx 90 and 31% of Plus achieved $\geq 5\%$ Between group differences, $p<.05$	Implementation Strategy CME <ul style="list-style-type: none"> • Mean 14 ± 21.9 patients reached per nurse care coordinator over 12-months • $86\pm .09\%$ of 5As addressed by nurse care coordinator across sessions CME Plus <ul style="list-style-type: none"> • Mean 24 ± 31.4 patients reached per nurse care coordinator over 12 months • $81\pm .18\%$ of 5As addressed by nurse care coordinator across sessions No between condition differences, $p>.05$ Clinical Weight Loss Intervention CME <ul style="list-style-type: none"> • On average, patients ($n=322$) lost $-1.8\pm 4.7\%$ at 6-months, $p<.05$. • 25% of patients achieved $\geq 3\%$ • 14% of patients achieved $\geq 5\%$ CME Plus <ul style="list-style-type: none"> • On average, patients ($n=244$) lost $-2.5\pm 4.7\%$ at 6-months, $p<.05$ • 29% of patients achieved $\geq 3\%$ • 19% of patients achieved $\geq 5\%$ No between condition differences, $p>.05$

Notes. 5As (Assess, Advise, Agree, Assist, and Arrange), CME-Continued medical education

Table 8. RE-AIM evaluation (*Adoption and Implementation*) of Carilion patient and healthcare employee trials

Components	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
Adoption <ul style="list-style-type: none"> Setting Staff 	Setting <ul style="list-style-type: none"> 100% (n=2) of practice sites initiated use of the MOHR tool Staff <ul style="list-style-type: none"> 63% (n=12) of providers reported initiating use of the MOHR tool at delayed site 	<ul style="list-style-type: none"> N/A 	Setting <ul style="list-style-type: none"> 100% (n=2) of fitness facilities initiated Plus Staff <ul style="list-style-type: none"> 100% (n=12) of fitness professionals [e.g., exercise physiologists (2), registered dietician (1) and trainers (9)] initiated Plus 	Implementation Strategy <ul style="list-style-type: none"> N/A for pilot phase Clinical Weight Loss Intervention CME <ul style="list-style-type: none"> Setting- 70% (n=16) of practices initiated delivery Staff- 61% (n=19) of nurse care coordinators initiated delivery CME Plus <ul style="list-style-type: none"> Setting- 86% (n=12) of practices initiated delivery Staff- 100% (n=14) of nurse care coordinators initiated delivery Differences between conditions, p<.05
Implementation <ul style="list-style-type: none"> Fidelity Costs 	<ul style="list-style-type: none"> 100% of implementation strategies were attempted The only implementation strategy successful at both sites was use of Carilion Direct nurse operators for MOHR administration Sites were challenged by patient interest, functioning of on-site computer station, and the time to complete MOHR tool 	<ul style="list-style-type: none"> Overall, 93% of Standard and 97% of Choice-SDM post-core was implemented as intended Two thirds of the Choice-SDM selected all maintenance components Support calls and group sessions were the most frequently declined in Choice-SDM 	<ul style="list-style-type: none"> Overall, 93% of FIT Rx 90 and 94% of Plus core program and 84% of post-core program was implemented as intended Group session attendance challenged in core Support calls and group sessions were the most frequently declined option in post-core 	Implementation Strategy CME <ul style="list-style-type: none"> 100% of training delivered as intended, unplanned additional feedback Total training costs- \$37 per LPN, \$51 per RN CME Plus <ul style="list-style-type: none"> 100% of training delivered as intended Total training costs-\$169 per LPN, \$237 per RN

	<p>Costs</p> <ul style="list-style-type: none"> For MOHR completion, early site averaged 25±4.8 minutes and delayed site averaged 22±2.9 minutes per patient visit beyond usual care 	<p>Costs</p> <ul style="list-style-type: none"> Standard delivery included 6 hours or \$173 per employee, while Choice-SDM delivery included 5 hours or \$151 per employee 	<p>Costs</p> <ul style="list-style-type: none"> FIT Rx 90 delivery included 15.5 hours or \$119 per employee, while Plus core delivery included 16.5 hours or \$146 per employee; post-core delivery averaged 5 hours or \$151 per employee 	<p>Clinical Weight Loss Intervention</p> <ul style="list-style-type: none"> \$559 per patient (\$467 for LPNs, \$642 for RNs) Staff hours averaged 12.5 hours per patient Total direct patient costs averaged \$500
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Table 9. RE-AIM evaluation (*Maintenance*) of Carilion patient and healthcare employee trials

Component	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
<p>Maintenance</p> <p>Individual-level</p> <ul style="list-style-type: none"> • % initial body weight • Proportion maintaining ≥3-5% initial body weight loss <p>Organizational-level</p>	<p>Individual-level</p> <ul style="list-style-type: none"> • N/A- Beyond scope of pilot phase <p>Organizational-level</p> <ul style="list-style-type: none"> • Delivery of the MOHR tool was not integrated into workflow or sustained at the early or delayed site beyond the pilot phase 	<p>Individual-level</p> <p>Present at Follow-Up</p> <ul style="list-style-type: none"> • Standard=-3.9±4.6% Choice-SDM=-4.9±6.0% at 9-months, p>.10 • 62% of Standard and 54% of Choice-SDM maintained ≥3% • 31% of Standard and 31% of Choice-SDM maintained ≥5% <p>Intention to Treat</p> <ul style="list-style-type: none"> • Standard=-3.7±3.4% and Choice-SDM=-4.2±5.4% at 9-months, p>.10 • 53% of Standard and 47% of Choice-SDM maintained ≥3% • 27% of Standard and 27% of Choice-SDM maintained ≥5% <p>No between group differences, p>.10</p> <p>Organizational-level</p> <p>Choice-SDM integrated into future FIT Rx 90 sessions with practice staff delivery</p>	<p>Individual-level</p> <p>Present at Follow-up</p> <ul style="list-style-type: none"> • FIT Rx 90= -2.6±3.5% and Plus= -4.6±3.6% at 9-months, p<.05 • 35% of FIT Rx 90 and 57% of Plus maintained ≥3% • 25% of FIT Rx 90 and 40% of Plus maintained ≥5% <p>Intention to Treat</p> <ul style="list-style-type: none"> • On average, employees lost FIT Rx 90= -2.3±3.5%, Plus= -3.5±3.2% at 9-months, p<.05 • 30% of FIT Rx 90 and 44% of Plus maintained ≥3% • 22% of FIT Rx 90 and 31% of Plus maintained ≥5% <p>Between group differences, p<.05</p> <p>Organizational-level</p> <ul style="list-style-type: none"> • Plus integrated into future FIT Rx 90 sessions 	<p>Individual-level</p> <p>CME</p> <ul style="list-style-type: none"> • On average, patients (n=271) lost -2.1±5.9% at 12-months, p<.05 • 23% of patients achieved ≥3% • 14% of patients achieved ≥5% <p>CME Plus</p> <ul style="list-style-type: none"> • On average, patients (n=195) lost -2.4±6.5% initial body weight at 9-months, p<.05 • 25% of patients achieved ≥3% • 16% of patients achieved ≥5% <p>Organizational-level</p> <ul style="list-style-type: none"> • <i>Setting-</i> 70% (n=16) of CME and 86% (n=12) of CME Plus practices continued offering beyond one year pilot, p<.05 • <i>Staff-</i> 52% (n=16) of CME and 79% (n=11) of CME Plus nurse care coordinators continued offering beyond one year pilot, p<.05

Notes. CME-Continuing medical education; MOHR- My Own Health Report

Table 10. Decision-making results and potential of tested strategy to act as translational solution in Carilion patient and healthcare employee trials

Components	My Own Health Report Assessment, Prioritization, & Engagement Tool	FIT Rx 90-1.0 Choice-Shared-Decision Making	FIT Rx 90-2.0 Behavioral Strategies	Carilion Healthy Lifestyles Action Plan & Consultation
<p>Decision-Making</p> <ul style="list-style-type: none"> • <i>New strategy or adaptation needed?</i> • <i>Ready for system integration?</i> 	<p>Strategy assessment</p> <ul style="list-style-type: none"> • Revised, integrated care staffing models and additional patient resources are needed to successfully implement and sustain optimal use • EHR and patient portal integration with linkages to clinical and community follow-up support are recommended <p>Readiness for integration</p> <ul style="list-style-type: none"> • Not ready for system integration 	<p>Strategy assessment</p> <ul style="list-style-type: none"> • Standard and Choice-SDM supported weight loss maintenance, Choice-SDM determined to not reduce effectiveness, but seen as improving adherence and modestly reduce costs <p>Readiness for integration</p> <p>Choice-SDM strategies deemed feasible for practice staff to deliver within the system and ready for integration</p>	<p>Strategy assessment</p> <ul style="list-style-type: none"> • Strategies deemed feasible to deliver and effective by the practice delivery team. Online survey needs enhancement to be more user-friendly <p>Readiness for integration</p> <ul style="list-style-type: none"> • FIT Rx 90 Plus deemed feasible for practice staff to deliver within the system and ready for integration 	<p>Strategy assessment</p> <ul style="list-style-type: none"> • CME Plus with consultation and action planning useful for increasing reach and adoption • Additional training needed to address wide variability in level of uptake and effectiveness • Healthy Lifestyles program feasible for nurse care coordinator delivery • Challenges with patient engagement and program retention <p>Readiness for integration</p> <ul style="list-style-type: none"> • CME Plus strategy ready for system integration in future continuing medical education offerings • Adaptations needed for special patient populations, low-income, and severe obesity for full system integration

<p>Translational Solution</p> <ul style="list-style-type: none"> • <i>Institutionalization</i> • <i>Sustained implementation</i> 	<ul style="list-style-type: none"> • N/A – Highly relevant to practice, but too many challenges existed during pilot phase of MOHR tool for integration into routine care 	<ul style="list-style-type: none"> • Choice-SDM integrated into Carilion’s future offerings of FIT Rx 90 program, participants consistently choose less intensive support components Research team still involved with training, delivery, and evaluation 	<ul style="list-style-type: none"> • Behavioral component integrated as standard care into FIT Rx 90 program Evaluating ongoing effectiveness, testing new modes of delivery using technology, and developing formal staff training program to support retention 	<ul style="list-style-type: none"> • Training ongoing and program recognized as current care option for chronic disease management in Carilion medical homes • Additional adaptations needed to optimize outcomes and sustain implementation
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Notes. IRB-Institutional Review Board; RE-AIM-Reach, Effectiveness, Adoption, Implementation and Maintenance; SDM-Shared decision-making

Table 11. Summary of strategies as translational solution for implementation and sustainability of evidence-based lifestyle obesity management

Adapted Evidence-based Strategy	Feasible for Implementation as Designed?	Critical elements of evidence maintained?	Achieved Clinically Meaningful Weight Loss?	Sustained within System?	Priority Perspective
• Assessment, Prioritization, and Engagement Tool	Yes	Yes	N/A	No	Research
• Choice-Shared Decision-Making	Yes	Yes	Yes	Yes	Shared
• Behavioral Strategies	Yes	Yes	Yes	Yes	Shared
• Action Planning and Consultation	Yes	Yes	Yes	Yes	Shared

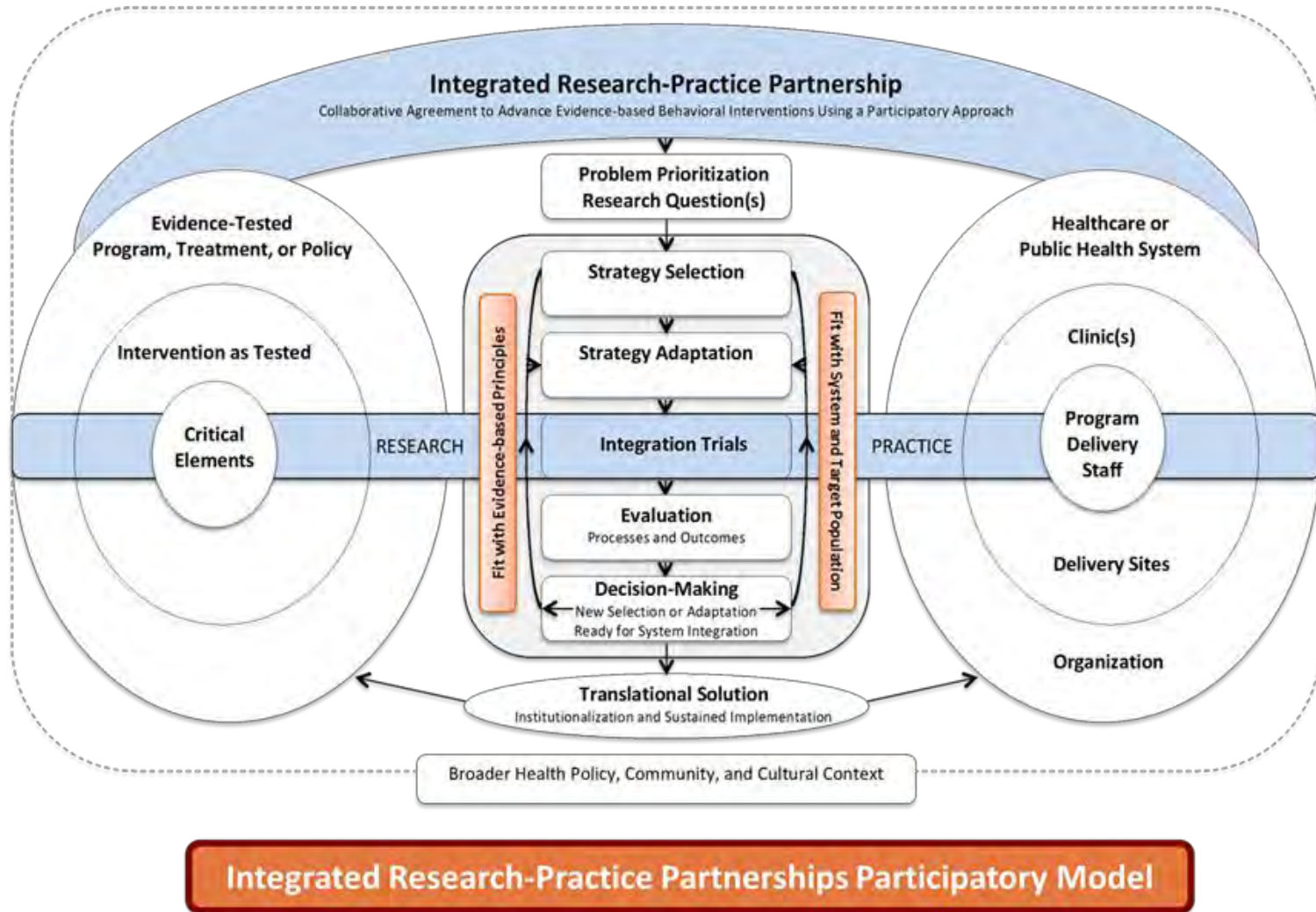
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Appendix 1.1. Integrated research-practice partnership model, refined 2015



Appendix 1.2. Expert committee input, components of a successful weight management program

**Carilion Clinic Components of a Successful Weight Management Program
Expert Committee Input, May 2013**

1	Exercise.
2	Nutrition education.
3	Counseling - mental health.
4	Whole health focus - sleep, chronic conditions.
5	Maintenance program - feedback loops for sustained engagement.
6	Cost effective - affordable, potential to fund through cost savings (population health mgmt.).
7	Options to meet varied needs - locations, hours available.
8	Scalable.
9	Social support.
10	Cognitive Behavioral Therapy - goal setting and tracking, problem solving, stress management.
11	Focuses on weight loss over time with small, continual successes.
12	Online tools.
13	Telephone based support strategies.
14	Includes focus on reduced sitting time (independent of increased exercise).
15	Systematic strategies to engage new participants and ensure that a high proportion of eligible patients/employees/community members are exposed to recruitment activities.
16	Includes sustained contact for at least 6 months.
17	High attendance at program sessions (defined as more than two thirds of the sessions).
18	Ensures that participants are engaged in approximately 26 hours of intervention activities.
19	Process for evaluation to determine degree to which clinically meaningful weight loss is achieved and proportion of participants that achieve it.
20	Uses a population approach.
21	Explicitly addresses relapse prevention.
22	Provides opportunities for early success and strategies to retain those who struggle initially.
23	Available across all Carilion Service areas.
24	Integrated with community and clinical resources.
24	Professionally produced education materials.
25	A viable business model for communities served.

Appendix 1.3. Carilion Clinic matrix of weight loss components and existing programs

CARILION CLINIC MATRIX OF WEIGHT LOSS COMPONENTS & EXISTING PROGRAMS				
		Carilion Clinic Programs		
	Components of Successful Weight Management Programs	FIT Rx/ FIT Rx 90	PATH	Weight Loss Solutions
1	Exercise	★	★	★
2	Nutrition education	★	★	★
3	Counseling-mental health			★
4	Whole health focus – sleep, chronic conditions		★	★
5	Maintenance program-feedback loops for sustained engagement	★	★	★
6	Cost-effective- affordable, potential to fund through cost savings (population health management)	★	★	
7	Options to meet varied needs – locations, hours available	★		
8	Scalability	★		
9	Social support	★	★	★
10	Cognitive behavioral therapy – goal-setting and tracking, problem-solving, stress management		★	
11	Focus on weight loss over time with small, continual successes		★	
12	Online tools			

Completed May 2013, Weight Loss Meeting Led by Strategic Development

Appendix 1.4. Carilion Clinic Healthy Hub proposed outline

Carilion Clinic Healthy Hub

Welcome to Carilion Clinic's Healthy Weight Center, a new hub for connecting patients, providers, employees, and community members to weight loss and weight loss maintenance programs and resources.

Patients

- On-line Assessment
- On-line Modules
- Healthy Lifestyle Challenges
- Register for In-Person Carilion Healthy Lifestyles Support Program
- Register for IVR-Telephone Support Carilion Healthy Lifestyles Service
- Social Networks

Providers

- Medical Weight Management Resources
- Patient Referrals
- CME Webinar
- Case Studies
- Feedback

Employees

- Carilion Wellness
- FIT Rx 90
- Weight Watchers at Work

Community

- Resources
 - Healthy Eating, Physical Activity, Weight Management, Sleep, and Stress
- Self-Referral to Call Center

Appendix 3.1. My Own Health Report tool survey



1. a. What is your height? _____ b. What is your weight? _____

2. Over the past **7 days**:

a. How many times did you eat **fast food meals** or **snacks**?

Less than 1 time 1-3 times 4 or more times

b. How many servings of **fruits/vegetables** did you eat each day?

5 or more 3-4 2 or less

c. How many **soda** and **sugar sweetened drinks** (regular, not diet) did you drink each day?

Less than 1 1-2 3 or more

3. Over the past **7 days**:

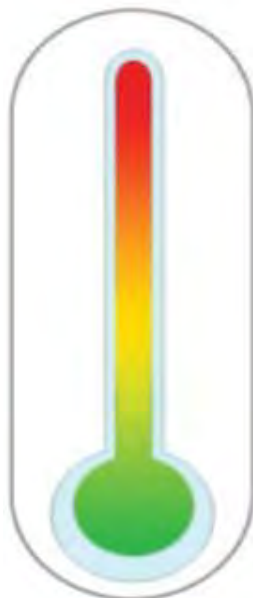
d. How many days did you get **moderate to strenuous exercise**, like a brisk walk?

(please circle) 0 1 2 3 4 5 6 7

e. On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise at this level? _____ minutes per day.

4. Please choose the number (0-10) that best describes how much stress you have been experiencing in the last 7 days? (please circle)

10
9
8
7
6
5
4
3
2
1
0



Extreme

Moderate

Appendix 3.2. My Own Health Report patient summary report

Patient Health Summary Report

AK 42 - Male

Date	Height	Weight	BMI
8/19/2013	6 feet 4 inches	210 pounds	25.6

YOUR Health Behaviors and Mental Health

	Recommended Score	Your Score	Level of Concern	Ready to Change?	Want to Discuss?
Overall Health Rating	Good to Excellent	Excellent	No Concern		
Body Mass Index	20-25	25.6	Some	★	★
Health Behaviors					
Fruit/Vegetable Intake	5+/day	5+/day	No Concern		
Fat; Food Intake	Less than 1 time/week	Less than 1 time/week	No Concern		
Soda/Sugary Beverage Intake	Less than 1/day	Less than 1/day	No Concern		
Physical Activity Participation	150+ minutes/week	225 minutes/week	No Concern		
Sleep	Never/rarely sleepy	Always sleepy	A Lot	★ ★	
Alcohol Intake	Never	Never	No Concern		
Tobacco Use	No	No	No Concern		
Illegal Drug/Prescription Use	Never misuse	Never misused	No Concern		
Mental Health					
Stress	Less than 5	10	A Lot	★	★
Anxiety/Worry	Not at all/rarely	Many days	Some	★	
Depression	Not at all/rarely	Not at all/rarely	No Concern		

★ = Most important to you

Keep up the GOOD Work!

- You are eating very little fast food.
- You eat lots of fruits and vegetables.
- You don't drink very many sodas or sugary drinks.
- You are meeting or exceeding the physical activity recommendations for health.
- You said there are few days you feel down, depressed, hopeless or have little interest or pleasure.
- You don't use tobacco.
- You never drink too much alcohol.
- You do not use illegal drugs or prescription medications for non-prescribed reasons.

Recommendations to Improve Your Health!

Medium Priority

- Excess weight can lead to a number of health problems. Increase physical activity and/or limit the unhealthy food you eat to reduce your weight.
- You said there are many days you feel nervous, anxious, on edge or unable to stop or control worrying. Discuss your anxiety if you think it is a problem.

High Priority

- You reported feeling stressed often. Discuss ways to reduce your stress.
- Try to get 7-8 hours of sleep each night.

Notes/Things to Discuss During My Appointment

Health Goals	
The best goals are those that are specific, measurable, achievable, realistic, and timely and focus on the who, what, where, when and how you will achieve them. List 1 to 3 goals that you want to try to improve.	
<p>Example Goal: What will you do? Decrease fast food by eating out 2-3 less times per week. How will you do it? Pack a lunch to bring to work 2 times per week and cook dinner one more time a week. By when? Gradually, over the next 3 weeks by decreasing fast food meals by one per week until I reach 3.</p>	
Goal #1:	
What will you do?	
How will you do it?	
By when?	
Goal #2:	
What will you do?	
How will you do it?	
By when?	
Goal #3:	
What will you do?	
How will you do it?	
By when?	

Follow-up Plan	
When:	
How:	

Appendix 3.3. My Own Health Report patient consent information sheet

About This Survey

You are invited to participate in a research study being conducted by researchers from the Carilion Clinic Department of Family Medicine. The study is about how clinics gather information on their patients' health habits and about how they use this information to improve care for their patients.

The purpose of the survey is to understand more about your experience at your recent clinic visit and about your health habits. Your thoughts and opinions will help us better understand how clinics use patient information about health habits.

If you decide to participate, please fill out the attached survey. It should take you about 15 minutes to complete. We are inviting you to participate because you recently had a visit at a clinic that is participating in this study.

Participation in this study is voluntary. Your answers on the survey, or your decision not to participate, will not change the care you receive at your health clinic. You will also not lose any of the benefits or legal rights to which you are entitled.

The risks involved in completing the survey are very small. We do not ask personal questions in the survey, but you may feel uncomfortable discussing your experience at the health visit or discussing your health habits. We will use the information you provide only for this research study.

We will protect your privacy. The information you provide us will not be shown to anyone outside this project, including your clinic. Your name and contact information will be linked to a survey ID number. This linking information will be destroyed when you return your survey. Your survey answers will not be linked to your name. Your identity will not be disclosed to anyone.

If you are willing to participate by completing this survey, please fill it out and return it in the postage-paid envelope. [*Or, for on-line survey, please click the button below to continue to the survey.*] Thank you.

For questions about this project, you may contact Mark Greenawald MD or Paul Estabrooks PhD, Principal Investigators, at 720-261-7587.

For questions about your rights as a research participant, please call the Institutional Review Board at Carilion Clinic at 540-853-0728.

Appendix 3.4. My Own Health Report patient recruitment letter-email content



<<DATE>>

<<PATIENT NAME>>

<<ADDRESS>>

Dear <<PATIENT NAME>>,

The physicians of Carilion Clinic Roanoke Salem are doing a research survey about how doctors can better help patients make healthy choices.

The enclosed survey asks some questions about your experience at our clinic and about your health habits.

It should take about 15 minutes to complete. Your answers to the survey will be kept confidential. No information that identifies you personally will be released to anyone, and the researchers will not be able to connect your survey responses to your name. Once completed, please return the survey in the paid self-addressed envelope.

Please read the “About This Survey” sheet before making a decision about participating. Participation is completely voluntary.

As a token of our appreciation, we have included \$2 for your time.

Your care at our practice will not be affected in any way if you decide not to complete the survey.

Thank you for your cooperation!

Sincerely,

Vice Chair
Carilion Clinic Department of Family Medicine

Appendix 3.5. My Own Health Report telephone script - Patient Experience Survey

Introduction

My name is _____ and I am a _____ (researcher or research coordinator or research assistant) from the Carilion Clinic Department of Family Medicine.

Why you want to speak with them:

I'm calling regarding your experiences at the Roanoke Salem Carilion Family Medicine Clinic (or Southeast Carilion Family Medicine Clinic). We are doing a research survey about how clinics can improve patient care. We are following up on a survey packet that we sent to you by _____ (mail /e-mail) about two weeks ago.

Immediate opportunity to opt-out:

Is it OK for me to talk with you about this survey?

- *If individual says no/not interested = stop. Thank them for their time but do not continue.*
- *If individual says yes/OK = continue.*
- *If individual asks about how you obtained their information say:*
 - Carilion Family Medicine Clinic wanted you to be aware of this research study and gave us permission to contact you.

Describe the study:

The research study is being conducted by Dr. Mark Greenawald, MD, Dr. Paul Estabrooks, PhD and associates from the Carilion Clinic Department of Family Medicine. We would like to know how clinics get information about their patients' health habits and how they use this information to improve patient care.

Your participation would involve filling out a short 15 minute survey. The survey will ask you questions about your experience at your recent clinic visit and about your health habits. You can do the survey online, by mail, or by phone with me now. There are no risks involved in doing the survey. We will use the information you provide only for this research study.

Participation in this study is completely voluntary and your responses will be kept private. Refusal to participate will not affect the care you receive at your health clinic.

Would you be interested in doing this survey by mail or online or on the phone?

REFUSAL SCRIPT:

- *If NO → Stop. Thank you so much for your time. If you reconsider, please feel free to contact Sallie Beth Johnson at 910-528-2302. Do not continue.*
- *If yes → Ask the patient if he/she prefers to do the survey now by phone, online, or on paper and submit by mail.*
 - If by phone, complete survey.
 - If online, confirm patient's e-mail, and e-mail RedCap instructions.

- If by mail, confirm patient's address and mail the survey with a prepaid return envelope.
- Also provide the patient with contact information for the project coordinator. Sallie Beth Johnson.

ADDITIONAL INFO FOR THOSE WHO COMPLETE SURVEY BY PHONE:

If you have any questions about the survey, please feel free to contact the Carilion Clinic Principal Investigators, Drs. Mark Greenawald or Paul Estabrooks, at 720-261-7587.

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please call the Institutional Review Board at 540-853-0728.

Appendix 3.6. My Own Health Report Patient Experience Survey

1. Thinking about your visits to the clinic within the last month, were you asked in any way about the following health topics? You may have been asked in-person, with a written form, or by an email. **Please mark for each topic.**

Eating/Diet	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Activity/Exercise	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tobacco/Smoking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alcohol Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Drug Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stress Level	<input type="checkbox"/> Yes <input type="checkbox"/> No
Anxiety/Depression	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sleep	<input type="checkbox"/> Yes <input type="checkbox"/> No

2. Did anyone in the clinic work with you to set specific goals to make changes in any of these areas? **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Activity/Exercise	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tobacco/Smoking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alcohol Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Drug Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stress Level	<input type="checkbox"/> Yes <input type="checkbox"/> No
Anxiety/Depression	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sleep	<input type="checkbox"/> Yes <input type="checkbox"/> No

3. Did anyone in the clinic recommend you seek assistance from another provider or program to help you make changes in any of these areas? *This could include being referred to a specialist, health education program, or a community resource such as a smoking quitline or Weight Watchers.* **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Activity/Exercise	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tobacco/Smoking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alcohol Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Drug Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stress Level	<input type="checkbox"/> Yes <input type="checkbox"/> No
Anxiety/Depression	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sleep	<input type="checkbox"/> Yes <input type="checkbox"/> No

My Own Health Report - Patient Experience Survey

4. Have you made any positive changes in these areas since your visit? **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Activity/Exercise	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tobacco/Smoking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alcohol Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Drug Use	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stress Level	<input type="checkbox"/> Yes <input type="checkbox"/> No
Anxiety/Depression	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sleep	<input type="checkbox"/> Yes <input type="checkbox"/> No

For the next questions, think about the doctors, nurses and other clinic staff you saw during your visits to the clinic over the past month. Did you feel like:

- | | Yes
Definitely | Yes
Somewhat | No |
|---|--------------------------|--------------------------|--------------------------|
| 5. they really cared about you as a person? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. you could trust them with your medical care? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

How often did the doctors, nurses and other staff:

- | | Never | Sometimes | Usually | Always |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 7. encourage you to ask questions? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. show interest in your questions and concerns? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. explain things in a way that was easy to understand? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

10. How long have you been going to this clinic?

- Less than 6 months
- At least 6 months but less than 1 year
- At least 1 year but less than 3 years
- At least 3 years but less than 5 years
- 5 years or more

My Own Health Report - Patient Experience Survey

11. How confident are you filling out medical forms by yourself?

- Extremely
- Quite a bit
- Somewhat
- A little bit
- Not at all

The next few questions ask for a bit more information about you.

12. In general, would you say your health is...

- Excellent
- Very good
- Good
- Fair
- Poor

13. What is your current age?

- 18-25
- 26-39
- 40-49
- 50-64
- 65-79
- 80 and older

14. What is the highest level of education that you have completed?

- Less than a high school degree
- High school degree
- Some college or vocational school
- College degree or more

15. Are you ...?

- Male
- Female

My Own Health Report - Patient Experience Survey

16. What is your race/ethnicity? *Check all that apply*

- African-American or Black
- Latino or Hispanic
- Asian, Asian-American or Pacific Islander
- White or Caucasian-American
- American Indian or Native American
- Other, please specify _____

These final questions ask about how you use the Internet and communicate with your doctor.

17. Do you ever go on-line to access the Internet or World Wide Web, or to send and receive email?

- Yes, Please answer questions b and 1c
- No, skip to next section

18. When you use the Internet, do you access it through...

- A regular dial-up telephone line
- Broadband such as DSL or cable
- A cell phone

19. In the past 12 months, have you used the Internet to look for health or medical information for yourself?

- Yes
- No

20. In what ways, would you feel comfortable receiving information from the clinic?

Please check all that apply

- By regular mail
- Over the phone
- By text
- By email
- Through a password protected website

Appendix 3.7. My Own Health Report provider consent information sheet

About This Survey

You are invited to take part in a Carilion Clinic research study. The study is about how clinics gather information on their patients' health habits. It also wants to learn how this data can improve patient care.

The purpose of the survey is to understand more about your experience helping your patients with health habits and psychosocial issues. Your thoughts and opinions will help us better understand how clinics can integrate patient data about health habits into the workflow of primary care.

If you decide to take part, please fill out the attached survey. It should take you about 10 minutes to complete. We are inviting you to take part because you had a visit at a clinic that is taking part in this study.

Taking part in this study is voluntary. Your answers on the survey, or your decision to take part, will not affect your position or your practice in any way

The risks involved in filling out the survey are very small. We do not ask personal questions in the survey, but you may feel uneasy discussing your experiences with patients. We will use the data you provide only for this research study.

We will protect your privacy. The researchers who receive your survey will not be able to identify you by name or connect your name to your survey responses. Your identity will not be shared with anyone.

If you are willing to take part and complete this survey, follow this link: {insert link}

Thank you.

For questions about this project, you may contact Dr. Mark Greenawald at (540)-526-5702 or Dr. Paul Estabrooks at (540) 857-6664, the Co-Principal Investigators on the study.

For questions about your rights as a research participant, please call staff of the Carilion Institutional Review Board (IRB) at (540) 853-0728.

Appendix 3.8. My Own Health Report provider recruitment letter-email content

<<Date>>

Dear <<PROVIDER NAME>>,

As part of the My Own Health Report (MOHR) project, Carilion Clinic Family Medicine Roanoke-Salem is doing a research survey about helping patients make healthy choices.

The survey asks some questions about your experience working with patients on improving health behaviors and psychosocial issues. It also asks about your experience using the MOHR tool.

It should take about 10 minutes to complete. Your answers to the survey will be kept confidential. No information that identifies you personally will be released to anyone, and the researchers will not be able to connect your survey responses to your name.

Please read the attached “About This Survey” sheet before making a decision about participating. Participation is completely voluntary.

Your practice will not be affected in any way if you decide not to complete the survey, but if you do choose to participate, the information will be used to help us make decisions about integrating these important patient reported outcomes into our practices.

Here is the link to the online survey {INSERT LINK}. Please complete the survey by {INSERT DATE}.

Thank you for your cooperation. We appreciate your time and welcome your recommendations and suggestions.

Sincerely,

Vice Chair of Academic Affairs
Carilion Clinic Department of Family and Community Medicine

Appendix 3.9. My Own Health Report Provider Experience Survey

My Own Health Report - Provider Experience Survey

1. Thinking about your patients' chronic disease/wellness visits to the clinic within the last month, how often did you ask about the following health topics? **Please mark for each topic.**

Eating/Diet	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Physical Activity/Exercise	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Tobacco/Smoking	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Alcohol Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Drug Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Stress Level	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Anxiety/Depression	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Sleep	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always

2. How often did you work with your patients to set specific goals to make changes in any of these areas? **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Physical Activity/Exercise	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Tobacco/Smoking	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Alcohol Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Drug Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Stress Level	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Anxiety/Depression	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Sleep	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always

3. How often did you recommend your patients seek assistance from another provider, service or program to help make changes in any of these areas? *This could include referring patients to a specialist, health education program, or a community resource.* **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Physical Activity/Exercise	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Tobacco/Smoking	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Alcohol Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Drug Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Stress Level	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Anxiety/Depression	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Sleep	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always

My Own Health Report - Provider Experience Survey

4. To your knowledge, have any of your patients made any positive changes in these areas since their visit? **Please mark for each area.**

Eating/Diet	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Physical Activity/Exercise	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Tobacco/Smoking	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Alcohol Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Drug Use	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Stress Level	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Anxiety/Depression	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always
Sleep	<input type="checkbox"/> Never	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Usually	<input type="checkbox"/> Always

If you answered Yes to any of the above areas, please share details on specific changes made by your patients.

For the next questions, reflect on your experience with the pilot My Own Health Report project at your clinic.

5. Did you use the My Own Health Report tool to discuss health behaviors and psychosocial issues with your patients?

Yes No

If yes, with approximately how many patients did you use the tool?

1-10 11-24 25 or more

6. Overall, how would you rate the My Own Health Report project at your clinic?

Excellent Very Good Good Fair Poor

7. What recommendations do you have for improving the My Own Health Report tool or summary report?

8. What recommendations do you have for improving the process of using the My Own Health Report tool with patients at your clinic?

9. What do you need to better help your patients improve their health behaviors and psychosocial needs?

10. Please add any additional comments or suggestions regarding the My Own Health Report project. ~ Thank you for your time and input.

Appendix 3.10. My Own Health Report contextual reporting form

MOHR Context Matters Worksheet

Research Site:

Clinic Name: _____ **Date Completed:** _____ **Beginning** **Mid** **End**

Instructions: Contextual factors affect all real world research projects, but seldom are identified or reported. The idea of this form is to provide a way to consider and report the contextual factors that are important for each participating network. Please identify **one person on your team who best knows each clinic** to complete this worksheet and return it to Suzanne Heurtin-Roberts, sheurtin@mail.nih.gov, **prior to beginning the fieldwork, in the middle of the project, and at the end** The person completing the form should get input from stakeholders with different points of view, e.g. other project team members, staff members with different roles at participating practices, any relevant health care system people (e.g. IT staff). This input can come from informal observations or interactions, and also could include group discussions. A half hour to complete the form is reasonable. The form completer may wish to keep brief notes of important contextual factors that become apparent along the way, and especially of any important local events, major changes in staff, policies, priorities, etc. We anticipate that the forms done at the middle and end of the project will be richer since you and your colleagues will have had a chance to consider important contextual factors that make themselves apparent during the course of your work. We should be able to co-author a paper together based on this work.

Contextual Factors Relevant for Understanding & Transporting Findings

(Factors to consider in identifying the ones important in *your* setting: Relevant theory or participant mental models, national, state and local public policy, community norms and resources, health care system organization, payment systems, IT support, practice culture and staffing, different patient populations and subgroups, available information, relevant historical factors or recent events, the culture and motivations surrounding monitoring and evaluation, relationship between the research team and participating practices; changes in these factors over time.

Footnotes:

The following factors changed in important ways over the course of the study:

Interpretive notes on key events and on how these contextual factors affected what happened during the study (internal validity) and what others should know to transport/re-invent the findings in their contexts (external validity)

Appendix 3.11. My Own Health Report exit interview semi-structured discussion guide, early site

Exit Interview Discussion Guide - Early Intervention Site

Guide for MOHR post-implementation presentation and semi-structured interview with clinical staff at the **early intervention site**

Overview

We want to conduct a mutual learning and feedback session with as many practice members involved in the MOHR implementation as possible (clinical and support staff). We would like for this to occur either as the last 50 patients are completing the MOHR assessment or within one month of completing MOHR assessments (preferably within 2 weeks).

For efficiency and to allow practice members to share perspectives, we want the facilitator to lead a group discussion through the below semi-structured presentation and question guide. Depending on the office and who implemented the MOHR assessment, participants should include at least one physician, nurse, front desk staff, office manager, the practice's primary MOHR contact, and any behavioral health personnel involved.

The session will serve two purposes:

- 1) To share practice feedback data – including the MOHR Reach and patient health behaviors.
- 2) To elicit positive and negative experiences about the MOHR implementation process, share lessons learned, provide suggestions for improvement, and explore interest in sustaining MOHR in its current or a modified format.

Facilitator Introductory Statement (adapt this to your style)

“Thank you so much for making the time to talk today. We have learned a lot from the MOHR project and we are very grateful for your participation. Today we want to share with you some preliminary data about your patients and your practice. We'd also like to hear about your experiences with implementing the MOHR assessment and your suggestions for improvements of the MOHR tool, as well as the implementation process. PLEASE be very candid in your comments and feedback! You will not hurt our feelings. You all do not need to agree. It is fine if you each have different opinions about the MOHR project. It would be helpful and important for us to hear these different opinions.”

Questions and Presentation Prompts about MOHR

NOTE – use this section to guide you and to write for notes. If the participants agree, please audio record the encounter.

Question 1. Please share your overall feelings or thoughts about the MOHR project.

PROMPTS:

- How was this experience for you? Staff? Patients?
- Do you have positive overall thoughts? Negative? Indifferent?

Question 2. What are your thoughts about the process you used for identifying eligible patients?

PROMPTS:

- What worked well?
- What sort of problems did you have?
- How could this process be improved?
- What would you do differently next time?

Question 3. [Show participants the Reach data diagram] Overall, about (XX%) of patients from your office invited to complete the MOHR assessment actually completed it. As you can see, there were variations in your patients' completion rate week to week. [If there was a trend or change in Reach over time, state the trend or change (e.g. "It looks like there was a trend of more patients completing the assessment over time.")]

PROMPTS:

- What are your thoughts about the number of patients who completed the MOHR assessment?
- Is this what you expected? Why or why not?
- Have you received any comments about the assessment from patients?
- Have you observed anything about which patients completed and did not complete the assessment?

Question 3b. Compared to other offices like yours, you had a (higher, lower, about average) percent of patients completing the MOHR assessment. Why do you think this is?

PROMPTS:

- Did you expect this? Why or why not?

Question 4. As you know, your patients completed the MOHR assessment (electronically, by paper), (at home, in the lobby, in the exam room), (2 weeks before, immediately before a visit), and (say if anyone helped them complete it). How did this method work for you (prompt each variation on how they did things)?

PROMPTS:

- Would you do it this way again?
- If not, how would you change it?

Question 5. [Show patient summary print out example and also have provider summary example- individual patient] Both your patients and your providers received summary reports similar to this...that described the patient's behaviors, identified needed improvements, allowed patients to mark which behaviors they were ready to change, allowed patients to say what the most important behavior was for them, and provided a framework for SMART goal setting. How well did this work for you? For your patients?

PROMPTS:

- What did you like the best and the least about these summaries?
- What suggestions do you have for improving the summaries?
- What would make the summaries more actionable?

- Would you like the summaries better integrated into your EMR? Do you have ideas about how this would work?

Question 6. We understand that most often you planned to have (the doctor, the nurse, someone else) meet with patients to review summaries and help patients set goals and make action plans. How well did that work?

PROMPTS:

- What part of that process was successful?
- What wasn't successful?
- Were there any patient factors that influenced this?
- Were there any factors about (the doctor, the nurse, someone else) that influenced this?
- What about the process would you change?

Question 7. (Show prevalence of different health behaviors among this practices patients). Here is a display of the frequency of different health behaviors and mental health issues among your patients (allow time for staff to review this visual before proceeding). What are your thoughts about this?

PROMPTS:

- What do you think about the distribution of your patients' unhealthy behaviors compared to the other sites?
- What do you think about the number of unhealthy behaviors patients had?
- How do you think your patients' behaviors influenced how you implemented the MOHR assessment?

Question 8. [Show goal setting (blank) page of patient summary] The patient summary provided a blank area to prompt and guide patients through goal setting. How did this goal setting exercise work for you?

PROMPTS:

- Did any patients complete these sections prior to the visit?
- Did you complete this section with any patients?
- What do you think about this goal setting exercise?
- What might make it more helpful for you and your patients?

Question 9. Behavioral and mental health counseling experts say it is important to provide some type of follow-up once a patient sets a goal to change a health behavior. How did/does follow-up work in your office before and after MOHR?

PROMPT:

- What do you think about this recommendation?
- Did you follow up with your patients about their goals?
- How did you follow-up with them? PROMPT: at next visit, by phone, by letter, etc
- How well did that process work?
- How did the MOHR assessment and tools assist (or not) with this process?

Question 10. Overall, did the MOHR assessment and tools help you to help your patients with their health behavior and psychosocial goals?

PROMPTS:

- For which topics did it work best?
- For which topics did it not help?
- Overall, what do you need to better help you help your patients improve their health behaviors and psychosocial needs?

Question 11. If the MOHR assessment and tools were modified based on feedback we receive and our lessons learned, would your office be interested in continuing to use it on an ongoing basis? This would not be part research, but just for your own benefit.

PROMPTS:

- Why or why not?
- If interested, what changes would you need to make for the MOHR assessment and tools to work in your setting?

Question 12. [Show proposed panel support tool] My last question is about a possible added feedback report that we are considering adding to the MOHR to help with population management. This report would be for the practice and would be available about all practice patients who complete the MOHR assessment. The report summarizes the most frequent problems among your patients, lists how many patients have multiple problems, and links issues that may place patients at even greater risk. What are your thoughts about a report like this?

PROMPTS:

- Would you use it?
- How can we make it more helpful for you and your patients?

Question 13. Do you have any other questions or comments?

Thank you for participating and offering your feedback.

Appendix 3.12. My Own Health Report summary of national trial results

PATIENTS COMPLETING MY OWN HEALTH REPORT (MOHR)

Practice Characteristics

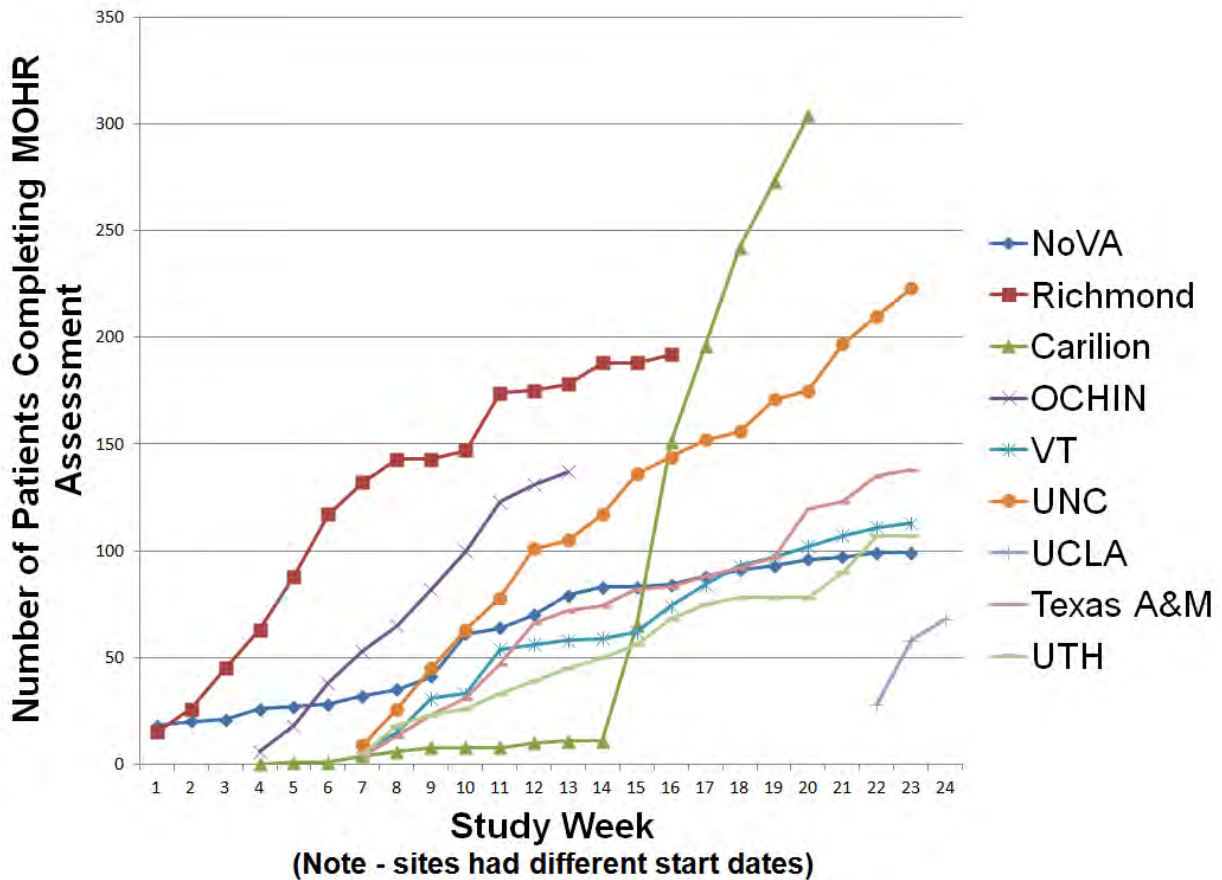
Site	Setting	Patients seen per year	Provider FTEs	Rooming staff FTE	Patient ethnicity / race		Insurance type		
					Latino	Black	Medicare	Medicaid	None
NoVA	S	1,500	1	2	20%	10%	9%	0%	1%
Richmond	R	2,500	1.6	7	1%	49%	12%	1%	49%
Carilion	U	3,400	5.3	16.9	1%	17%	26%	1%	17%
OCHIN	R	3,500	5.5	15	3%	1%	13%	3%	1%
Vermont	R	9,500	5	13.5	1%	5%	13%	1%	5%
UNC	R	1,100	4.5	12	2%	60%	49%	2%	60%
UCLA	U	2,180	2	6	75%	25%	5%	45%	50%
Texas A&M	R	4,800	2	6	48%	23%	2%	15%	38%
UTH	U	2,800	3	19	82%	6%	1%	82%	6%

Have PCMH designation – Carilion, Vermont, UNC, UTH, (OCHIN), (UCLA) (Applying)
 No behavioral change expertise – NoVA and OCHIN (self reported) (rest said “some” or “a lot”)

Practice Implementation Strategy

Site	MOHR Format	Where Completed	Who Completes	Target Population	Invitation	Clinician Summary
NoVA	Web	Home	Patient	Scheduled wellness or diabetes care	Mailed 2 weeks prior	Fax → paper summary
Richmond	Paper	Lobby then exam room	Patient then doctor	Presenting non-acute patients	In person	Paper
Carilion (wk 4-14)	Web	Home	Patient	30 scheduled non-acute patients per week	Mailed 2 weeks prior	Fax → paper summary
Carilion (wk 15-19)	Phone	Home	Carilion Direct	All scheduled non-acute patients	Telephone	Fax → paper summary
OCHIN	Web	Home	Patient	Patients scheduled 3 weeks prior	Mailed 2 weeks prior	Fax → paper summary
Vermont	Web	Home	Patient	Scheduled chronic or wellness patients	Mailed 2-4 weeks prior	Fax → paper summary
UNC	Web	Lobby	Patient (coordinator)	Chronic and wellness patients who consent	Coordinator approach in lobby	Print → paper summary
UCLA	Web / kiosk	Lobby	Patient (coordinator)	Chronic and wellness patients	Coordinator approach in lobby	Fax → paper summary
A&M (wk 1-24)	Web	Exam room	MA and coordinator	Non-acute patients	MA approach in lobby	Print → paper summary
A&M (wk 25+)	Web	Exam room	MA and coordinator	Non-acute patients	MA approach in lobby	Print → paper summary
UTH (wk 7-10)	Web	Exam room	MA	All patients	MA approach in lobby	Print → paper summary
UTH (wk 11-20)	Web	Exam room	MA	Wellness patients	MA approach in lobby	Print → paper summary
UTH (wk 21+)	Web	Exam room	Coordinator	Wellness and chronic patients	Coordinator approach in lobby	Print → paper summary

Number of New Users per Week



MOHR Completion Rate by Fielding Strategy

Overall: 1381 of 2554 (54.1%)

Mailed MOHR Invitation

- NoVa: 99 of 344 (28.8%)
- Carilion: 11 of 450 (2.4%)
- OCHIN: 137 of 444 (30.9%)
- VT: 113 of 248 (45.6%)

Completed MOHR by phone

- Carilion: 293 of 468 (62.6%)

Patient complete in lobby if not doctor does with patient

- Richmond: 192 of 437 (43.9%)

Staff complete for patient in lobby or exam room

- UNC: 223 of 262 (85.1%)
- UCLA: 68 of 86 (79.1%)
- Texas A&M: 138 of 179 (77.1%)
- UTH: 90 of 153 (58.8%)

Appendix 3.13. My Own Health Report exit interview semi-structured discussion guide, delayed site

Exit Interview Discussion Guide- Delayed Intervention Site

Guide for MOHR presentation and semi-structured interview with clinical staff at the **delayed intervention site**

Overview

We want to conduct a learning and feedback session with stakeholders at the MOHR delayed intervention sites. Ideally, this should occur after the early intervention site completes their exit interview.

For efficiency and to allow practice members to share perspectives, we want the facilitator to lead a group discussion through the below semi-structured presentation and question guide. Participant stakeholders should include the practice's primary MOHR contact and other clinical staff including physicians, nurses, front desk staff, office manager and any behavioral health personnel.

The session will include sharing the experiences of the early intervention site followed by:

- 3) A discussion to understand the delayed sites perception on the feasibility of offering the MOHR tool, and
- 4) Objectively offering the delayed site an opportunity to field the MOHR tool.

Facilitator Introductory Statement (adapt this to your style)

“Thank you so much for making the time to talk today. We have learned a lot from our early intervention sites’ experiences with fielding the MOHR tool. Today we want to share with you some preliminary data about these practices’ experience to learn about your perspective on the feasibility of other practices doing this. We’d also like to introduce you to the MOHR tool and see if you would like to use it with your patients. PLEASE be very candid in your comments and feedback! You will not hurt our feelings. You do not all need to agree amongst yourselves. It is fine if you each have different opinions about the MOHR tool. In fact we want to hear about different opinions.”

Questions and Presentation Prompts about MOHR

NOTE – use this section to guide you and to take notes. If the participants agree, please audio record the encounter and send the recording to VCU.

Question 1. Please share you currently know about the MOHR assessment and project. What are your overall feelings and reactions to the MOHR project.

PROMPTS:

- If the site is not familiar with the MOHR assessment or MOHR study, please detail them about both.
- Do you think the MOHR assessment would be a valuable tool to implement in your practice and patients?

- Do you have positive overall thoughts? Negative? Indifferent?

Question 2. [Describe the process the early site used to field the MOHR assessment.] What are your thoughts about how your partner site got patients to complete the MOHR assessment?

PROMPTS:

- Would that process work for you? Why or why not?
- What types of problems would you anticipate in doing something similar in your practice?
- How might you do it differently?
- What recommendations do you have to improve this process?

Question 3. [Describe ways other practices fielded the MOHR assessment then show participants the Reach data diagram.] Your partner got xx% of patients to complete the MOHR assessment. As you can see, there were week to week and practice to practice variations in completion rates. What are your reactions to these findings?

PROMPTS:

- What are your thoughts about the number of patients who completed the MOHR assessment?
- Is this what you would expect? Why or why not?
- What results in your practice? Why or why not?
- Does this data influence whether you would want to implement MOHR? If yes, how?

Question 4. Compared to other offices, your practice partner, had a (higher, lower, about average) percent of patients completing the MOHR assessment. Why do you think this is?

PROMPTS:

- Would you expect this if you were to implement the MOHR assessment? Why or why not?

Question 5. [Show patient summary print out example and also have provider summary example – individual patient] Both patients and providers receive summary reports similar to this...that describe the patient's behaviors, identify needed improvements, allow patients to mark which behaviors they were ready to change, allow patients to say what the most important behavior was for them, and provide a framework for SMART goal setting. What do you think about these summaries?

PROMPTS:

- Do you think these summaries would work well in your practice?
- What do you like the best and the least about these summaries?
- What suggestions do you have for improving the summaries?
- What would make the summaries more actionable?
- Would you like the summaries integrated into your EMR? If yes, do you have ideas about how this would work?

Question 6. Your partner site planned to have (the doctor, the nurse, someone else) meet with patients to review summaries and help patients set goals and make action plans. How do you think that would work for you?

PROMPTS:

- How successful do you think this would be at your site?
- What might some of the challenges be in terms of patients and staff?
- How would you do this at your site?
- Does this part of the MOHR project influence whether you would like to implement MOHR at your site? If yes, how?

Question 7. [Show prevalence of different health behaviors among this practices patients.] Here is a display of the frequency of different health behaviors and mental health issues among patients at your partner site (allow time for staff to review this visual before proceeding). What are your thoughts about this?

PROMPTS:

- What do you think about the distribution of your matched clinic's patients' unhealthy behaviors compared to the other sites?
- What do you think about the number of unhealthy behaviors patients had?
- Do you think your patients would look similar or different? How?
- Does this information influence how you would implement MOHR in your clinic?
- Does this influence whether you would like to implement MOHR in your clinic? If yes, how?

Question 8. [Show goal setting (blank) page of patient summary] The patient summary provides a blank area to prompt and guide patients through goal setting. Do you think this goal setting form would work for your site?

PROMPTS:

- Do you think your patients would complete these sections prior to the visit?
- Do you think you would complete this section with patients?
- What do you think about this goal setting exercise?
- What might make it more helpful for you and your patients?
- Does this goal-setting exercise influence whether you would like to implement MOHR in your practice?

Question 9. Behavioral and mental health counseling experts say it is important to provide some type of follow-up once a patient sets a goal to change a health behavior. How would you likely follow-up with patients with unhealthy behaviors and mental health issues?

PROMPTS:

- What do you think about this recommendation?
- How does this follow-up work in your office now? How do you think it would work with MOHR? PROMPT: at next visit, by phone, by letter, etc
- Do you think the MOHR assessment and tools could assist (or not) with this process?
- What else would you need to help you better follow up with patients?

Question 10. Overall, do you think that the MOHR assessment would help you to help patients with their health behavior and psychosocial goals?

PROMPTS:

- Why? Why not?
- For which topics do you think it would work best?
- For which topics do you not think it would be as helpful?
- Overall, what do you need to better help you to help your patients improve their health behaviors and psychosocial needs?
- Does the experience at your partner site influence whether you would like to implement MOHR at your site?

Question 11. Is your office interested in implementing the MOHR tool?

PROMPTS – If “yes”

- Why?
- How do you want to field MOHR to your patients?
- What help do you need to get started?
- Discuss and plan how to help the site use MOHR

PROMPTS – If “no”

- Why not?
- Do you think this could be done at other practices?
- What changes are needed for this to work in your setting?
- What changes are needed for this to work in primary care more generally?
- What would you say to other practices about our findings and about the MOHR assessment?

Question 12. Do you have any other questions or comments?

Thanks so much.

Appendix 3.14. My Own Health Report mock provider panel report

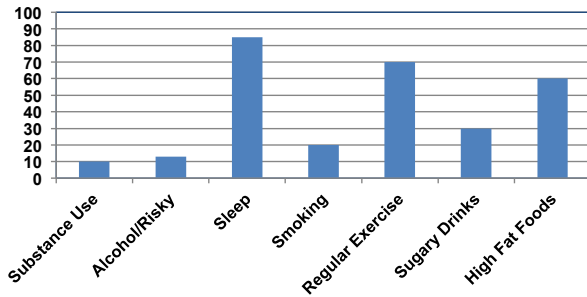


PANEL REPORT

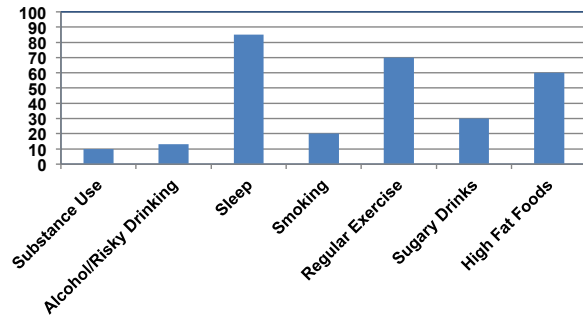
Clinic: _____ Report Date: _____ Based on Number Patients: _____
 Survey Completion Date: _____ Your Clinic: _____ Provider # _____
 All Clinics: _____

Health Behaviors in Need of Attention:

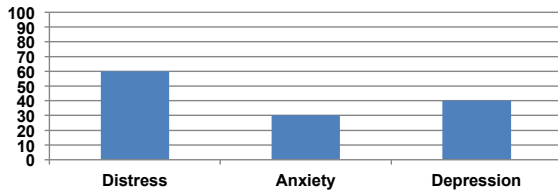
1. Behavioral Health Issues
 A. Last Year N = _____



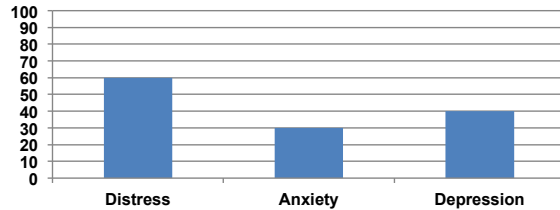
B. Last 30 Days N = _____



2. Psychosocial and Mental Health Issues:
 A. Last Year N = _____



B. Last 30 Days N = _____



3. Pattern Issues: % Self-Reported BMI: < 25% = ____%; 25-29% = ____%; 30-39% = ____%; 40+% = ____%

A. Percent of patients with 3 or more areas positive:
 3 or more = ____%
 4 or more = ____%
 5 or more = ____%

B. Special Issues:
 % Distress and Sedentary = ____%
 % Depressed and BMI ≥ 30 = ____%
 % Distress, Sedentary, and BMI ≥ 30 = ____%

4. CLICK below to see more detail on: A) Risks by Race B) Risks by Age C) Risks by Income D) Risks by Gender

Appendix 4.1. FIT Rx 90 exercise prescription



EXERCISE PRESCRIPTION

Date _____

PATIENT INFORMATION

Name _____

D.O.B. _____

Phone _____

Email _____

PHYSICIAN/CLINICIAN INFORMATION

Physician/Clinician Name _____

Practice Contact (PC) Name _____

Please mark the appropriate condition(s) for which exercise is to be prescribed:

- Diabetes
- Arthritis
- Osteoporosis
- Cardiac Conditions
- Weight Loss
- Hypertension
- Orthopedic Conditions
- Other _____

Exercises may include:

- | DO | DON'T |
|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> Cardiovascular Conditioning |
| <input type="checkbox"/> | <input type="checkbox"/> Strength Training |
| <input type="checkbox"/> | <input type="checkbox"/> Balance and Flexibility |

**ACSM guidelines followed unless otherwise noted/prescribed.*

List any precautions/special conditions for exercise:

PC Phone _____

PC Email _____

PC Fax _____

BEST METHOD TO CONTACT THE PHYSICIAN/CLINICIAN

Please check any/all that apply:

- Call with patient updates/progress reports.
- Email patient updates/progress reports.
- Fax patient updates/progress reports.
- No patient follow-up required at this time.

PATIENT INSTRUCTION

Please contact Director of Wellness Development Jenna Bartlett, or bring this exercise prescription to a Carilion Wellness facility and present to the front desk upon arrival.

FIT Rx 90 program lasts 90 days.

Provider License Number/State _____

Physician's Signature (Required) _____

***Patient will be subject to pre and post lab work and DEXA scan during the program.**

For facility location maps, visit our website at CarilionWellness.com.

For additional questions, contact Jenna as listed below.

phone (540) 992.2993 • fax (540) 857.5300 • JLBartlett@carilionclinic.org



Appendix 4.2. FIT Rx 90 healthcare employee consent form

Consent to Take Part in a Research Study

Study Title: Keeping the Weight Off After FIT Rx 90

Investigators:

Paul Estabrooks, PhD

Mark Greenawald, MD

Professor of Family Medicine Vice Chair of Family Medicine

1 Riverside Circle, Suite 104 1 Riverside Circle, Suite 102

Roanoke, VA 24016

Roanoke, VA 24016

720-261-7587

540-526-250

What is Informed Consent?

You are being asked to take part in a research study. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent.

This consent form may have words or information you do not understand. The research staff will explain anything that you do not clearly understand. Please ask as many questions as you need to make sure that you know what will happen to you in this study and why you are being asked to be in it.

What is this study about and why are you asking me to be in it?

The purpose of this study is to test two different ways to help people keep their weight off. You have been asked to be in this study because you recently completed the FIT Rx 90 weight loss program and were able to lose some weight.

After a weight loss program, it sometimes helps to follow up with people through meetings, phone calls, and text messages or emails. This follow-up can help people keep the weight off, but no one really knows how much follow-up is needed. This study will try to find out what types of follow-up help people maintain their weight.

There will be about 30 to 40 people in the study. You can expect to be in the study for about 6 months after the FIT Rx 90 program ends.

What will happen in this study?

If you decide to take part, you will be randomly assigned to one of two groups. That means that you will be assigned to one of the groups by chance, like by the flip of a coin. Randomization means you will not have a choice which group you belong to. You must agree to be randomized to be involved in this study.

Both of the groups last for 6 months and will help you with goal setting, give you a chance for follow-up, and let you choose to either stay with your current weight or lose more weight. Group 1 is called the **Standard Maintenance Program** and includes the following: 3 weight loss maintenance classes lasting about 1 hour each, 9 resource telephone calls lasting about 15-20 minutes each, and 24 weekly email or text motivational messages. You will also be asked to report your weight by email or text once a week. Finally, an updated progress report will be provided to your physician after the first 3 months of the maintenance program and again at the completion of the 6-month program.

Group 2 is called the **Individually Designed Maintenance Program**. This program allows participants to choose which of the Standard Maintenance Program parts they get. You could choose to get the whole program or you could choose to just do the classes, or the telephone calls, or the emails/texts. You could also choose a program with fewer classes, calls, or messages.

If you agree to participate, we will need permission to use the measurements that you did at the beginning and end of the FIT Rx 90. This includes your starting and finishing weight, BMI, body composition, and survey results. We will also collect your attendance data at the fitness facility and FIT Rx 90 sessions.

As a part of the program, you will need to attend 3 study assessments. Each assessment will take about 45-60 minutes. The first one will be at the beginning of the maintenance program; the second one will be 3 months later, and the last one will be at the end of the 6-month maintenance program.

The assessments will be done in-person and include:

- Surveys about your food and drink behaviors, physical activity behaviors, quality of life and weight loss strategies
- Height and weight
- Blood pressure
- Body composition

We will also use the fitness center records to determine if you maintained a membership and how often you attend over the course of the maintenance program. However, a membership or regular attendance at the fitness center is not required.

Finally, with your permission we will record some of the telephone calls to help us make sure we are delivering the program well and to help us with future maintenance programs. Your name will not be used in these recordings.

What are the risks or discomforts involved with being in this study?

The risks of this study are minimal. Based on your participation in FIT Rx 90, the risks can be compared to those ordinarily encountered in daily life.

This study may include risks that are unknown at this time. You will be informed of significant new findings that develop during the course of this study that may affect your willingness to continue to participate in this study. In the unlikely event that you are injured during the study, you will be responsible for the related costs.

What are the benefits to me for taking part in this study?

This study is designed so that all participants get an opportunity to receive a weight loss maintenance program, but you might not benefit personally from taking part in this study. Still you may benefit from learning appropriate weight maintenance strategies to improve your eating or physical activity behaviors, further weight loss, and/or improvement in health conditions.

The findings of this study could have a benefit to others by helping us to understand what types of follow-up help people keep their weight off and if letting participants decide on their own program design helps.

Are there any other options to being in this study?

Your option is to not take part in the study.

How will you keep my information confidential?

The research records will be kept private on a password-protected computer in a locked office. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

HIPAA Authorization to use your health information:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers: name, address, telephone number, e-mail address or medical record number.
- Demographic information: as age, race, gender.
- Assessments that will be done for the study.
- Information from surveys or questionnaires done for this study.
- Attendance and membership records from the fitness facility

The investigator and research team may share information about you with:

- Your physician in the form of a weight loss maintenance progress report.
- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. This authorization lasts until the study is finished.

Will I get paid for being in the study?

Participation in this study is at no cost to you except for your time completing the program and assessment activities. If you select to receive text messages rather than email, you may incur wireless carrier charge fees for receiving messages.

You will get a gift card for your time involved in completing each of the 3 and 6 month assessments, including:

- Middle of the maintenance program (3-months): \$25 gift card
- End of the maintenance program (6-months): \$50 gift card

You will also get small non-monetary prizes at the group sessions to help you reach your goals.

Will researchers be paid for this study?

This study does not have any sponsors. It does not have any funding. None of the investigators or research staff will receive money or other types of payment from this study.

What if I want to stop being in the study before it is finished?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

Who can answer my questions?

Contact Paul Estabrooks at 720-261-7587 for questions about the research or if you think you have been harmed as a result of this research. If you have questions about your rights as a research subject, you may contact staff of the Carilion IRB at (540) 853-0728.

Appendix 4.3. FIT Rx 90 program information sheet



FIT Rx 90 Activities and Evaluations Information Sheet

Here is a list of activities and evaluations that are included in the FIT Rx 90 program.

Activities

- Kick-off group information session
- Initial one-to-one evaluation with Fitness Manager
 - Includes tour of fitness center

First 90 Days- 1-3 Months: Core Program

- 6 one-to-one sessions with a personal trainer
 - Scheduled at your convenience at the BAC or RAC
- 5 group nutrition consultations with a registered dietician
 - Scheduled every two weeks at the BAC and RAC
- Free gym membership incentive with attendance at least 12 times a month or up to \$36/month discount payroll deduction

3-9 Months: Additional Support-Maintenance Program

- Weekly motivational messages
- Weekly self-reported weight
- 9 telephone support calls
 - Offered biweekly during months 3-6 and then monthly for the remaining three months. Each call will last 15-20 minutes.
- 3 weight maintenance classes
 - Occur at three months, 6 months and 9 months

You can choose which components of the maintenance program you would like to receive.

Evaluations

Surveys and measurements taken by your Fitness Manager will occur at the start of the program, 3-months and 9-months. Each evaluation will last about 45-60 minutes. Measurements include weight, circumference measures, body fat % and blood pressure. In addition, lab work conducted by Employee Health will be completed to determine your triglycerides, HDL, LDL, total cholesterol and hemoglobin A1C3.

Some people when trying to lose weight might lose body fat, but also gain muscle - so the scale might not tell them much about their true progress. Because of this, we are also offering an optional opportunity to complete a Dual X-Ray Absorptiometry (DXA) scan. A DXA scan can tell you when you are losing fat mass and gaining muscle. The test does include a small amount of radiation, but not as much as you would be exposed to if you were scanned in the security line at the airport. The DXA scan, takes about 15 minutes, and is offered at VT-Riverside 1, Suite 104.

The evaluations are intended to show progress with your healthy eating, physical activity and weight loss goals. In addition, the evaluations will help improve the FIT Rx 90 program. It is important for all individuals who start FIT Rx 90 to also complete the evaluation process.

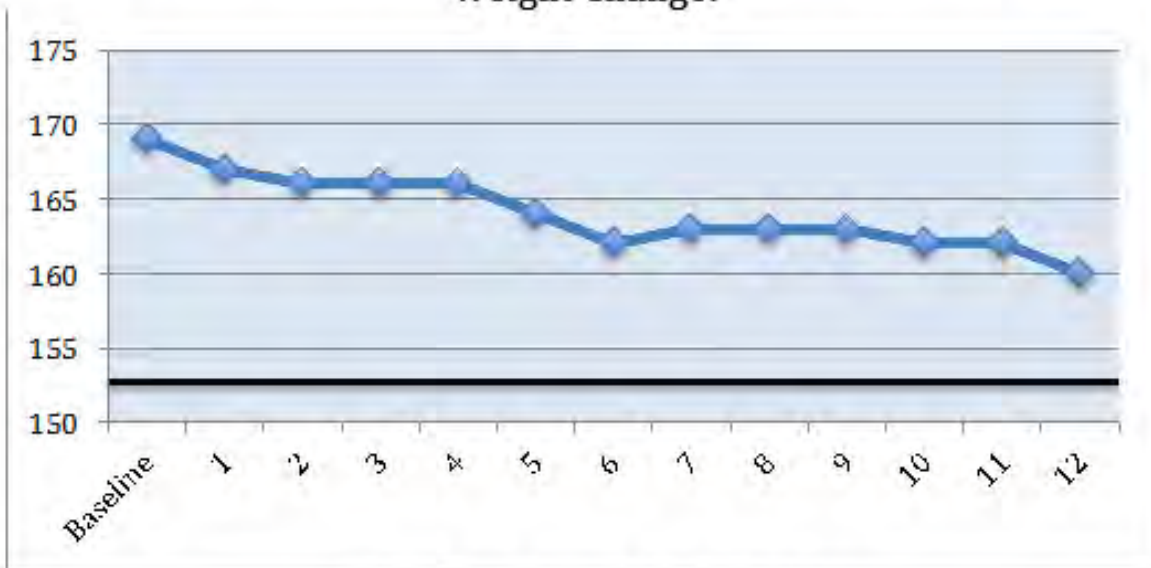
Appendix 4.4. FIT Rx 90 progress report summary



Participant #####

PROGRESS REPORT SUMMARY

Weight Change:



*Black line shows goal weight

Personal Training and Nutrition Attendance

Attended 6 /6 personal training sessions

Attended 5 /5 group nutrition sessions

Activity Log:

Aerobic: Average of 4 days per week, average of 45 minutes at a time

Strength: Average of 4 days per week, average of 20 minutes at a time

*Based on on-line survey reports

Food Log:

Average of 6 days per week eating fruits/vegetables

Average of 4 servings of fruits/vegetables per day

Appendix 4.5. FIT Rx 90 motivational messages for weight loss maintenance

“Keeping the Weight Off After FIT Rx 90” Motivational Messages	
Participants will receive a weekly message tailored to their healthy eating, physical activity, weight loss goals and preferences. Coaches will select appropriate messages from this list based on participant’s assessments and support sessions. Message ID#s will be tracked.	
ID	Messages: Behavior Change for Weight Loss/Maintenance
M1	Focus on behavior, not weight. Remember that your behavior must change before weight can change.
M2	Write down all the benefits of losing weight. Rank your top three reasons. Refer to the list a lot!
M3	It takes time for the healthy new behaviors you’re learning to become habits. Every step, every day, is important.
M4	If you can stay focused on a healthy lifestyle, the weight will take care of itself. That includes a balanced diet, daily physical activity, getting enough sleep and managing stress.
M5	What you do to maintain your weight should be things you look forward to doing. You want to make weight control enjoyable and comforting, not unpleasant and tiresome.
M6	“I’m not losing weight. I’m getting rid of it. I have no intention of finding it again.” – I bet you can relate to this message.
M7	If you focus on results, you won’t change. But if you focus on change, you’ll get results.
M8	Don’t think too far ahead. Look at what you can do today to make your program work for you.
M9	It’s not always about pushing yourself. It’s about pushing yourself in the right direction.
M10	One pound at a time, one day at a time, one meal at a time. It can be done and the results, awesome!
M11	Reward yourself with something that matters to you every time you reach a goal. Make your reward a non-food item.
ID	Messages: Encouragement for Slips or Lapses
M12	Weight loss is like driving: If you ever veer off the road, just make a U-turn and head back in the right direction.
M13	Accept the fact that on some days, you’ll have setbacks. Rather than give up on your program entirely, simply start fresh on the next day. Believe in yourself.
M14	Keep your response to an eating or exercise lapse simple. Focus on the things you know you can do and avoid drastic changes. You’ll soon get back on track!
M15	When it is obvious that the goals cannot be reached, don’t adjust the goals, adjust the action plan. – Confucius
M16	If Plan A fails, remember you have 25 letters left. What’s your Plan B?
M17	99.9% of all people trying to lose weight and be active experience lapses. Lapses can and should be useful learning experiences.
ID	Messages: Healthy Self-Image and Self-Talk
M18	Acknowledge that you’re a person of value who can contribute to your community and to others, regardless of what you weigh.
M19	Feeling good about what you achieve, even if it seems minor, can help keep you motivated. Each time a goal is met, set a new and more challenging one.
M20	Try to build your self-esteem. Don’t hide behind oversized clothing. Dress in clothing that makes you feel good about yourself.
M21	Compare yourself to you, not others. Everyone is unique in his or her own way.
M22	Doing something nice for someone can boost self-esteem. Take time to talk with a friend or send a card to someone, include one of your new healthy recipes.
M23	Negative self-talk can produce anxiety. Be aware of what you say to yourself -make it positive.
M24	Be happy with who you are and not who you imagine yourself being. Think of a skill or talent that you take special pride in. Then fill in the blank, “I like the fact that I can _____.”

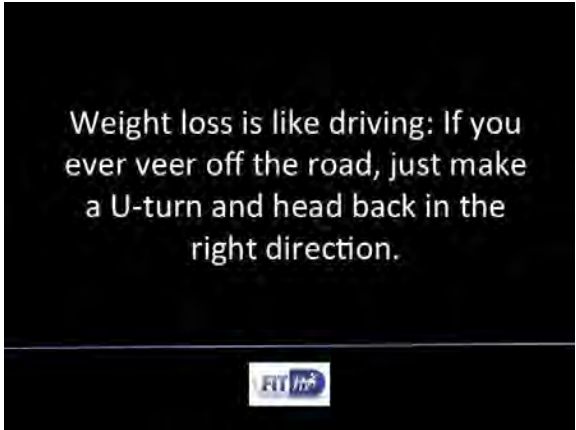
ID	Messages: Support
M25	Buddy up: Exercise can be a lot more fun when you do it with others. Take a walk with a co-worker, your family, your dog, or a neighbor.
M26	Enlist the support of family and friends in your weight loss efforts; be sure to let them know exactly how they can be most helpful.
M27	Increase your chance of sticking to your walking program by getting a walking buddy. A companion can help keep you motivated and make you feel safer.
M28	Getting support from others is not a sign of weakness. If you feel that you need help, ask for it.
M29	Friends – even spouses – may sometimes feel intimidated by your efforts to lose weight. It's up to you to let them know how important their support is to you.
M30	Set up a regular "activity date" with a friend or family member.
M31	Don't let unsupportive friends distract you from your goals. Try to be around people who share similar goals and who are willing to provide support.
ID	Messages: Stress and Time Management
M32	Learning to say no to things that aren't essential gives you time for things you really want to do.
M33	Eating to ease stress almost always ends in overeating. Look for other ways to cope with stress, including exercise, regular mealtimes and getting enough sleep.
M34	To reduce stress, try organizing your day to avoid conflict and last-minute panic. Tackle unpleasant tasks early and get them over sooner.
M35	Walk and talk out your stress with a friend.
M36	Try to a yoga class to reduce stress and connect your mind and body.
M37	Make a "To-Do" list at the beginning of each day and label items: "A" (most important), "B" (important, but can be put off for a while), or "C" (not time-sensitive, can be put off).
M38	It's not about having time. It's about making time.
M39	If your schedule is full, you can still find time to exercise for brief periods during the day. For example, do three 10-minute sessions in place of one 30-minute session.
ID	Messages: Physical Activity
M40	Struggling to start your walk? Think about how good you'll feel when you are done.
M41	Try listening to music while you exercise. Upbeat music can rev you up. It makes the workout seem easier and the time pass more quickly. Have any power song suggestions?
M42	Make exercise a priority today. If you treat it as secondary, exercise will quickly drop to the bottom of your to-do list.
M43	Change your exercise routine occasionally and do a variety of activities to avoid workout boredom.
M44	Choose exercises that you can do regardless of the weather, such as mall walking or indoor swimming,
M45	Exercise is a reward, not a punishment for eating.
M46	There are 1,440 minutes in a day. Can you spare 30-90 of them for exercise?
M47	300 minutes of moderate intensity physical activity will burn about 1400 calories per week!
M48	There is no elevator to success. You have to take the stairs. (Calorie Challenge You burn 10 calories taking the stairs vs. 1.5 calories waiting on or for an elevator.)
M49	Get off the bus or trolley one or two stops early and walk the rest of the way.
M50	Choose activities that fit your personality. If you prefer solitude, consider walking or jogging. If group activities appeal to you, consider a Zumba class.
M51	Try out a new activity that you've always wanted to do. Base your decision on personal appeal and not necessarily on what you think will help you lose weight.
M52	Fight fatigue with fitness – exercise has a relaxing yet energizing effect that can play a powerful role in relieving feelings of fatigue.

M53	Stay positive: Remind yourself of your past successes, and picture yourself being active for a lifetime
M54	Mix things up when you exercise. Don't feel tied to just one type of activity, such as walking. Occasionally, try biking or swimming instead. Keep in fun!
M55	Keeping a positive attitude about exercise is important for success. If you start thinking, "exercise is boring", you'll quickly lose motivation.
M56	Give yourself some slack. For example, it's OK to take a day off from exercising now and then – if you feel you really need it. You're not in exercise boot camp.
M57	Try not to think of physical exertion while you exercise. Think of pleasant thoughts or enjoyable things to do at the same time that you're physically active.
M58	Exercise should not be painful. Muscle soreness after exercise is common, but pain during exercise can be a signal of impending injury. Stop what you're doing and consult your doctor.
M59	Interval training, which alternates periods of high/low intensity, can improve your aerobic fitness and add variety to your program.
M60	Add hills to your walk. For every 2 percent grade increase, you'll burn approximately 25% more calories walking.
M61	Take to the outdoors, and you may find that you'll refresh your routines, and your spirit. Check out roanokeoutside.com .
M62	Train for an event, such as a 5K. The moment you register, you'll have a new sense of purpose and a concrete goal that will push you to achieve more. Here's a link to upcoming events in the Roanoke area: starcitystriders.com .
M63	Set a timer or alarm on your phone to remind you to be active.
M64	Choose the right time – Some of us are naturally morning people. Others prefer to be active at the end of the day. Listen to when your body likes to move and it will be more fun.
M65	Focus on a feeling -if you focus on how you feel each time you exercise, you'll get all the benefits of burning calories, plus the reinforcement of remembering how good it felt to do it, which should increase your motivation to do more
M66	Try to make a positive association with sweating – after all, it is a sign that you are burning calories.
M67	Walk and talk when chatting on the phone with friends and family.
M68	Save time getting ready - Keep your exercise shoes and clothes in the car or at your office
ID	Messages: Physical Activity Benefits
M69	Burning an extra 100 calories/day through increased physical activity could ward off a gain of 10 pounds of over the next year.
M70	Better sleep: Researchers find that people who are regularly active - including regular walkers - fall asleep more quickly, sleep more soundly, and are more refreshed in the morning.
M71	Brain benefits: Studies show that physically active people have better memory, reaction time, and concentration.
M72	Think about what you can do to stay active. Can you make physical activity a part of your vacation? Can you fit it a morning or evening walk?
M73	It's summer - Drink lots of water before, during and after physical activity.
ID	Messages: Physical Ideas for the Office
M74	Walk around the block. Got a coffee break? Got a few free minutes? Take a walk outside and get some fresh air (and extra steps).
M75	Walk and talk. Need to discuss something with a co-worker? A walking meeting can be more productive and healthier too!
M76	Lift weights while you talk. Keep a weight near the telephone; Pick it up when you get a call and pump your arms while you talk.
M77	Work your abs. You can strengthen tummy muscles while sitting in a Chair. Sit straight, tighten muscles and release. Repeat.

M78	One or Two Challenge: Get off the elevator one or two floors before your destination and take the stairs.
ID	Messages: Healthy Eating
M79	I will not feel deprived when I bypass junk food. I will feel empowered that I made the healthy choice.
M80	If you keep good foods in your fridge, you will eat good foods.
M81	The best food comes in its own package.
M82	Keep your kitchen stocked with lots of healthy options such as chunks of fruits and veggies.
M83	Make cooking a family event. Get your children involved with the prep work. This will help to teach them about healthy eating, and it also serves as a way for you to spend time with your children.
M84	Changing a family pattern is difficult at first. Start by eating one more meal at home each week than you normally do. You may save calories and money.
M85	Check restaurant web sites for menus. You can look for healthy options before you eat there.
M86	Rather than dwell on what you can't eat, focus on what you can eat. Granted, you may no longer be able to eat a large bowl of ice cream every evening, but you can have ice cream on occasion.
M87	Counteract all-or-nothing thinking. Try not to label a food as being either "good" or "bad". You can eat most foods in moderation. It's even OK to have dessert once in a while.
M88	Test your menu skills. Carefully review items and look for terms that may indicate how the food is prepared or what ingredients may be included. Try to identify sources of hidden calories.
M89	Plan your meals. Start planning what you will eat at your next meal. Plan what you will eat for the next several days, including snacks.
M90	Pack lunch while you cook dinner. You can cook once and eat twice by making "planned-overs" at dinnertime. Make an extra serving or two and pack them to-go as you clean up the evening meal.
M91	Add nutrition to your commute. It's easy, it's tasty and it's doesn't have to be messy! Pack a piece of string cheese, an apple or a bag of grape tomatoes for the car or bus.
M92	Pump up with protein power. Many office treats are all sugar and fat. For long-lasting brain and body power, add some protein with nuts, seeds or yogurt.
M93	Switch to a fruit dish. Tempted by the cookie jar or candy dish? Switch to a fresh fruit bowl.
M94	Start the day with breakfast, especially one high in fiber and moderate protein, to help control calories for the rest of the day.
M95	Drink to your health. Staying well-hydrated helps you think more clearly, be less cranky and do less mindless munching. It is also one of the best skin treatments in the world.
M96	Treat yourself well. When it's time to eat, give yourself a real break. Stop working, stop rushing and give yourself a few minutes to really savor whatever you are eating.
M97	Use the K.I.S.S. principle for candy. Keep It Small Sweetie! Skip those expensive, high-calorie, king-size bars. Slowly savor a chocolate kiss or enjoy a "fun-size" version of your favorite candy treat.
M98	Eating a few nuts on a regular basis can keep you on your healthful eating plan by helping you feel full longer.
M99	Get to know legumes, the family name for lentils, peas, all beans and peanuts. They're high in protein while almost free of saturated fats.
M100	Just because bread is brown doesn't mean it is whole grain. The first ingredient should say whole grain, whole wheat or rye.
M101	Choose breakfast cereals that are high in fiber and low in sugar
M102	Aim to drink more water this week; using water bottles can help track how much you've had and they're mobile
M103	Soups are satisfying - they take a long time to eat, fill up your stomach, and leave you feeling full for longer (just watch the salt)

M104	Every bit of food you eat doesn't have to be an excellent source of nutrition. Your main goal is to choose foods that promote good health more often than you choose those that don't.
M105	Look for ways to make a favorite recipe more nutritious. This might include reducing the amount of sugar, using low-fat products and substituting beans for meat.
M106	When you don't have time to make a healthy meal, stop at a grocery store or deli for a healthy sandwich, soup or prepared entrée that's low in fat and calories.
M107	When you know you'll be eating out (and eating extra calories), try to increase the amount of exercise you do on that day.
ID	Messages: Fruits and Vegetables
M108	Over the day include a variety of foods from all food groups: Vegetables, fruits, whole grains, low-fat dairy products, and lean protein foods.
M109	Is half your plate fruits and vegetables? Rate your plate this week.
M110	Eat the rainbow –each color of fruit provides nutrients for your body
M111	Including more fruit & veggies in your meals makes it much easier to achieve & maintain a healthy weight.
M112	Microwave vegetables to serve with dinner; when grilling out, add vegetables and fruit.
M113	Consider growing some of your own produce. It's not as hard as you may think. If you don't have space for a garden plot, you can grow items such as tomatoes and peppers in outdoor pots.
M114	Check out your local farmer's markets for fresh, seasonal produce: roanokevalleylocavore.com/markets.htm
M115	You don't have to like all vegetables and fruits, just some of them. To increase the number of servings you eat, try preparing them in different ways, for example, grilling or making fruit smoothies.
ID	Messages: Snacking
M116	To cut down on snacking at the movie theater, eat something healthy before you leave home. Drink water or a calorie-free beverage while you're there.
M117	Check your hunger level. Are you actually hungry? Or are you tired? Bored? Lonely? Happy? Or did you just see a food commercial on TV? If you aren't hungry, skip the snack until you are.
M118	Check your fluid level. Are you thirsty rather than hungry? Since it's easy to confuse the signals for hunger and thirst, try drinking a refreshing glass of water before you dig into a snack.
M119	Check portion sizes. Most super-sized snacks are loaded with fat, sugar and calories. If you want a sweet or salty treat, start with a small size or share a biggie size with a friend.
ID	Messages: Mindful Eating
M120	Research shows that when people eat slowly and mindfully they tend to eat less food. Check out mindlesseating.org for more tips and fun ideas.
M121	Put down your utensils for 10-15 seconds after a few bites.
M122	Focus on your food. Look at the food on your plate. Notice how each bite feels and tastes. Take time to enjoy the taste and smell of the food.
M123	Create a calm eating environment. With less stress or chaos, you can pay attention to what you are eating. Turn off the TV and computer, and try not to eat on the run.
ID	Messages: Food Cravings and Feelings
M124	When a craving doesn't come from hunger, eating will never satisfy it.
M125	You can assist your weight loss journey by keeping 100-150 calorie snacks handy.
M126	Keep foods that you crave out of the house, or at least, out of site. If you feel you must have a package of cookies in the house, tuck them away in the back of the cupboard.
M127	The urge to eat can often be due to a certain mood and not to physical hunger. When the mood sets in, try to distract yourself by going for a walk, calling a friend or running an errand.
M128	Totally denying yourself a food you enjoy, such as chocolate, is a sure way to fuel a craving. A more sensible approach is to treat yourself to it now and then – but in small amounts

M129	Desserts equal stressed spelled backwards – control your sweet tooth when your stressed by choosing fruits
M130	When you feel lonely, do you turn to food for comfort? Make a list of things you can do when you are lonely - - call a friend, take a walk, watch a movie...
M131	Learn to recognize true hunger and ignore cravings. If you ate just a couple of hours ago and your stomach isn't rumbling, give the craving time to pass before you reach for snack food.
ID	Messages: Inspiration and More Quotes
M132	Life is like a bicycle. To keep your balance you must keep moving.
M133	Exercise is your king, and nutrition is your queen. Together, they create your fitness kingdom.
M134	If it doesn't challenge you. It doesn't change you.
M135	Success is the sum of small efforts, repeated day in and day out. - Robert Collier
M136	Don't give up what you want most, for what you want now.
M137	Every morning you get a chance to begin again.
M138	The victory is not always to the swift, but to those who keep moving.
M139	Movement is the celebration of life. – John Selland
M140	Physical activity will add years to your life and life to your years.
M141	The body achieves what the mind believes.
M142	You don't have to cook fancy or complicated masterpieces – just good food from fresh ingredients. - Julia Child
M143	You don't stop playing because you grow old you grow old because you stop playing. - Ben Franklin
M144	Some people want it to happen, some wish it would happen, others make it happen.
ID	Messages: Final Weeks
M145	Regardless of how much weight you've lost, the fact that you've stayed with the program for this long is an important achievement.
M146	Acknowledge the vital role you've played in making your program a success.
M147	It was your commitment to losing weight that got you started. It was your energy and persistence that kept you going.
M148	Giving yourself credit for what you've accomplished helps raise your confidence level so that you can manage whatever challenges may come along in the future.
M149	In the months and years ahead, take time to occasionally reconfirm your commitment to weight control. Enjoy your journey.
M150	Review your reasons for wanting a healthy weight and the benefits you receive from a healthier lifestyle.



Message Format:

Weekly motivational messages will be sent as an email or text message.

Message Sources: *Mayo Foundation for Medical Education and Research, Eat Smart, Move More NC, Diabetes Prevention Program, Centers for Disease Control and Prevention, ChooseMyPlate.com*

Appendix 4.6. FIT Rx 90 support call script and tracking sheet

FIT Rx 90 Telephone Support Call

5As: Assess - Advice - Agree - Assist - Arrange

ID: _____ **Location:** _____ **Coach:** _____

Contact Information: Cell: _____ Work: _____ Home: _____

CALL # ____

Original Scheduled Date: _____ **Time:** _____

Reschedule Notes:

Call Result: Completed Declined Unable to Reach

Length of Call: _____ minutes (**Goal- 15-20 minutes**)

o **Introduction** – Shared purpose of calls: progress check-in, share successes and problem-solve any needed areas- will also verify call schedule

Assess—Advise: Physical Activity, Nutrition and Healthy Weight

< How would you rate your progress toward achieving your healthy weight goal?

(0-really struggling to 10-really successful) **Rating:** _____

- *Use Motivational Interviewing technique to explore rating*
- *Why didn't you rate your progress a _____ (a lower response 0-2)?*
- *What would it take for you to rate your progress a _____ (a higher response 8-10)?*

(This question helps identify areas of prior success and also helps inform potential actions for change.)

Notes on Rating:

< What is your current weight in pounds? _____ Pounds

< What is your goal weight by the end of program? _____ Pounds

Achieved/Maintaining \geq 10%? Yes No

(Refer to Target Weight Chart for Recommended Weight Goal: 5% loss=_____ ; 10% loss=_____)

< Have you been doing any tracking?

- Tracking Weight
- Tracking Physical Activity
- Tracking Fruits & Vegetables
- Tracking Fat
- Tracking Sugary Drinks
- Tracking Calories
- Other:

< Physical Activity - Aerobic & Muscle-Strengthening

Over the last week, how many total days did you do moderate-intensity aerobic activity?

Total Days: _____ (Recommended Goal: 5 or more days)

On average, how many minutes of aerobic activity did you do each of those days?

Average Minutes: _____ Current Total Minutes: _____
(Recommended Goal: 300 minutes)

Over the last week, on how many days did you do muscle strengthening activities?

Total Days: _____ (Recommended Goal: At least 2)

On average, how many minutes of muscle strengthening activity did you do on each of those days?

Average Minutes: _____ (Recommended Goal: 15 minutes)

< Fruits & Vegetables

How many days did you eat fruits and vegetables last week?

Total Days: _____ (Recommended Goal: 7 days)

On average, about how many servings of fruits and vegetables did you eat on each of those days?

Average Servings: _____ (Recommended Goal: 5 or more servings)

< Fats

Which of the following high-fat foods did you track over the past week?

- Add-ons
- Dairy
- Meat
- Fried Foods and Snacks
- Sweets and Desserts

< Sugary Drinks

Total # of Sweetened Juices:

Total # of Sweet Tea or Coffee Drinks:

Total # of Sodas:

<Calories

What are your recommended calories per day?

Average # of Calories:

Total # of Calories-Day 1:

Total # of Calories-Day 2:

Total # of Calories-Day 3:

Agree: Decision-Making and Goal-Setting to Meet Recommendations

Set SMART Goals (Specific, Measurable, Action-oriented, Realistic, and Time-based) for the next two weeks/until the next call

Physical Activity Goals:

Nutrition Goals:

Assist: Problem-Solve and Address Barriers to Goals

- What may make it difficult for you to achieve your goals?
- What would be helpful to overcome your barriers?

Arrange: Schedule Follow-Up on Progress

Next Call Date:

Additional Notes:



“Keeping the Weight Off After FIT Rx 90” ASSESSMENT

Please answer the below survey questions. Your answers will be used to help determine areas to continue to focus on during your weight loss program. All of the information you provide will remain private.

Well-Being

1. How do you feel? On a scale from 1-5, please circle the number on each item that indicates how you feel today. 1 being “not at all” and 5 being “very much so”.

Optimistic

1 2 3 4 5

1 2 3 4 5
Healthy

Stressed

1 2 3 4 5

1 2 3 4 5

Confident

Strong

1 2 3 4 5

1 2 3 4 5

Energetic

Disciplined

1 2 3 4 5

2. Overall, I would rate my health as:

- Excellent
- Good
- Average
- Fair
- Poor

3. My results from the first 3 months in the Fit-Rx90 program:

- Far exceeded my expectations
- Were better than I expected
- Met my expectations
- Were not as good as I expected
- Fell far short of my expectations

Physical Activity

4. Please rate your **physical activity/exercise progress** in the FIT Rx 90 program. On a scale from 0-10, please circle the number on each item that indicates your progress. 0 being “really struggling” and 10 being “really successful”.

0 1 2 3 4 5 6 7 8 9 10

5. On average, how many days do you exercise or do some type of physical activity?

- None
- 1-2 days per week
- 3-4 days per a week
- 5-7 days per a week

6. On the days you engage in physical activity, how long do you exercise?

- 1-5 minutes
- 16-30 minutes
- 31-45 minutes
- 46-60 minutes
- More than 60 minutes

7. On average, how many days per week do you do 60-90 minutes of moderate aerobic exercise (activity that get your heart and lungs working)?

_____ days

8. On average, how many days per week do you do muscle-strengthening exercises for your entire body?

_____ days

9. On average, how many days per week do you do stretches for your entire body?

_____ days

10. What are your barriers to maintaining an exercise program? Mark (x) all that apply.

- Knowledge
- Time
- Childcare
- Illness or health condition
- Other: _____
- None of the above. I am able to maintain a consistent exercise routine.

11. Do you have any injuries/pain that prevent you from participating in activities?

- Yes
- No

If yes, please describe:

Nutrition

12. Please rate your **healthy eating progress** in the FIT Rx 90 program. On a scale from 0-10, please circle the number on each item that indicates your progress. 0 being “really struggling” and 10 being “really successful”.

0 1 2 3 4 5 6 7 8 9 10

13. What are your barriers to maintaining a healthy eating program? Mark (x) all that apply.

- Knowledge – what to eat, how to prepare
- Time – cooking, shopping, preparing healthy meals
- Food cravings
- Emotional/stress eating
- Eating out
- Illness or health condition
- Other: _____
- None of the above. I am able to maintain a consistent healthy eating routine

*** Note: There are two additional nutrition surveys: 1) Dietary Intake Screener and 2) Beverage Questionnaire to complete. Both surveys are attached.**

Sleep

14. On average, how many hours of sleep do you get a night?

- Less than 5 hours
- 6-8 hours
- More than 8 hours

Weight Loss/Maintenance

15. Which of the following strategies do you use to lose or maintain your weight? Mark (x) how often you use each strategy.

Strategies	Never	Sometimes	Most of the Time	All of the Time
Weight-loss goal - Have a weight loss/maintenance goal				
Dietary goal - Have a fat and/or calorie goal that is consistent with your weight loss/maintenance goal				
Calorie balance - Use healthy eating and activity to keep a calorie balance				
Physical activity goal - Get at least 150 minutes of moderate-intensity physical activity per week				

Strategies	Never	Sometimes	Most of the Time	All of the Time
Exercise safety - Measure exertion and avoid injury				
Lifestyle activity - Engage in lifestyle activities (e.g., parking further away)				
Food substitutions - Make healthy substitutions for foods that are high in fat and calories				
Food Plate - Use the current MyPlate and its recommendations				
Regular pattern of eating - Eat three meals				
Portion Control - Use scales, measuring cups, and spoons				
Label Reading - Read nutrition labels				
Problem-solving - Brainstorm new solutions to problems that inhibit your progress				
Stress Reduction - Work on preventing stress and coping with unavoidable stress				
Relapse Prevention - Identify what causes slips and recover from them				
Positive Thinking - Identify your negative thoughts and talk back to them with positive ones				
Time Management - Practice strategies for fitting in exercise and healthy eating into your schedule				

Other Concerns

19. Please add any additional comments that concern you or that you would like to share about your health.

Thank you for taking the time to complete this survey.

Appendix 4.8. FIT Rx 90 dietary screener questionnaire

DIETARY SCREENER QUESTIONNAIRE

These questions are about foods you ate or drank during the past month, that is, the past 30 days. When answering, please include meals and snacks at home, at work or school, in restaurants, and anyplace else.

Mark an to indicate your answer. To change your answer, completely fill the box for the incorrectly marked answer (). Then mark an X in the correct one. Your answers are important.

- How old are you (in years)?

--	--	--	--

 years

- Are you male or female?

- Male
 Female

- During the past month, how often did you eat hot or cold cereals? *Mark one .*

- Never → Go to question 4.
 1 time last month
 2-3 times last month
 1 time per week
 2 times per week
 3-4 times per week
 5-6 times per week
 1 time per day
 2 or more times per day

- During the past month, what kind of cereal did you usually eat? – *Print cereal.*

- If there was another kind of cereal that you usually ate during the past month, what kind was it? – *Print cereal, if none leave blank.*

- During the past month, how often did you have any milk (either to drink or on cereal)? Include regular milks, chocolate or other flavored milks, lactose-free milk, buttermilk. Please do not include soy milk or small amounts of milk in coffee or tea. *Mark one .*

- Never → Go to question 8.
 1 time last month
 2-3 times last month
 1 time per week
 2 times per week
 3-4 times per week
 5-6 times per week
 1 time per day
 2-3 times per day
 4-5 times per day
 6 or more times per day

- During the past month, what kind of milk did you usually drink? *Mark one .*

- Whole or regular milk
 2% fat or reduced-fat milk
 1%, ½%, or low-fat milk
 Fat-free, skim or nonfat milk
 Soy milk
 Other kind of milk – *Print milk.*

- During the past month, how often did you drink regular soda or pop that contains sugar? Do not include diet soda. *Mark one .*

- Never
 1 time last month
 2-3 times last month
 1 time per week
 2 times per week
 3-4 times per week
 5-6 times per week
 1 time per day
 2-3 times per day
 4-5 times per day
 6 or more times per day



9 During the past month, how often did you drink 100% pure fruit juices such as orange, mango, apple, grape and pineapple juices? Do not include fruit-flavored drinks with added sugar or fruit juice you made at home and added sugar to. Mark one .

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

During the past month, how often did you drink coffee or tea that had sugar or honey added to it? Include coffee and tea you sweetened yourself and presweetened tea and coffee drinks such as Arizona Iced Tea and Frappuccino. Do not include artificially sweetened coffee or diet tea.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

During the past month, how often did you drink sweetened fruit drinks, sports or energy drinks, such as Kool-Aid, lemonade, Hi-C, cranberry drink, Gatorade, Red Bull or Vitamin Water? Include fruit juices you made at home and added sugar to. Do not include diet drinks or artificially sweetened drinks.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

During the past month, how often did you eat fruit? Include fresh, frozen or canned fruit. Do not include juices.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat a green leafy or lettuce salad, with or without other vegetables?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day



14 During the past month, how often did you eat any kind of fried potatoes, including french fries, home fries, or hash brown potatoes?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat any other kind of potatoes, such as baked, boiled, mashed potatoes, sweet potatoes, or potato salad?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat refried beans, baked beans, beans in soup, pork and beans or any other type of cooked dried beans? Do not include green beans.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat brown rice or other cooked whole grains, such as bulgur, cracked wheat, or millet? Do not include white rice.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, not including what you just told me about (green salads, potatoes, cooked dried beans), how often did you eat other vegetables?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you have Mexican-type salsa made with tomato?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day



20 During the past month, how often did you eat pizza? Include frozen pizza, fast food pizza, and homemade pizza.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you have tomato sauces such as with spaghetti or noodles or mixed into foods such as lasagna? Do not include tomato sauce on pizza.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat any kind of cheese? Include cheese as a snack, cheese on burgers, sandwiches, and cheese in foods such as lasagna, quesadillas, or casseroles. Do not include cheese on pizza.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat red meat, such as beef, pork, ham, or sausage? Do not include chicken, turkey or seafood. Include red meat you had in sandwiches, lasagna, stew, and other mixtures. Red meats may also include veal, lamb, and any lunch meats made with these meats.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat any processed meat, such as bacon, lunch meats, or hot dogs? Include processed meats you had in sandwiches, soups, pizza, casseroles, and other mixtures.

Processed meats are those preserved by smoking, curing, or salting, or by the addition of preservatives. Examples are: ham, bacon, pastrami, salami, sausages, bratwursts, frankfurters, hot dogs, and spam.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day



25 During the past month, how often did you eat **whole grain bread** including toast, rolls and in sandwiches? Whole grain breads include whole wheat, rye, oatmeal and pumpernickel. Do not include white bread.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

26 During the past month, how often did you eat **chocolate** or any other types of candy? Do not include sugar-free candy.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat **doughnuts**, sweet rolls, Danish, muffins, pan dulce, or pop-tarts? Do not include sugar-free items.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat **cookies, cake, pie or brownies**? Do not include sugar-free kinds.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat **ice cream or other frozen desserts**? Do not include sugar-free kinds.

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

During the past month, how often did you eat **popcorn**?

- Never
- 1 time last month
- 2-3 times last month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day



Appendix 4.9. FIT Rx 90 beverage questionnaire

Beverage Questionnaire

Instructions:

In the past month, please indicate your response for each beverage type by marking an "X" in the bubble for "how often" and "how much each time"

Subject ID _____

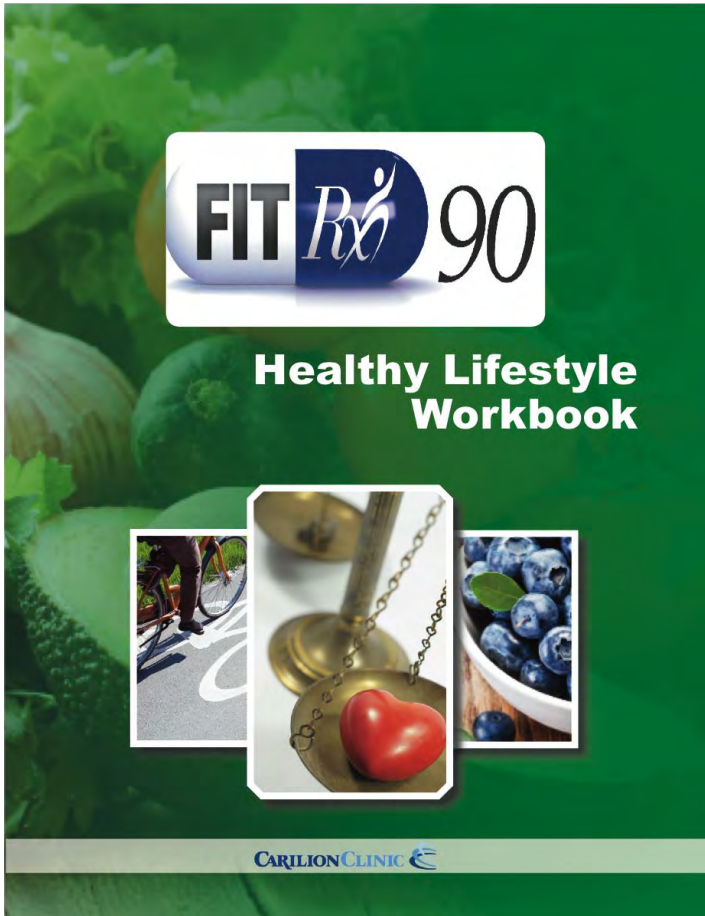
Date _____

1. Indicate how often you drank the following beverages, for example, you drank 5 glasses of water per week, therefore mark 4-6 times per week
2. Indicate the approximate amount of beverage you drank each time, for example, you drank 1 cup of water each time, therefore mark 1 cup under "how much each time"
3. Do not count beverages used in cooking or other preparations, such as milk in cereal
4. Count milk added to tea and coffee in the *tea/coffee with cream beverage category* **NOT** in the milk categories

Type of Beverage	HOW OFTEN (MARK ONE)							HOW MUCH EACH TIME (MARK ONE)				
	Never or less than 1 time per week (go to next beverage)	1 time per week	2-3 times per week	4-6 times per week	1 time per day	2+ times per day	3+ times per day	Less than 6 fl oz (3/4 cup)	8 fl oz (1 cup)	12 fl oz (1 1/2 cups)	16 fl oz (2 cups)	More than 20 fl oz (2 1/2 cups)
Water	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
100% Fruit Juice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sweetened Juice Beverage/ Drink (fruit ades, lemonade, punch, Sunny Delight)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Whole Milk	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reduced Fat Milk (2%)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Low Fat/Fat Free Milk (Skim, 1%, Buttermilk, Soy milk)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Soft Drinks, Regular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diet Soft Drinks/Artificially Sweetened Drinks (Crystal Light)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sweetened Tea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tea or Coffee, with cream and/or sugar (includes non-dairy creamer)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tea or Coffee, black, with/without artificial sweetener (no cream or sugar)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beer, Ales, Wine Coolers, Non-alcoholic or Light Beer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hard Liquor (shots, rum, tequila, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wine (red or white)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Energy & Sports Drinks (Red Bull, Rockstar, Gatorade, Powerade, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (list):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Virginia Polytechnic Institute and State University, 2010

Appendix 5.1. FIT Rx 90 program materials



MY FitRx90 ACTION PLAN

"The most important thing I will do today is to make a commitment to myself and develop a personal lifestyle plan to achieve a healthy weight!"



STEP: 1 WHAT MOTIVATES ME?

My most important reasons for achieving a healthy weight are:



STEP 2: MY WEIGHT LOSS GOAL

My Current Weight	My 9-Month Goal Weight	My 90 Day Goal Weight	Pounds to Lose Each Month
_____ pounds	_____ pounds	_____ pounds	_____ pounds



STEP 3a: MY PHYSICAL ACTIVITY GOAL

Health experts agree that you should do **60 minutes** of aerobic activities on **5 days** each week. You should also include about **15 minutes** of muscle strengthening activities on **2 days** each week.

To meet this recommendation, I will start slowly at my own level and gradually work my way up.

Aerobic Activities	
I am currently doing:	I will begin doing:
_____ minutes	_____ minutes
_____ days each week	_____ days each week
Muscle Strengthening Activities	
I am currently doing:	I will begin doing:
_____ minutes	_____ minutes
_____ days each week	_____ days each week



A-10

What's Your Target Weight?

My Current Weight (pounds)	My 9-Month Goal Weight	My 90 Days Goal Weight	Pounds to Lose Each Month	My Current Weight (pounds)	My 9-Month Goal Weight	My 90 Days Goal Weight	Pounds to Lose Each Month
130	117	124	1.4 - 2.0	300	270	285	3.3 - 5.0
135	122	128	1.4 - 2.3	305	275	290	3.3 - 5.0
140	126	133	1.6 - 2.3	310	279	295	3.4 - 5.0
145	131	138	1.6 - 2.3	315	284	299	3.4 - 5.3
150	135	143	1.7 - 2.3	320	288	304	3.6 - 5.3
155	140	147	1.7 - 2.7	325	293	309	3.6 - 5.3
160	144	152	1.8 - 2.7	330	297	314	3.7 - 5.3
165	149	157	1.8 - 2.7	335	302	318	3.7 - 5.7
170	153	162	1.9 - 2.7	340	306	323	3.8 - 5.7
175	158	166	1.9 - 3.0	345	311	328	3.8 - 5.7
180	162	171	2.0 - 3.0	350	315	333	3.9 - 5.7
185	166	175	2.1 - 3.3	355	320	337	3.9 - 6.0
190	171	180	2.1 - 3.3	360	324	342	4.0 - 6.0
195	175	185	2.2 - 3.3	365	329	347	4.0 - 6.0
200	180	190	2.2 - 3.3	370	333	352	4.1 - 6.0
205	184	194	2.3 - 3.7	375	338	356	4.1 - 6.3
210	189	199	2.3 - 3.7	380	342	361	4.2 - 6.3
215	193	204	2.4 - 3.7	385	347	366	4.2 - 6.3
220	198	209	2.4 - 3.7	390	351	371	4.3 - 6.3
225	202	213	2.6 - 4.0	395	356	375	4.3 - 6.7
230	207	218	2.6 - 4.0	400	360	380	4.4 - 6.7
235	211	223	2.7 - 4.0	405	365	385	4.4 - 6.7
240	216	228	2.7 - 4.0	410	369	390	4.6 - 6.7
245	220	233	2.8 - 4.0	415	374	394	4.6 - 7.0
250	225	237	2.8 - 4.3	420	378	399	4.7 - 7.0
255	229	242	2.9 - 4.3	425	383	404	4.7 - 7.0
260	234	247	2.9 - 4.3	430	387	409	4.8 - 7.0
265	239	252	2.9 - 4.3	435	392	413	4.8 - 7.3
270	243	257	3.0 - 4.3	440	396	418	4.9 - 7.3
275	248	261	3.0 - 4.7	445	401	423	4.9 - 7.3
280	252	266	3.1 - 4.7	450	405	428	5.0 - 7.3
285	257	271	3.1 - 4.7	455	410	432	5.0 - 7.7
290	261	276	3.2 - 4.7	460	414	437	5.1 - 7.7

Appendix 6.1. Components of CME and CME Plus training planned and completed during pilot phase

Training Components	Description	CME Training		CME Plus Training	
		Planned	Completed	Planned	Completed
Instructive workshop conducted during professional development	<ul style="list-style-type: none"> A 2 ½ hours training session, led by the research team, providing an overview of the healthy lifestyle, clinical weight loss intervention, along with nutrition, physical activity, and intensive behavioral therapy recommendations for weight management 	√	√	√	√
Distribution of facilitator materials for nurse care coordinators (electronic format)	<ul style="list-style-type: none"> Twenty lesson plans and guided scripts for facilitating either in-person or telephone sessions Teach-back questions to assess patient understanding of each session’s material Electronic health record smart-phrase templates for documenting implementation of each session’s components and patient progress Program evaluation forms for each session 	√	√	√	√
Distribution of patient education materials (electronic format)	<ul style="list-style-type: none"> Twenty session healthy lifestyle workbook adapted from the national Diabetes Prevention Program Patient action plan form, including goal-setting and problem-solving to reach weight, physical activity, and nutrition recommendations Target weight chart (5-10% initial body weight loss at 6- and 12-months) Commitment contract for program engagement to be signed by Care Coordinator and patient Tracking logs for documenting aerobic and muscle-strengthening activity, fruit and vegetable, high fat food, calorie, and sugar-sweetened beverage consumption Appendix materials including muscle-strengthening exercises and strategies to overcome obstacles for lifestyle change 	√	√	√	√
Behavioral rehearsal of patient sessions	<ul style="list-style-type: none"> Role-playing of initial core program sessions; nurse care coordinators taking turns acting as facilitator and patient Role-playing of post-core program sessions; research team and experienced nurse care coordinators taking turns acting as facilitator and patient 	√	√	√	√

Training Components	Description	CME Training		CME Plus Training	
		Planned	Completed	Planned	Completed
Consultation with nurse care coordinators during regularly scheduled team meetings	<ul style="list-style-type: none"> Four ninety-minute consultee-centered sessions, led by the research partners using adapted 5As (Assess, Advise, Agree, Assist, and Arrange) format, at 1-3-6-and 12-months post-initial workshop training Additional technical assistance (i.e., questions and answers) offered by research team to support the implementation of the clinical weight loss intervention 			√	√
Action planning	<ul style="list-style-type: none"> Personal action plan form for nurse care coordinators to identify reach goals for patient engagement at 1-3-6 and 12-months post initial training session, barriers to patient engagement, and strategies to overcome obstacles at their practice site; Completion of form facilitated by research team Regional action plan form for nurse care coordinators to identify composite reach goals for patient engagement at 1-3-6 and 12-months post initial training session, summarize barriers to patient engagement, and strategies to overcome obstacles throughout the practice region; Completion of form facilitated by research team 			√	√
Case review	<ul style="list-style-type: none"> Thirty minute panel discussions led by research team with nurse coordinators adopting the intervention to reflect and provide feedback on a patient case (n=4); Occurred at 3-and 6-months consultations; Topics included: recruitment, method of delivery, session progress, adaptations, level of patient engagement, behavior and weight change 			√	√
Feedback	<ul style="list-style-type: none"> Reports to nurse care coordinators of implementation strategies found to be successful in practices and patient success stories with weight loss and behavior change: Conducted by senior care coordinator team during monthly meetings and encounters 		√	√	√

Notes. √-Yes, documentation of implementation by integrated research-practice partnershi

Appendix 6.2. Smartphrase template used by nurse care coordinators to document session activity in the electronic health record

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 1

Patient identified by name and date of birth.

Patient's Main Concern Today:

Medications and allergies reviewed and updated?	{YES NO WITH COMMENT:10726712}
Side effects or problems with costs of meds?	{AMB YES NO:2100::"no"}
Current tobacco use?	@TOBHXP@
Exercise level?	{exercise level:31265}
Current diet?	{Desc; diets:16563}

Psychosocial /Safety:
Adequate support system? {yes no:314532}
Feels safe in home? {yes no:314532}
Falls in the last 6 months? {AMB YES NO:2100}
Advanced directive? {yes no:314532}
Learning barriers? {BARRIERS TO LEARNING MED ED:2100018877}

Patient Education:
Reviewed unwanted outcomes of obesity such as diabetes, hypertension, heart disease, cancer, joint and mobility problems, poor sleep, and increased healthcare costs. Advised that losing 10% of body weight will decrease chances of these negative outcomes and improve quality of life. Reviewed weight loss strategies of aerobic exercise, muscle strengthening, and healthy eating using MyPlate.
Patient verbalized understanding of above education using teach-back method.

Action Plan:
Patient motivators: ***

Weight loss goal: * pounds over the next 12 months (or *** pounds per month)**
Current aerobic physical activity: *** minutes per day; *** days per week

Aerobic physical activity goal: * minutes per day; *** days per week**
Current muscle strengthening activity: *** minutes per day; *** days per week

Muscle strengthening goal: * minutes per day; *** days per week**
Current servings of fruits and vegetables per day: ***

Fruit and Vegetable Goal: * servings per day**

Wrap Up:
Patient signed contract committing to participate in Healthy Lifestyles Program. Copy of contract and Action Plan given to patient to keep.
Patient to complete physical activity and food tracking logs for next session. Will follow up with patient in 1 week to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 2

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

Patient Education:

Reviewed benefits of physical activity. Some of these benefits include helping to lose weight and keep it off, improving mood, sleeping better, and lower risk of diseases (such as diabetes, heart disease, and some cancers). Discussed that one goal of program is to have participant work up to 60 minutes of moderate intensity physical activity 5 days per week and to perform muscle strengthening activities 2 times per week. Reviewed importance of setting goals that are realistic, time based, and specific.

Patient verbalized understanding of above education using teach-back method.

Action Plan (Continued from Session 1):

Obstacles to achieving physical activity goal: ***

Strategies to overcome obstacles: ***

Obstacles to reaching fruit and vegetable goal: ***

Strategies for overcoming obstacles: ***

Tools and resources: ***

Wrap Up:

Patient instructed to complete “How Active Am I Now” and “Make a Plan to Be Active” assignments this week. Also instructed to review exercise safety information provided and continue to track physical activity and fruits/vegetables in tracking log. Will follow up with patient in 1 week to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 3

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

Patient Education:

Reviewed common barriers to physical activity including not having enough time and not enjoying exercise. Discussed lifestyle changes to help add physical activity into the day (taking the stairs instead of the elevator, parking at the back of the parking lot, riding stationary bike or jumping rope while watching TV, taking a walk during lunch break). Discussed strategies for making exercise more enjoyable. Introduced “talk test” as a way of determining the intensity of physical activity. One should be able to carry on a conversation during moderate intensity physical activity but not sing a song.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete handouts titled Overcoming Barriers, Find Time to Be Active, Lifestyle Activity, and Make a Plan to Be Active before next week’s session. Also reminded to continue to track physical activity and fruits/vegetables in tracking log. Will follow up with patient in 1 week to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 4

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

Patient Education:

Reviewed healthy eating using the My Plate method. Discussed the recommendation that half of the plate should be made up of fruits and vegetables. Also reviewed recommendations for grains, dairy, and protein as part of a healthy meal. Discussed importance of cutting back on foods high in fat, added sugars, and salt. Encouraged regular meal times and a slow pace when eating. Advised to be aware of portion sizes and keep them reasonable.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete handouts titled What's On Your Plate, Build Your Own Healthy Meal and Rate Your Plate before next week's session. Also reminded to continue to track physical activity and fruits/vegetables in tracking log. Will follow up with patient in 1 week to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 5

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

Patient Education:

Discussed dietary fat and the importance of monitoring how much fat is eaten. Reviewed reading labels as a way to find hidden fats in food. Discussed tips for limiting the amount and type of fat that is eaten: avoid eating too many pastries, cakes, and cookies; pick leaner types of meat like chicken or turkey; choose fat-free or low-fat milk, yogurt, and cheese; enjoy “meatless Mondays”; use lower-fat methods of cooking such as baking, grilling, roasting, and broiling instead of frying; and try flavoring foods with spices instead of high fat dressings or toppings.

Patient verbalized understanding of above education using teach-back method.

Action Plan:

Aerobic physical activity goal: * minutes per day; *** days per week**

Muscle strengthening goal: * minutes per day; *** days per week**

Obstacles to achieving physical activity goal: ***

Strategies to overcome obstacles: ***

Fruit and Vegetable Goal: * servings per day**

Obstacles to reaching fruit and vegetable goal: ***

Strategies for overcoming obstacles: ***

Wrap Up:

Patient instructed to complete the handouts titled Practicing to Be A Fat Detective, Reading Your Labels, and Ways to Eat Less Fat. Reminded to continue to track physical activity and fruits/vegetables, and instructed to start tracking high fat foods using tracking log. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 6

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Patient Education:

Discussed monitoring sugar in the foods eaten, and reviewed the difference between natural sugars and added sugars. Advised cutting back on foods with added sugar. Reviewed reading nutrition labels and ingredient lists to find hidden sugars. Encouraged cutting back on sugary drinks and choosing water or unsweetened flavored soda water instead.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete handouts titled Rethink Your Drink and Find the Added Sugars before the next session. Patient to continue tracking physical activity, fruits/vegetables, and high fat foods, and instructed to start tracking sugary drinks using the provided tracking log. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 7

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Patient Education:

Discussed that getting to and keeping a healthy body weight is all about balancing the amount of calories consumed with the amount of calories burned during physical activity. To lose weight, the number of calories consumed must be less than the calories used during daily activity. Reviewed strategies of controlling portion size, tracking calories consumed, and switching out high calorie foods for lower calorie foods.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled Guess the Calories before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and instructed to start tracking calories using the provided tracking log. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 8

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed triggers that can lead to slipping back into unhealthy eating habits and a less active lifestyle. Reviewed example red light triggers such as not having time, feeling tired, keeping junk food in the house, and eating at the buffet in a restaurant. Gave examples of green light triggers such as scheduling physical activity on the calendar, keeping walking shoes by the door, having cut up vegetables in the refrigerator, and keeping fresh fruit on the counter that can help to overcome red light triggers. Encouraged patient to identify red light triggers in their life and come up with strategies for replacing the red light triggers with green light triggers. Recommended developing a motivational message to help provide encouragement when encountering triggers that might lead to unhealthy choices. Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled Thinking About Activity Cues before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NO

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 9

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed 5 steps of problem solving. Patient encouraged to try to find the action or behavior chain that led to the problem. Discussed brainstorming options to solve problem and picking one option to try. Reviewed developing a positive action plan to try. If action plan does not work, patient encouraged to problem solve again. Reinforced that problem solving is a process and that patient should not give up.

Also discussed tips for eating out while trying to lose weight. Provided tips for choosing healthier options when eating in restaurant.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled Problem Solving Practice before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 10

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed negative thoughts and how they can stand in the way of progress towards a goal. Talked about importance of stopping negative thoughts as they happen and instead talking back with positive thoughts. Reviewed how excuses are one type of negative thinking that can allow one to stray from what is healthy and productive. Discussed strategies for overcoming negative thoughts and excuses.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled Practice Talking Back before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 11

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed ways to jump start activity routine to re-energize and avoid slipping back into old habits. Reviewed ways to add variety to exercise plan and improve aerobic fitness. Reviewed how aerobic fitness means the heart does a good job of pumping oxygen through the blood to other muscles. Talked about the acronym FITT to remember that the frequency, intensity, time, and type of aerobic activity is important. Reviewed using the talk test to measure intensity of exercise.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled Preventing Boredom before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 12

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed definition of social cues as occasions that trigger us to behave in a certain way around other people. The way we respond to social cues are often habits that have been formed over time and may be hard to break. Reviewed healthy ways to deal with social cues: staying away from the cue, changing the cue, and practicing responding in healthier ways to offers of unhealthy foods. Also discussed ways to add helpful cues such as spending time with others who make healthy food choices and lead active lifestyles. Provided tips for making special events and celebrations fun while still making healthy lifestyle choices.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handouts titled *What are Social Cues*, *Getting Support From Others*, *My Problem Social Cues*, *My Helpful Social Cues*, and *For Special Events* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 13

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed stress and how it occurs when we allow events or situations in our lives to overwhelm our ability to cope with them. Stress can occur with any change: good or bad, big or small. Reviewed forms of stressors: physical, environmental, social and emotional. Provided tips for decreasing stress such as saying no, planning ahead, relying on others for support, and staying physically active. Discussed stress related to following the Healthy Lifestyle program, and ways to overcome those stressors so that patient can achieve goals.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handouts titled *Stress In Your Life*, *Managing Stress*, and *Your Plan For Stress* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 2 weeks to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 14

Patient identified by name and date of birth.

Weekly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Congratulated patient for making it this far in the Healthy Lifestyle program. Discussed importance of staying motivated to continue to achieve health and weight loss goals, and provided tips for keeping motivation. Assisted patient in developing an action plan for staying motivated through the rest of the program.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handouts titled *Progress Review* and *My Mini-Plan For Staying Motivated* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 1 month to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 15

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed mindful eating and how that means choosing enjoyable foods that are also good for the body and focusing the senses to find pleasure in the food eaten. Mindful eating also means being aware of levels of hunger and fullness. Reviewed benefits of mindful eating such as preventing overeating, improving the experience of eating, and learning how to ignore urges to snack that aren't linked with hunger. Provided tips for eating mindfully: eat slowly, focus on food, create calm eating environment, and learn to refocus on food after a distraction.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handout titled *Practice Eating Mindfully* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 1 month to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 16

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed stress and time management in today's session. Reviewed how stress is not always negative--events such as a wedding or birth can be positive stressors. Discussed how too much stress can have a negative effect on the body and mind and may be a barrier to making changes to exercise and eating behaviors.

Reviewed tips for lowering stress levels: set boundaries and practice saying no; plan ahead and organize schedule; and keep a positive attitude and remember the good things in life.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handouts titled *Assess Your Stress*, *How Do I Spend My Time*, and *What Will I Do With My Time* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 1 month to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 17

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed how sitting too much, either on the job, or during free time, has some serious health consequences. People who sit a lot tend to weigh more, have a higher risk for getting diabetes, have higher blood pressure, and have unhealthy levels of blood fats and higher blood sugar. Reviewed ways to avoid sedentary lifestyle and to incorporate physical activity into work and leisure time.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to complete the handouts titled *What's in Your Week* and *Lifestyle Activity* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 1 month to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 18

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Reviewed that fiber is a part of plant foods that our bodies can't digest. It is found in whole grains, fruits/vegetables, beans, nuts, and seeds. Foods high in fiber tend to be low in fat and calories. They also need to be chewed which slows down the eating process. Fiber also absorbs water which creates bulk and can help you feel full. Discussed how by incorporating fiber and increasing the volume of food, one can consume fewer calories while enjoying a satisfying portion of food and keeping hunger in check.

Discussed ways to increase the volume in meals: adding fruits/veggies to increase water and fiber, adding water to dishes cooked, eating more salads, and adding legumes to dishes.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to review the handout titled *Ways to Increase Volume in Your Meals* before the next session. Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories. Will follow up with patient in 1 month to discuss progress towards goals and to continue weight loss education.

@ME@ @TD@ @NOW@

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 19

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Discussed how well-rounded physical fitness is made up of four basic components: cardiovascular fitness, flexibility, muscular strength, and muscular endurance. Reviewed how muscle-strengthening (or strength training) is any type of physical activity in which muscles are moved against resistance.

Discussed the benefits of muscle strengthening: increases strength and endurance, minimizes loss of muscle tissue associated with aging, assists with maintaining bone strength, improves sense of well being, and reduces the risk of injury. Reviewed ways to warm up and cool down before and after muscle strengthening exercises.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Patient instructed to try to get in 2-3 days of muscle strengthening per week over the next few weeks.

Patient to continue tracking physical activity, fruits/vegetables, high fat foods, sugary drinks, and calories.

Will follow up with patient in 1 month for final session of Healthy Lifestyles program.

Care Coordination Visit
Healthy Lifestyles Weight Management Program
Session 20

Patient identified by name and date of birth.

Monthly Review

Patient reported weight: ***

Patient weight at start of program: ***

Total weight loss during program: ***

Aerobic physical activity performed *** days in the past week for *** minutes each time.

Muscle strengthening activity performed *** times in the past week.

Fruits/Vegetables eaten *** days in the past week. *** servings eaten each day.

High fat foods eaten in the past week:

Add-Ons: *** times

Dairy: *** times

Meats: *** times

Fried Food: *** times

Sweets: *** times

Sugary Drinks consumed in the past week:

Sweetened Juices: ***

Sweet Tea or Coffee: ***

Soda or Energy Drinks: ***

Total Calories Consumed:

Day 1: ***

Day 2: ***

Day 3: ***

Patient Education:

Congratulated patient on making it to the last week of the Healthy Lifestyles program. Discussed how making lifestyle changes for weight management involves an on-going self-review process that includes looking back at old habits or ways of thinking and looking forward to new approaches for lifestyle change. Research shows that people who have been successful at losing weight have several things in common: weighing more than once per week, having a plan for getting back on track when regain occurs, regular eating patterns, and regular physical activity.

Discussed setting long term weight loss or maintenance goals and tips for reaching those goals.

Encouraged continued tracking of food intake and physical activity once program complete.

Patient verbalized understanding of above education using teach-back method.

Wrap Up:

Encouraged patient to complete *Long-Term Goals* and *Tell Your Story* activities. Patient encouraged to call care coordinator for weight loss questions or concerns in the future and follow up as needed.

@ME@ @TD@ @NOW@

Appendix 6.3. Structure, content, and 5As to be addressed in Healthy Lifestyles clinical weight loss intervention

Structure			Session Topic	Assess	Advise	Agree	Assist/Arrange
Core Phase	Month 1	Weekly - Session 1	<i>Welcome & Action Plan Part I</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Initial body weight loss Benefits of weight loss, physical activity, and healthy eating 	<u>Action Plan</u> <ul style="list-style-type: none"> Motivation for weight loss Weight loss goal (total pounds and pounds per month) Days and minutes of aerobic and muscle-strengthening activity Days and servings of fruits and vegetables 	<ul style="list-style-type: none"> Partner with patient on commitment contract Instruct patient to track physical activity and fruit and vegetable intake Schedule patient follow-up in one week
		Weekly - Session 2	<i>Move those Muscles & Action Plan Part II</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Benefits and types of physical activity Safe and easy stretches Importance of goal-setting and tracking 	<u>Action Plan</u> <ul style="list-style-type: none"> Strategies to overcome obstacles for physical activity and healthy eating Tools and resources to reach goals (people, places, and equipment) 	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Review exercise safety and tracking log progress Instruct patient to track physical activity and fruit and vegetable intake Schedule follow-up in one week
		Weekly - Session 3	<i>Be Active</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Strategies to be more active each day Include the F.I.T.T principles (frequency, intensity, time & type of PA) in activity plan 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity and fruit and vegetable intake

Structure		Session Topic	Assess	Advise	Agree	Assist/Arrange
Core Phase						<ul style="list-style-type: none"> Schedule follow-up in one week
		Weekly - Session 4	<i>Healthy Eating with My Plate</i> <ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Recommend following <i>My Plate</i> dietary guidelines How to read nutrition labels Simple switches to healthy eating 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity and fruit and vegetable intake Schedule follow-up in one week
	Month 2	Bi-Weekly - Session 5	<i>Be a Fat Detective</i> <ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Understand different types of fat Identify hidden and added fats Complete nutrition label reading activity 	<u>Action Plan</u> <ul style="list-style-type: none"> Days and minutes of aerobic and muscle-strengthening activity Days and servings of fruits and vegetables Strategies to overcome obstacles for physical activity and healthy eating 	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, and high fat foods intake Schedule follow-up in one week
	Bi-Weekly - Session 6	<i>Be a Sugar Detective</i> <ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods 	<ul style="list-style-type: none"> Understand added sugars and empty calories Complete finding added sugars in nutrition labels activity 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, and sugar sweetened-beverage intake Follow-up in two weeks 	

Structure			Session Topic	Assess	Advise	Agree	Assist/Arrange
Core Phase	Month 3	Bi-Weekly - Session 7	<i>Tipping the Calorie Balance</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages 	<ul style="list-style-type: none"> Understand calorie balance, energy requirements, and portion control Strategies for lowering calorie intake 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in two weeks
		Bi-Weekly - Session 8	<i>Taking Charge of What's Around You</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Understand healthy and unhealthy food and activity cues Develop plan to handle unhealthy cues 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in two weeks
	Month 4	Bi-Weekly - Session 9	<i>Problem-Solving & 4 Keys to Healthy Eating Out</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Learn 5 steps to problem solving Action planning to resolve common physical activity and diet-related problems Overcome common challenges for eating healthy in restaurants Ask for what you want when eating out 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in two weeks

Structure		Session Topic	Assess	Advise	Agree	Assist/Arrange
	Bi-Weekly - Session 10	<i>Talk Back to Negative Thoughts & Slippery Slope of Lifestyle Change</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening activity • Fruit and vegetables • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • Motivational thinking to keep away from the negative spiral • Ways to break negative thoughts • How to recover from common slips • Action planning to recover from slips 	N/A	<ul style="list-style-type: none"> • Provide instructions on completing workbook activities • Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake • Follow-up in two weeks
Month 5	Bi-Weekly - Session 11	<i>Jump Start Your Activity Plan</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening activity • Fruit and vegetables • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • Overcoming lack of motivation • Revisit F.I.T.T. principles • Practicing the “talk-test” to measure intensity during PA 	N/A	<ul style="list-style-type: none"> • Provide instructions on completing workbook activities • Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake • Follow-up in two weeks
	Bi-Weekly - Session 12	<i>Make Social Cues Work for You</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening activity • Fruit and vegetables • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • How to create social support and identify a friend/family member to support healthy lifestyles • Planning for social events 	N/A	<ul style="list-style-type: none"> • Provide instructions on completing workbook activities • Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake • Follow-up in two weeks
Month 6	Bi-Weekly	<i>You Can Manage Stress</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening 	<ul style="list-style-type: none"> • Identifying where stress begins • Tips to handle stress 	N/A	<ul style="list-style-type: none"> • Provide instructions on completing workbook activities

Structure			Session Topic	Assess	Advise	Agree	Assist/Arrange
		- Session 13		<ul style="list-style-type: none"> activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Action planning to handle common personal stressors 		<ul style="list-style-type: none"> Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in two weeks
		Bi- Weekly - Session 14	<i>Ways to Stay Motivated</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Review of progress and achievements over the past 6-months Steps to stay motivated during post-core phase Identify personal motivators and healthy ways to reward success 	<p><u>Action Plan</u></p> <ul style="list-style-type: none"> Motivation for ongoing weight loss or weight loss maintenance Weight loss/maintenance goal (total pounds and pounds per month) Days and minutes of aerobic and muscle-strengthening activity Days and servings of fruits and vegetables Strategies to overcome obstacles for physical activity and healthy eating 	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in one month
Post-Core	Month 7	Monthly - Session	<i>Mindful Eating</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening 	<ul style="list-style-type: none"> Discuss what mindful eating means and how it benefits weight loss 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities

Structure		Session Topic	Assess	Advise	Agree	Assist/Arrange	
Phase		15		<ul style="list-style-type: none"> activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Practice ways to eat slowly and mindfully at home 		<ul style="list-style-type: none"> Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in one month
	Month 8	Monthly - Session 16	<i>Stress and Time Management</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Revisit triggers for stress and ways to handle them Strategies to better manage time and stress Develop a schedule and plan to help manage time for more physical activity 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in one month
	Month 9	Monthly - Session 17	<i>Standing Up for Your Health</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables High fat foods Sugar-sweetened beverages Calorie consumption for three days 	<ul style="list-style-type: none"> Discuss sedentary behavior and importance of standing instead of sitting Track the amount of time spent sitting over 1 week and reflect on it Identify ways to lower sitting time 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake Follow-up in one month
	Month 10	Monthly - Session	<i>More Volume, Fewer Calories</i>	<ul style="list-style-type: none"> Weight Aerobic and muscle-strengthening activity Fruit and vegetables 	<ul style="list-style-type: none"> Introduce concept of volumetrics and the difference between “calorie-dense” and “nutrient-dense” foods 	N/A	<ul style="list-style-type: none"> Provide instructions on completing workbook activities Instruct patient to track physical activity, fruit and

Structure		Session Topic	Assess	Advise	Agree	Assist/Arrange
	18		<ul style="list-style-type: none"> • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • Discuss role, benefits, and importance of eating more fiber 		<ul style="list-style-type: none"> • vegetable, high fat foods, sugar-sweetened beverage, and caloric intake • Follow-up in one month
Month 11	Monthly - Session 19	<i>Strengthen Your Exercise Program</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening activity • Fruit and vegetables • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • Discuss components of a well-rounded physical fitness program and benefits of muscle strengthening activities • Review muscle strengthening guidelines 	N/A	<ul style="list-style-type: none"> • Provide instructions on completing workbook activities • Instruct patient to track physical activity, fruit and vegetable, high fat foods, sugar-sweetened beverage, and caloric intake • Follow-up in one month
Month 12	Monthly- Session 20	<i>Looking Back and Looking Forward</i>	<ul style="list-style-type: none"> • Weight • Aerobic and muscle-strengthening activity • Fruit and vegetables • High fat foods • Sugar-sweetened beverages • Calorie consumption for three days 	<ul style="list-style-type: none"> • Emphasize lifestyle changes involve an on-going self-review process • Reflection on self-awareness, personal responsibility, and willingness to continue with behavior changes 	<p><u>Action Plan</u></p> <ul style="list-style-type: none"> • Motivation for ongoing weight loss or maintenance • Weight loss/maintenance goal • Days and minutes of aerobic and muscle-strengthening activity • Days and servings of fruits and vegetables • Strategies to overcome obstacles 	<ul style="list-style-type: none"> • Provide instructions on setting long-term goals • Ask if you may share patient's healthy lifestyle-weight loss journey with other patients • Encourage patient to call if additional assistance is needed

Appendix 6.4. Training evaluation for nurse care coordinators administered post-workshop

HEALTHY LIFESTYLE WEIGHT LOSS PROGRAM
NURSE CARE COORDINATOR TRAINING EVALUATION

Please offer your feedback on today's training (X).

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The training met my expectations.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I will be able to apply the knowledge learned.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. The content was organized and easy to follow.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. The trainers were knowledgeable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Participation and interaction were encouraged.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Adequate time was provided for questions and discussion.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Overall, how do you rate today's training?	Excellent	Good	Average	Poor	Very Poor
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. What aspects of today's training were most valuable for you?

9. What aspects of today's training could be improved?

(Over >)

Confidence Ratings

Circle your rating on a scale from 0 to 10. 0= “Not at all confident” 10 = “Very confident”

10. After today’s training, how confident are you in implementing the healthy lifestyle weight loss program with your patients?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

11. How confident are you that you will be able to reach 10 or more patients in the coming year to offer the healthy lifestyle weight loss program?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

12. How confident are you that you will be able to reach 20 or more patients in the coming year to offer the healthy lifestyle weight loss program?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

13. How confident are you that you will be able to reach 30 or more patients in the coming year to offer the healthy lifestyle weight loss program?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

14. How confident are you that you will be able to reach 40 or more patients in the coming year to offer the healthy lifestyle weight loss program?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

15. How confident are you that you will be able to reach 50 or more patients in the coming year to offer the healthy lifestyle weight loss program?

Confidence Level	0	1	2	3	4	5	6	7	8	9	10
-------------------------	---	---	---	---	---	---	---	---	---	---	----

16. Any additional comments? _____

Thank you for taking the time to offer your valuable feedback!

Appendix 6.5. Sample program evaluation for nurse care coordinators to provide feedback on session delivery

CARILION CLINIC * CARE COORDINATOR PROGRAM EVALUATION

SESSION #1: ACTION PLAN

Session Date: _____

Patient’s MRN#: _____

Coordinator Initials: _____

1. How well do you think the session met each of the objectives?

Circle your rating on a scale from 1 to 10.

1= “did not meet objective” 10 = “completely met the objective”

At the end of the session, patients will be able to:										
Describe the expectations of the program	1	2	3	4	5	6	7	8	9	10
Identify the benefits of losing 10% of initial body weight	1	2	3	4	5	6	7	8	9	10
Describe aerobic and muscle strengthening exercises	1	2	3	4	5	6	7	8	9	10
Identify healthy eating strategies based on MyPlate	1	2	3	4	5	6	7	8	9	10
Initiate a personal action plan for weight loss	1	2	3	4	5	6	7	8	9	10

2. What lesson plan and workbook sections were discussed during the session? Check all that apply.

- Weight Loss Strategies - 10% Initial Body Weight
- Introduction to Physical Activity Guidelines
- Introduction to Healthy Eating - MyPlate Guidelines
- Program Contract
- Tracking Log

3. What activities were introduced during the session? Check all that apply.

- Action Plan: Step 1: What Motivates Me?
- Action Plan: Step 2: My Weight Loss Goal
- Action Plan: Step 3a: My Physical Activity Goal
- Action Plan: Step 4: My Healthy Eating Goal
- Teach-Back

4. Did you add any additional activities, props or other materials to the session?

- Yes
- No

If yes, please note additions:

5. Overall, how engaged was your patient in this session?

Circle your rating on a scale from 1 to 10.

1= "Not at all engaged" 10 = "Completely engaged"

Patient Engagement Level	1	2	3	4	5	6	7	8	9	10
---------------------------------	---	---	---	---	---	---	---	---	---	----

Please explain.

6. What worked best for this session?

7. Any suggestions and/or ideas for improving this session?

Thank you for taking the time to offer your valuable feedback!

Appendix 6.6. Sample Smartphrase chart extraction form for implementation quality based on the 5As

Healthy Lifestyle Weight Management Program		Chart Reviewer ID: _____	
Session 2 Extraction Form		Extraction Date: ___/___/___ Patient Study ID: _____	
Visit Date: ___/___/___		Format: In-Person, Phone, MyChart	
Care Coordinator ID: _____		Practice ID: _____ Region ID: _____	
ASSESS	Implementation (X) <input type="checkbox"/> Completed <input type="checkbox"/> Partially Completed <input type="checkbox"/> Not Completed		
	Care Coordinator Delivery:		
Weekly Review	Yes (X)	No (X)	Patient Outcome/Value:
Patient weight			_____ lbs
Aerobic physical activity performed			_____ days in the past week for _____ min/time
Muscle strengthening activity performed			_____ times in past week
Fruits/vegetables eaten			_____ days in the past week _____ servings eaten each day
ADVISE	Implementation (X) <input type="checkbox"/> Completed <input type="checkbox"/> Partially Completed <input type="checkbox"/> Not Completed		
	Care Coordinator Delivery:		
Patient Education	Yes (X)	No (X)	Comments:
Reviewed benefits of physical activity			
Discussed that one program goal is to have participant work up to 60 min. of moderate intensity PA 5 days/week and to perform strengthening activities 2 times/week			
Reviewed importance of setting goals that are realistic, time based, and specific			
Patient verbalized understanding of above education using teach-back method			

AGREE	Implementation (X) <input type="checkbox"/> Completed <input type="checkbox"/> Partially Completed <input type="checkbox"/> Not Completed		
	Care Coordinator Delivery:		Comments:
<i>Action Plan</i>	Yes (X)	No (X)	
Obstacles to achieving physical activity goal			
Strategies to overcome obstacles			
Obstacles to reaching fruit and vegetable goal			
Strategies for overcoming obstacles			
Tools and resources			
ASSIST/ ARRANGE	Implementation (X) <input type="checkbox"/> Completed <input type="checkbox"/> Partially Completed <input type="checkbox"/> Not Completed		
	Care Coordinator Delivery:		Comments:
<i>Wrap-Up</i>	Yes (X)	No (X)	
Patient instructed to complete "How Active Am I Now" and "Make a Plan to Be Active" assignments this week			
Also instructed to review exercise safety information provided and continue to track physical activity and fruits/vegetables in tracking log			
Will follow up with patient in 1 week to discuss progress towards goals and to continue weight loss education			

Other Session Comments/Report of Adaptations:

Completed reflects that the entire section parts are filled in

Partially completed reflects the section has some parts completed, but not all

Not completed reflects that the section has no information sections completed

Appendix 6.7. Semi-structured focus group discussion guide for nurse care coordinators with high program engagement

Carilion Healthy Lifestyles Weight Loss Program Focus Group Discussion Guide

HIGH PROGRAM ENGAGERS

Welcome

Hello and welcome to our conference call. Thank you for taking the time to join us today. We are on this call today to conduct a focus group. A focus group is a group discussion on a specific topic. We will be talking to you today about engaging patients with the Carilion Healthy Lifestyles Weight Loss Program.

We are interested in learning from you about the strategies you have used to recruit and retain patients. In addition, we are interested in hearing specifics about your program delivery strategies and how your patients are responding. You have been selected for participation in this focus group because you have been identified as a Care Coordinator who has been able to successfully engage a large number of patients with the pilot program over the past year.

Please feel free to share your ideas and opinions, even if they are different from others. There are no right or wrong answers. We want to get as many points of view as we can. All your views, ideas, and patient experiences are important.

Anything we say here is confidential. Individual's names will not be shared with anyone. Only a summary of our group discussion will be compiled as part of the pilot program evaluation. We also hope you do not share with others anyone's individual answers from the group today. The session will last approximately 45 minutes.

If there are no objections, we will be taping this discussion to make sure we don't miss any of your comments. We will also be taking notes. However, notes are often not as complete as when we tape record the discussion. Does anyone object to taping? Since we will be taping, please try to speak up, so the tape recorder picks up your answers. Since this a group discussion you do not have to wait for me to call on you to speak, but please try to speak only one person at a time.

(Obtain verbal consent.) (Start recording.)

Introductions

Before I start asking questions, what I would like to do for openers is have each of you **tell us your first name, your clinic(s) location, and how long you have served as a Carilion Care Coordinator.**

Thank you for your introductions.

Overall Experience Helping Patients with Weight Loss

Now, let's start with a general discussion about helping patients will weight loss.
Here's my first question.

1. When you think of helping patients with weight loss, what one or two words first come to mind?

> Probe: Tell me more about how this word(s) captures your experience or thoughts on the issues

Motivation to Offer Program

This time last year, each of you were introduced to the Carilion Healthy Lifestyles program through a brief training and received materials to help facilitate the program with your patients. The materials include the Healthy Lifestyle workbook sessions, lesson plans, and telephone scripts.

Thinking back to when you started the pilot with the Carilion weight loss program, what motivated you to start?

2. What motivated you to start piloting the Carilion Healthy Lifestyles weight loss program materials at your clinic(s)?

Patient Recruitment and Referrals

3. What strategies have you used at your clinic(s) to receive patient referrals for program participation?

> Probes: Which of these strategies are most useful? Least/not useful?

4. What are your key messages when presenting the program to patients?

> Probes: How do patients respond? What message(s) seems to work best?

5. What are the main reasons your patients decide to participate?

6. Did anyone have a patient referred to the program that decided not to participate? If so, what were their main reasons for deciding not to participate?

Program Delivery

Moving beyond recruitment, let's now discuss some details of delivering the program. Please share with us how you are using the materials at your clinic.

7. What format(s) are you using to deliver the program to patients?

> Probes: Face to Face, Phone, Email, or MyChart? Individual, Family, or Group? Any challenges with format?

8. What program session structure are you using with your patients?

> Probes: To what degree, are you following the proposed schedule? Any changes in frequency? How long is your typical session?

Program sessions cover a variety of healthy eating, physical activity, and behavioral topics and include different activities to help patients achieve their weight loss goals.

9. What adaptations or changes have you made to program sessions to engage your patients?

> Probes: Are you using the Commitment contract? Action plan? Tracking? Adaptations for specific patient needs?

Patient Retention

Keeping patients engaged throughout a year of program activities can be challenging.

10. To what extent, have your patients interacted with the program over-time?

> Probe: What is the typical number of sessions you have been having with patients?

11. What strategies have you used to keep patients engaged in the program?

> Probes: What strategies seem to work best? Not as effective?

Program Tips and Suggestions

As a Care Coordinator who has been able to really make use of the Carilion Healthy Lifestyles Program materials at your clinic and engage a large number of patients over the past year, think about what has been your key to your success.

12. How you have been able to integrate the Carilion Healthy Lifestyles program with your other Care Coordinator duties?

13. What tips do you have for your fellow Care Coordinators who may be struggling with starting the program at their clinic?

14. What additional tools and resources would help you to deliver the program and support your patients with weight loss and lifestyle change?

(As time allows, any additional comments?)

~~~~~

Thank you for taking the time to share your experiences and ideas with us. We greatly appreciate your feedback and firsthand insights. We've learned a lot from you today. Please continue to offer your suggestions and share your experiences with your fellow Care Coordinators. (Stop recording.)

(Stop recording.)

**Duration: \_\_ minutes**

**Appendix 6.8.** Semi-structured focus group discussion guide for nurse care coordinators with low program engagement

## **Carilion Healthy Lifestyles Weight Loss Program Focus Group Discussion Guide**

### **LOW PROGRAM ENGAGERS**

#### **Welcome**

Hello and welcome to our conference call. Thank you for taking the time to join us today. We are on this call today to conduct a focus group. A focus group is a group discussion on a specific topic. We will be talking to you today about engaging patients with the pilot Carilion Healthy Lifestyles weight loss program.

You have been selected for participation in this focus group because you have been identified as a Care Coordinator who in the past year has not had a chance to start the program or has been struggling to get patients enrolled. We are interested in learning more about your barriers and challenges. In addition, we are interested in hearing your suggestions on strategies to better support Care Coordinators in helping patients with weight loss and lifestyle change.

Please feel free to share your ideas and opinions, even if they are different from others. There are no right or wrong answers. We want to get as many points of view as we can. All your views, ideas, and patient experiences are important.

Anything we say here is confidential. Individual's names will not be shared with anyone. Only a summary of our group discussion will be compiled as part of the pilot program evaluation. We also hope you do not share with others anyone's individual answers from the group today. The session will last approximately 45 minutes.

If there are no objections, we will be taping this discussion to make sure we don't miss any of your comments. We will also be taking notes. However, notes are often not as complete as when we tape record the discussion. Does anyone object to taping? Since we will be taping, please try to speak up, so the tape recorder picks up your answers. Since this a group discussion you do not have to wait for me to call on you to speak, but please try to speak only one person at a time.

(Obtain verbal consent.) (Start recording.)

#### **Introductions**

Before I start asking questions, what I would like to do for openers is have each of you **tell us your first name, your clinic(s') location, and how long you have served as a Carilion Care Coordinator.**

Thank you for your introductions.

#### **Overall Experience Helping Patients with Weight Loss**

Now, let's start with a general discussion about helping patients will weight loss.

Here's my first question.

##### **1. When you think of helping patients with weight loss, what one or two words first come to mind?**

*> Probe: Tell me more about how this word(s) captures your experience or thoughts on the issue.*

*Low Program Engagers- Focus Group Discussion Guide, cont.*

### **Motivation to Offer Program**

This time last year, each of you were introduced to the Carilion Healthy Lifestyles weight loss program through a brief training and received materials to help facilitate the program with your patients. The materials include the Healthy Lifestyle workbook sessions, lesson plans, and telephone scripts.

### **2. After participating in the training session, what were your plans for piloting the Carilion Healthy Lifestyles weight loss program materials at your clinic(s)?**

*> Probes: Did you expect to use them? Not use them?*

### **Barriers to Offer Program**

### **3. What are the major challenges to offering the program at your clinic?**

*> Probes: Physician support? Patient interest? Care Coordinator capacity?*

### **Patient Recruitment and Referrals**

For those of you who have tried to enroll at least one patient in the program, let's talk about recruitment and referrals.

### **4. What strategies have you tried at your clinic(s) to receive patient referrals for program participation?**

Tell us more about the specifics of how the program is "pitched" to patients at your clinic.

### **5. What were your key messages when presenting the program to patients?**

*> Probe: How did patients respond?*

Let's talk about your patients' decision-making process regarding program participation.

### **6. Did anyone have a patient referred to the program that decided not to participate? If so, what were their main reasons for deciding not to participate?**

### **Program Delivery**

Moving beyond recruitment, let's now discuss some details related to program content, activities, and structure.

The Carilion Healthy Lifestyles weight loss program addresses weight loss using a lifestyle approach, including healthy eating, physical activity, and behavior change sessions. Program activities included a commitment contract, action plan, workbook assignments, and tracking.

### **7. What are your thoughts regarding the program content?**

*> Probes: Commitment contract? Action Plan? Homework and Tracking?*

*Low Program Engagers- Focus Group Discussion Guide, cont.*

The program was originally structured to follow the Medicare obesity counseling reimbursement schedule. This included a total of 20 behavior change sessions over a year; 4 weekly in the first month, 10 biweekly over the next five months, and then 6 monthly. Each session would last approximately 45 minutes and be delivered individually face to face or over the phone.

**8. What are your thoughts regarding the program delivery structure?**

*> Probes: Appropriate frequency and length for patients? How could it be better structured for Care Coordinator delivery?*

**Program Suggestions and Needed Resources**

**9. What adaptations or changes need to be made to the program?**

*> Probes: Suggestions to be more appropriate for patients? Suggestions to be more appropriate for Care Coordinator delivery?*

**10. What additional tools and resources would help you support your patients with weight loss and lifestyle change?**

*> Probes: Training? Materials?*

(As time allows, any additional comments?)

~~~~~

Thank you for taking the time to share your experiences and ideas with us. We greatly appreciate your feedback and firsthand insights. We've learned a lot from you today. Please continue to offer your suggestions.

(Stop recording.)

Duration: __ minutes

Appendix 7.1. Program session core and post-core session schedule adaptations across trials

National Diabetes Prevention Program	DiaBEAT-it	FIT Rx 90-2.0	FIT Rx CUSTOM and FIT Rx 90-3.0	Carilion Healthy Lifestyles – Community Health Educators	Carilion Healthy Lifestyles – Nurse Care Coordinators
CORE (6-months)	CORE (6-months)	CORE (3-months)	CORE (3-months)	CORE (6-months)	CORE (6-months)
1- Welcome to the National DPP	0- Introduction; Teach back & teach to goal	0- Group kick-off, Action Plan	0- Group kick-off, Action Plan	0- Orientation, Action Plan	1- Welcome & Action Plan
2- Be a Fat and Calorie Detective	1- Move those Muscles	1- Move Those Muscles	1- Welcome & Action Plan	1- Move those Muscles	2- Move those Muscles
3- Three Ways to Eat Less Fat and Few Calories	2- Being Active-A Way of Life	2- Being Active- A Way of Life	2- Move those Muscles & Be Active	2- Being Active-A Way of Life	3- Being Active- A Way of Life
4- Healthy Eating	3- Healthy Eating with MyPlate	3- Healthy Eating with MyPlate	3- Healthy Eating with MyPlate & Eating Out	3- Healthy Eating with MyPlate	4- Healthy Eating with MyPlate
5- Move Those Muscles	4- Be a Fat Detective	4- Be a Fat Detective	4- Taking Charge of What’s Around You	4- Be a Fat Detective	5- Be a Fat Detective
6- Being Active- A Way of Life	5- Be a Sugar Detective	5- Be a Sugar Detective	5- Tipping the Calorie Balance	5- Be a Sugar Detective	6- Be a Sugar Detective
7- Tipping the Calorie Balance	6- Tipping the Calorie Balance	6- Tipping the Calorie Balance	6- Problem-Solving	6- Tipping the Calorie Balance	7- Tipping the Calorie Balance
8- Take Charge of What's Around You	7- Take Charge of What’s Around You	7- Taking Charge of What’s Around You	7- Be a Fat Detective	7- Take Charge of What’s Around You	8- Taking Charge of What’s Around You
9- Problem Solving	8- Problem-Solving	8- Problem Solving	8- Talk Back to Negative Thoughts & Slippery Slope	8- Problem-Solving	9- Problem-Solving & Four Keys for Eating Out
10- Four Keys to Healthy Eating Out	9- Four Keys to Healthy Eating Out	9- Four Keys to Healthy Eating Out	9- Be a Sugar Detective	9- Four Keys to Healthy Eating Out	10- Talk Back to Negative Thoughts & Slippery Slope
11- Take Back to the Negative Thoughts	10- Talk Back to Negative Thoughts	10- Talking Back to Negative Thoughts	10- Stress and Time Management	10- Talk Back to Negative Thoughts	11- Jump Start Your Activity Plan
12- Slippery Slope of Lifestyle Change	11- Slippery Slope of Lifestyle Change	11- Slippery Slope of Lifestyle Change	11- Jump Start Your Activity Plan	11- Slippery Slope of Lifestyle Change	12- Make Social Cues Work for You
13- Jump Start Your Activity Plan	12- Jump Start your Activity Plan	12- Jump Start Your Activity	12- Ways to Stay Motivated	12- Jump Start your Activity Plan	13- You can Manage Stress
14- Make Social Cues Work for You	13- Make Social Cues Work for You			13- Make Social Cues Work for You	14- Ways to Stay Motivated
15- You Can Manage Stress	14- Shaking Your Salt Habit			14- Shaking Your Salt Habit	
16- Ways to Stay Motivated	15- You Can Manage Stress			15- You Can Manage Stress	
	16- Ways to Stay Motivated			16- Stress & Time Management	
				17- Mindful Eating	
				18-Ways to Stay Motivated	

National Diabetes Prevention Program	DiaBEAT-it	FIT Rx 90-2.0	FIT Rx CUSTOM and FIT Rx 90-3.0	Carilion Healthy Lifestyles – Community Health Educators	Carilion Healthy Lifestyles – Nurse Care Coordinators
POST-CORE* (6-months)	POST-CORE (6-months)	POST-CORE (6-months)	POST-CORE (6-months)	POST-CORE (6-months)	POST-CORE (6-months)
17- Welcome to Post-Core	17- Mindful Eating	13- Move More for Maintenance	13- Move More for Maintenance	19- Standing Up for Your Health	15- Mindful Eating
18- Fats – Saturated, Un-saturated, and Trans Fat	18- Stress & Time Management	14- Slips, Preventing Relapse	14- Slips, Preventing Relapse	20- More Volume, Fewer Calories	16- Stress and Time Management
19- Food Preparation and Recipe Modification	19- Standing Up for Your Health	15- Maintainer Thinking Looking Back & Looking Forward	15- Maintainer Thinking & Looking Back & Looking Forward	21- Strengthen Your Exercise Program	17- Standing Up for Your Health
20- Healthy Eating –One Meal at a Time	20- More Volume, Fewer Calories			22- Healthy Cooking	18- More Volume. Fewer Calories
21- Healthy Eating with Variety and Balance	21- Strengthen Your Exercise Program			23- Healthy Sleep	19- Strengthen Your Exercise Program
22- More Volume, Fewer Calories	22- Looking Back & Looking Forward			24- Looking Back & Looking Forward	20- Looking Back & Looking Forward
23- Staying on Top of Physical Activity					
24- Stepping Up to Physical Activity					
25- Balance Your Thoughts for Long-Term Maintenance					
26- Handling Holidays, Vacations, and Special Events					
27- Preventing Relapse					
28- Stress and Time Management					
29- Heart Health					
30- A Closer Look at Type 2 Diabetes					
31- Looking Back & Looking Forward					

* Coach selection of 6-10 topics for 22-26 session program delivery