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Incentivizing healthy lifestyle behaviors to reduce cardiovascular risk in people with serious mental illness: An equipoise randomized controlled trial of the wellness incentives program

Sarah I. Pratt[a,*], Mary F. Brunette[a], Rosemarie Wolfe[b], Emily A. Scherer[c], Haiyi Xie[b,c], Stephen Bartels[a,b], Joelle C. Ferron[a], Kelley Capuchino[d]

[a] Department of Psychiatry, The Geisel School of Medicine at Dartmouth, Hanover, NH, United States of America
[b] Department of Community and Family Medicine, The Geisel School of Medicine at Dartmouth, Hanover, NH, United States of America
[c] Department of Biomedical Data Sciences, The Geisel School of Medicine at Dartmouth, Hanover, NH, United States of America
[d] Division of Behavioral Health, New Hampshire Department of Health and Human Services, Concord, NH, United States of America

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ABSTRACT

Background: Medicaid recipients with serious mental illness die 25–30 years earlier than people in the general population due to health conditions that are modifiable through lifestyle changes. Cardiovascular diseases from excess weight, smoking, and sedentary lifestyle contribute substantially to this life expectancy disparity. The current study evaluated the impact of incentives on participation in weight management programming (for overweight and obese adults) and smoking cessation treatment (for regular smokers).

Methods: Participants were Medicaid recipients with disabling mental illness receiving services at any one of 10 community mental health centers across New Hampshire. Using an equipoise stratified randomized design, $n = 1348$ were enrolled and assigned to one of four weight management programs (Healthy Choices Healthy Changes: HCHC) and $n = 661$ were enrolled and assigned to one of three smoking cessation interventions (Breathe Well Live Well: BWLW). Following assignment to an intervention, participants were randomized to receive financial incentives (to attend weight management programs, or to achieve abstinence from smoking) or not. Data were collected at baseline and every 3 months for 12 months.

Discussion: New Hampshire's HCHC and BWLW programs were designed to address serious and preventable health disparities by providing incentivized health promotion programs to overweight/obese and/or tobacco-smoking Medicaid beneficiaries with mental illness. This study was an unprecedented opportunity to evaluate an innovative statewide implementation of incentivized health promotion targeting the most at-risk and costly beneficiaries. If proven effective, this program has the potential to serve as a national model for widespread implementation.

1. Introduction

Medicaid beneficiaries with serious mental illness (SMI) represent the nation's most dramatic health disparity population, with a life expectancy gap that has worsened over the past several decades and is now 25–30 years shorter than the general population [1–3]. Much of this disparity is due to higher prevalence of heart disease, diabetes, COPD, and obesity [4–10], with cardiovascular disease as the leading cause of premature mortality [11,12]. Risk factors include physical inactivity [13], poor diet [14,15], and high rates of smoking [16–18].

Abbreviations: SMI, serious mental illness; COPD, chronic obstructive pulmonary disease; CO, carbon monoxide; MIPCP, The Medicaid Incentives for the Prevention of Chronic Diseases; HCHC, Healthy Choices, Healthy Changes; CMHC, Community Mental Health Center; In SHAPE, Individualized Self Health Actualization Plan for Empowerment; NH, New Hampshire; US DHHS, United States, Department of Health and Human Services; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision; BWLW, Breathe Well, Live Well; NRT, Nicotine Replacement Therapy; CBT, Cognitive Behavioral Therapy; NHANES, National Health and Nutrition Examination Survey; 6MWT, 6 Minute Walk Test; BMI, Body Mass Index; PHQ-9, Patient Health Questionnaire – 9 item; SF-12, 12 Item Short Form Health Survey; HDL, high-density lipoprotein; LDL, low-density lipoprotein; HbA1c, Hemoglobin A1c; MMSE, mini-mental status exam; ANOVA, analysis of variance.

* Corresponding author at: Department of Psychiatry, The Geisel School of Medicine at Dartmouth, 2 Pillsbury Street, Suite 401, 03301, United States of America.
E-mail address: sarah.i.pratt@dartmouth.edu (S.I. Pratt).

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The obesity rate among people with SMI is twice that in the general population [19–21]. And, while smoking rates in the general population have declined over the past several decades, they have remained high for people with SMI, with lifetime smoking rates estimated at an alarmingly high 50–83% [22–25].

The cost of providing health care to this group is disproportionately high. For example, combined per capita expenditures for Medicaid recipients with schizophrenia are 2½–4 times greater than for beneficiaries without a psychiatric disorder [26]. These high costs, coupled with the staggering disparity in life expectancy, makes people with SMI a major priority for health promotion interventions.

An emerging evidence-base supports the effectiveness of combined exercise and diet interventions tailored for people with SMI [27–30]; however, there is substantial room for improvement as confirmed by a recent review of healthy lifestyle interventions for this group [31]. Evidence-based smoking cessation interventions (e.g., counseling plus medication) increase abstinence in people with SMI [31–33], but mental illness factors and biological vulnerability to nicotine addiction contribute to suboptimal cessation, and high relapse to smoking [34,35]. Also, cessation interventions are not widely available in the community. Thus, novel strategies to engage this group in health behavior change targeting obesity and smoking are needed.

Economic incentives encourage short-term health behavior changes, but are less effective for longer term outcomes (e.g., weight loss) [36–38], and relapse is common after external rewards are withdrawn [36,38–40]. In a review of 111 RCTs [36] of incentive programs tested in people with SMI, findings were equivocal. Most studies rewarded proximal outcomes (i.e., attendance at groups), versus distal outcomes (i.e., weight loss), and none specifically tested the impact of incentives on engagement in exercise or on weight loss [41]. Evidence supporting the value of incentives for smoking cessation among people with SMI is more consistent. Incentives are associated with greater reductions in carbon monoxide (CO) levels and/or abstinence [42–46]; however, only a small number of relatively short-term studies in this area have been conducted.

The Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) program, included in Section 4108 of the 2011 Affordable Care Act, aimed to examine the impact of incentives on adoption of healthy behaviors to improve overall health, prevent disease, and reduce health care expenditures in Medicaid beneficiaries. This paper describes the intervention components, study design, and evaluation methods for New Hampshire's MIPCD-sponsored "Healthy Choices, Healthy Changes" (HCHC) incentive program to reduce cardiovascular risk factors among people with SMI.

2. Methods

2.1. Study design

We conducted a longitudinal, pragmatic trial in which we enrolled Medicaid recipients with SMI from 10 community mental health centers (CMHCs) in the state of NH and assessed consenting participants at baseline and quarterly for 12 months. Incentives Counselors, full-time staff funded by the grant, recruited, consented and enrolled participants. The Incentives Counselors helped participants decide which interventions to select for randomization (equipoise design), using a shared-decision making paradigm; conducted baseline and quarterly assessments; tracked participant involvement and activities in the HCHC programs; and distributed the cash incentives. The Committees for the Protection of Human Subjects at Dartmouth College and the New Hampshire Department of Health and Human Services reviewed and approval all study materials. No study procedures were completed prior to obtaining written informed consent.

2.2. Randomization

We chose to use a pragmatic design, equipoise-stratified randomization, in order to strike a balance between random assignment to condition and provision of intervention choice. Also, we wanted our findings to be generalizable to the population of people with mental illness making choices about treatments for tobacco dependence and obesity. Incentives Counselors provided information about the available program options and helped participants make decisions about which programs were acceptable in a process of shared decision-making. Participants could choose to omit interventions they found unacceptable, as long as they were willing to be randomly assigned to at least two programs. Thus, participants selected one of several equipoise strata containing all of the programs to which they were willing to be randomized. Within a stratum, a participant was randomized with equal probability to one of the programs. For example, if a participant was only willing to be randomized to two of the four possible weight management programs, the participant was included in the equipoise stratum that contained just those two programs. Then, the participant was randomized to one of those two programs with a 50% chance of being assigned to each. Participants were simultaneously randomly assigned to receive additional cash rewards for engagement in healthy lifestyle programming, or not. Thus, a second randomization to receive incentives (or not) occurred after the initial treatment program was assigned.

2.2.1. Randomization in the weight management programs

Participants could choose to be randomly assigned to up to four weight management interventions, (see Fig. 1). Half of the participants were also randomly assigned to receive additional cash incentives for attendance at Weight Watchers meetings and/or attendance at a gym.

2.2.2. Randomization in the tobacco programs

All participants who were regular smokers received a cash reward for participating in web-based, motivational tobacco education [47]. Individuals who were interested in receiving smoking cessation programming could continue with the program and choose to be randomly assigned to up to three program options (as shown in Fig. 2). All participants received cash rewards for evidence of participation in cessation programming. Half of participants were also randomly assigned to receive repeated rewards for biologically verified abstinence over 4 weeks.

2.3. Study sites

Ten private, not-for profit Community Mental Health Centers (CMHCs) serve the 10 geographical regions covering the entire state of New Hampshire and offer a very similar set of mental health services using similar types of staff to the same target population of people who are disabled by their mental illness. Collectively, the CMHCs provide publicly funded mental health services to the approximately 15,000 adults with mental illness across the state each year.

2.4. Participants

All HCHC participants had serious mental illness by virtue of being disabled and receiving Medicaid benefits. Participants were age 18 or older with a mental health diagnosis and receiving services at one of the 10 participating CMHCs in NH. Participants were excluded if they were living in an institution, or if they had a diagnosis of dementia or a terminal illness expected to result in death within 12 months.

Eligibility for the HCHC Weight Management programs required body mass index (BMI) $\geq 25\ kg/m^2$, failure to adhere to United States, Department of Health and Human Services Physical Activity Guidelines (≥ 2.5 h/week. of moderate or 75 min/week. vigorous activity in more than one session), medical clearance for exercise, and expressed desire

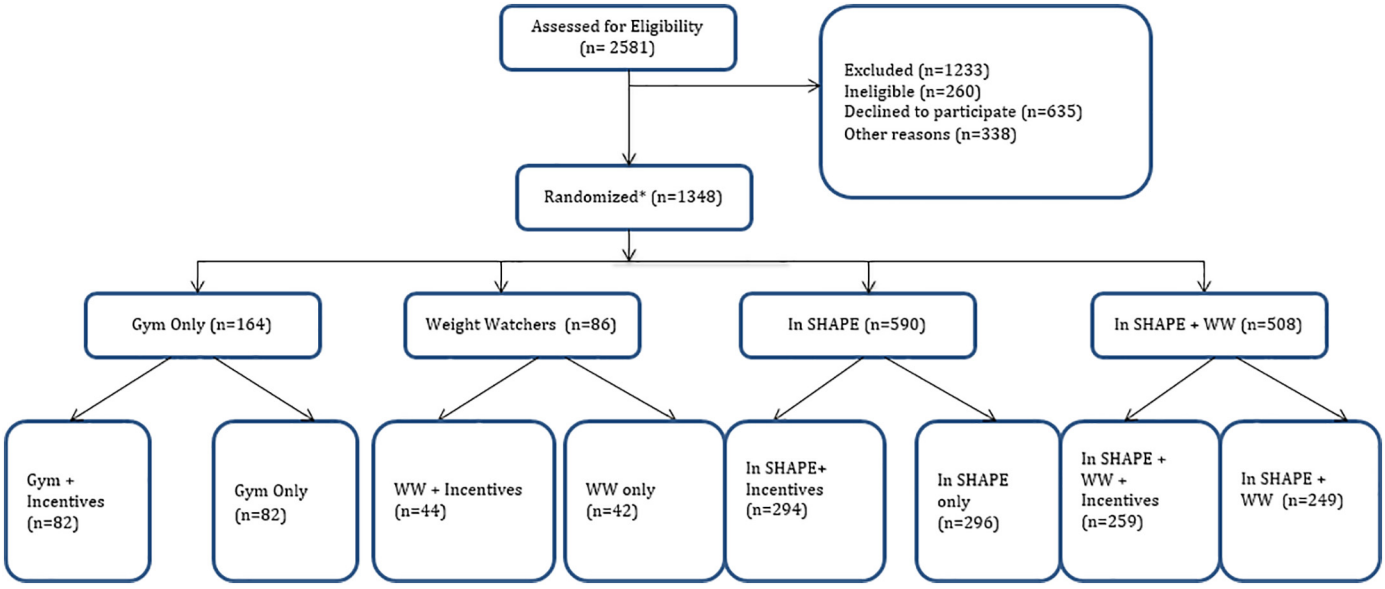

Fig. 1. Study flow for 1348 overweight Medicaid beneficiaries with mental illness.
WW = Weight Watchers.
*Randomized groups are unequal because equipoise randomization requires the participant to choose at least 2 interventions and then they are randomized based on their preference.

to participate in a healthy eating and exercise program. Individuals were excluded if they were unable to walk or if they were pregnant or planning to become pregnant within 1 year.

All CMHC clients who were smoking daily were eligible to receive Tobacco Education. Eligibility for the smoking cessation programming ("Breathe Well, Live Well") required smoking ≥10 cigarettes/day, breath carbon monoxide (CO) ≥8 ppm, and desire to quit smoking. Individuals with a current substance (alcohol or drug) DSM-IV-TR dependence diagnosis and active substance use within the 3 months prior to enrollment were excluded.

2.5. Recruitment, enrollment and consent procedures

The HCHC staff implemented several specific promotion and recruitment strategies. Direct advertising included letters to eligible consumers explaining the HCHC programs, and posters and brochures in waiting rooms and community venues frequented by consumers, such as public libraries. Research staff provided informational meetings, presentations at existing group forums (e.g., peer support groups), and recruitment events to which eligible consumers were invited. Marketing was also directed to CMHC staff, including weekly email

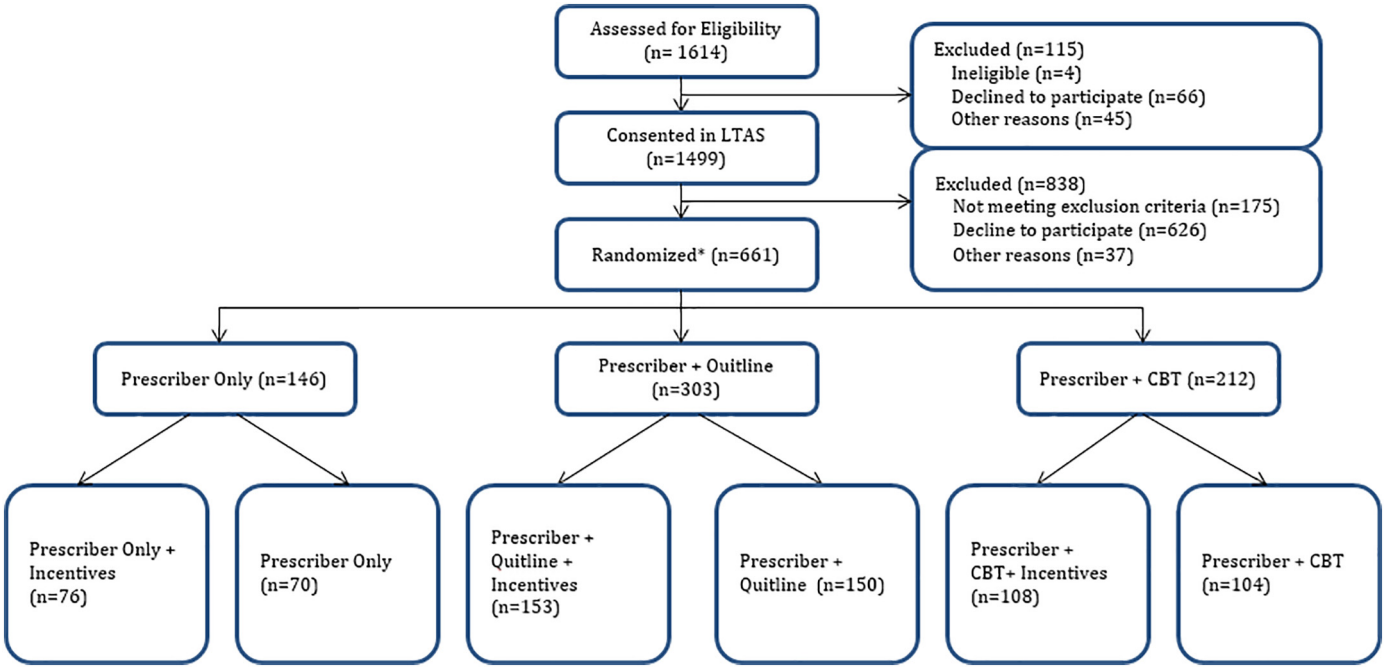

Fig. 2. Study flow for 661 daily smoking Medicaid beneficiaries with mental illness.
CBT = Cognitive Behavioral Therapy; LTAS = Let's Talk About Smoking.
*Randomized groups are unequal because equipoise randomization requires the participant to choose at least 2 interventions and then they are randomized based on their preference.

reminders, informational meetings, and assertive solicitation of referrals at treatment team meetings. Descriptions and progress on the HCHC programs were also provided to leaders from all 10 CMHCs.

Incentive Counselors provided potential participants with a detailed, plain language, written and verbal description of the program, its requirements, the incentives and rewards, and the required outcomes evaluations. The randomization process and the chances associated with assignment to groups were also described. Incentive Counselors proceeded with obtaining informed consent for consumers who were interested in participating after discussing the program, answering questions, and assessing their understanding with an informed consent evaluation tool developed for the HCHC program.

2.6. Interventions and incentives

2.6.1. Overview

Four Weight Management programs were available to participants who were overweight or obese. Tobacco Education was available to consumers who were daily smokers. Three smoking cessation options were available, as part of the BWLW program, to smokers interested in quitting.

2.6.2. Incentives overview

Principles of contingency management were used to design the incentives structure created for the Weight Management and BWLW interventions. Among the 10 MIPCD grantees, New Hampshire was the only state to use cash as a reward. We considered using gift cards based on concerns that cash might be used to purchase unhealthy items such as cigarettes, alcohol or unhealthy foods. However, we decided to use cash to maximize the salience and potential power of the reward, given the freedom it would afford participants to use it for whatever purpose would be most desirable. For example, many participants reported using cash rewards to pay for expenses such as utility or credit card bills, household expenses, birthday gifts, or gas for their vehicles. Consistent with the importance of immediacy, participants could collect the rewards they earned each week, during open office hours offered by their Incentives Counselor. Assistance was provided for anyone who did not have transportation to come to the CMHC to collect rewards. Transportation assistance was also available to all participants (including those not eligible to earn cash rewards) to enable travel to any study-related activity, including research assessments and attendance at gyms or Weight Watchers.

2.6.2.1. Weight management program options. As shown in Table 1, Program 1 consisted of a free gym membership for 12 months. (CMHC leaders negotiated memberships at local fitness facilities at $20 per participant per month or less, which were paid for by the grant.) Participants were able to choose among the fitness facilities partnering with the CMHC in their region. Incentives Counselors established participants' memberships and paid the membership fees.

Program 2 consisted of the In SHAPE (Individualized Self Health Actualization Plan for Empowerment) program, as described elsewhere [27,28,48], which included a free gym membership for 12 months as well as individual weekly meetings with a certified fitness trainer, "Health Mentor," opportunities for group exercise and healthy eating education, and quarterly group motivational "celebrations." Participants were expected to meet with Health Mentors once a week for 45–60 min at their gym of choice to discuss weekly objectives, receive instruction on exercise and healthy eating, assist with managing psychiatric symptoms that interfered with engagement in fitness activities, and to receive encouragement and feedback on healthy lifestyle behaviors. We trained Health Mentors to use motivational strategies to empower participants to feel efficacious and responsible for their long-term fitness and health. They were also trained to help participants focus on personally meaningful goals, e.g., avoiding disease in order to live to see a grandchild graduate from high school, or getting a desired job, versus weight loss alone.

Program 3 consisted of a free Weight Watchers membership for 12 months. Weight Watchers is the longest running, least expensive, and most widely disseminated and accessible commercial weight-management program. Weight Watchers employs evidence-based strategies for weight loss including food journaling, frequent group support, regular weight monitoring, attention to energy balance, learning nutritious and sustainable eating habits, and addressing the emotional component of weight loss using cognitive-restructuring techniques. Membership includes attendance at an unlimited number of meetings per week, although most members attend one per week. For the first 12 weeks of Weight Watchers sessions, group leaders, who are successful lifetime members, provide written curricula on healthy eating for weight loss and a verbal and written explanation of the program's "point" system. Participants receive a slide ruler type calculator to measure foods, in "points," simplifying use of the system. Members are encouraged to exercise 20 min daily. HCHC participants were also able to access the on-line version of Weight Watchers, which includes a variety of weight loss resources.

For the HCHC program, we received a substantial discount in membership cost and established a system for tracking attendance of our study participants' attendance at local Weight Watchers meetings (i.e., a special stamp was created for the Weight Watchers log book as proof of attendance). The research team coordinated with and provided training to regional Weight Watchers leaders on group behavioral management strategies (e.g., addressing people who dominate the conversation at a Weight Watchers meeting).

Program 4 consisted of a combination of both Programs 2 and 3 – the In SHAPE program as described above, in addition to a free Weight Watchers membership for 12 months.

2.6.2.2. Weight management incentives. Participants who were randomly assigned to receive cash rewards for engaging in healthy lifestyle programming were potentially eligible for two kinds of rewards. Individuals who had a gym membership (Programs 1, 2 and 4) could receive $5 each time they went to the gym without their Health Mentor (for those in Programs 2 and 4), up to three times per week. We did not reward participants for going to the gym with In SHAPE Health Mentors based on prior trials of In SHAPE in which participants found it much more difficult to go to the gym without the

Table 1
HCHC program options.

Weight management options			
Program 1A: Gym membership for 12 months	Program 2A: In SHAPE for 12 months	Program 3A: Weight Watchers membership for 12 months	Program 4A: In SHAPE + Weight Watchers for 12 months
Program 1B: Program 1A + $5 each for up to 3 weekly gym visits	Program 2B: Program 2A + $5 each for up to 3 weekly gym visits	Program 3B: Program 3A + $10 for 1 weekly meeting	Program 4B: Program 4A + $5 each for up to 3 weekly gym visits
Tobacco Cessation: "Breathe Well, Live Well"(BWLW) Options			
Program 1A: $30 for Prescriber Visit	Program 2A: $15 for Prescriber Visit + $20 ea. for 3 Quitline sessions	Program 3A: $15 for Prescriber Visit + $5 ea. for 12 telephone CBT sessions	
Program 1B: Program 1A + cash for biologically confirmed abstinence	Program 2B: Program 2A + cash for biologically confirmed abstinence	Program 3B: Program 3A + cash for biologically conformed abstinence	

Health Mentor. We rewarded up to three gym visits per week based on the prevailing US DHHS Physical Activity Guidelines recommending exercise three times per week. Participants were required to sign into a log book at the gym to verify attendance, a practice common at gyms providing data to insurance companies that provide stipends for gym memberships contingent on attendance. In SHAPE Health Mentors gathered the log sheets weekly and provided them to the Incentives Counselor, who was responsible for verification and distribution of incentive payments.

Participants with a Weight Watchers membership (Programs 3 and 4) could receive $10 for attending one Weight Watchers meeting in the community each week, given that this is the standard, minimal expectation for program attendance. Group leaders stamped participants' weigh-in log books to verify attendance at meetings. Participants were required to show their Incentives Counselor their stamped book in order to receive the cash reward.

2.6.3. Tobacco program options

2.6.3.1. Tobacco education. The "Let's Talk About Smoking" program is a web-based motivational enhancement tool that was developed by members of our research group with input from over 80 people with SMI, and has been proven to be usable and effective among people who lack computer experience, and have cognitive deficits and/or poor reading skills [47,49,50]. The program includes a guided self-assessment of the pros and cons of smoking, education about personal health and financial costs of smoking, video testimonials of smokers with SMI who have successfully quit, and information about cessation treatments (nicotine replacement therapy, medication, counseling, Quitline, etc.). Research staff facilitated use of the program on a laptop computer at a CMHC office. Let's Talk About Smoking was offered to all CMHC consumers who were daily smokers, regardless of their interest in quitting smoking. All participants who completed the program received $50. Completion of the program and interest in smoking cessation were required for continuation to the Breathe Well, Live Well program.

2.6.3.2. Breathe Well, Live Well (BWLW) tobacco cessation program options. Given that brief counseling and prescription of cessation medication is recommended by the US Public Health Service [51] and increases successful quitting [52], all BWLW options included a required visit with a prescriber at the CMHC to discuss medications and nicotine replacement therapy (NRT). The NH Bureau of Behavioral Health provided training to prescribers at all 10 CHMCs to offer evidence-based cessation pharmacotherapy tailored to smokers with SMI [53]. Participants were not obligated to use pharmacotherapy and none was provided as part of the study; however, NRT and medications are covered by Medicaid insurances in the state. Participants were required to submit a signed letter from their prescriber as evidence of this visit to obtain a reward and to participate in the Quitline and CBT programs.

Program 1 consisted of the Prescriber Visit to discuss pharmacologic cessation aids and obtain prescriptions if desired (see Table 1). Participants assigned to Program 1 received $30 for completing the visit.

Program 2 consisted of the Prescriber Visit described above, for which participants received $15, as well as supported referral to the NH Tobacco Helpline. This Quitline service was available free-of-charge to residents in the state. Quitlines are an integral part of nationwide tobacco control efforts [54,55]. The NH Tobacco Helpline provides an average of three free telephone counseling sessions with a cessation counselor to help smokers quit and to support new quitters. Incentives Counselors facilitated an introductory call to the Helpline to ensure that participants established a connection with Helpline staff who would then make appointments for the three standard telephone sessions. Participants could obtain rewards for participating in Helpline calls ($20 each). Incentives Counselors verified with NH Helpline staff that calls had occurred before issuing rewards. We held regular meetings with the Helpline administrator during the first several years of the study to trouble shoot barriers to call completion and to provide information about the potential effect of SMI symptoms on participation in the Helpline.

Program 3 consisted of the Prescriber Visit described above, for which participants received $15, as well as cognitive behavior cessation therapy (CBT) delivered by phone. The evidence-based CBT offered in the BWLW program was an adaptation of the Freedom from Smoking program [56–60] that included 12 weekly sessions teaching strategies for preparing to quit, resisting urges to smoke, and preventing relapse. One month after session 12, the Telephone Counselor offered a brief supportive phone call to the participant. Tobacco treatment specialists with experience working with people with SMI delivered the sessions. A large body of research supports the efficacy of behavioral smoking cessation treatment over the telephone [61]. Participants received $5 cash for each completed session. The Telephone Counselor provided records to Incentives Counselors to verify attendance at calls.

In considering the incentive amounts for each of the three BWLW programs, we attempted to strike a balance between the effort required to participate in each session, and the desire to provide a similar level of reward for participating in each of the three programs. The total amount that could be earned for Programs 2 and 3 ($75) were identical, while the amount that could be earned for Program 1 was less ($30) given that only one session was required.

2.6.3.3. Additional cash incentives for smoking abstinence. Participants in the three BWLW programs were randomly assigned to receive additional incentives for abstinence in conjunction with one cessation attempt during the 12-month study period or no additional incentives. Participants who were eligible to receive cash for abstinence were instructed to call the Incentives Counselor when they initiated their quit attempt. They were directed to come to the CMHC site on the following Monday to provide a breath carbon monoxide (CO) sample. Participants with CO $\leq$ 6 ppm received $50. Those with CO $\geq$ 6 were encouraged to continue with their cessation attempt and to return to the CMHC on Wednesday and Friday for additional assessments of CO level; those with CO $\leq$ 4 ppm received $50 for each testing day. All participants were encouraged to continue working on their cessation attempt and to return the following week on Monday, Wednesday and Friday for assessment of CO level and urine cotinine (individuals using nicotine replacement therapy provided CO only). People with CO $\leq$4 ppm and cotinine $<$ 100 ng/mL received $50 for each testing day. Participants were invited to return one and 2 weeks later and could receive $75 for each visits if abstinence was objectively confirmed using the same CO and cotinine criteria. Participants with verified abstinence at each visit could earn $450.

2.7. Measures

Trained research staff assessed all participants at baseline and quarterly for 12 months. Participants were compensated $15 for each assessment. Staff utilized structured interviews to obtain demographic and questionnaire information, entering responses and measurements entered directly into an online data capture platform.

2.7.1. Measures used to evaluate weight management programs

The primary outcomes were (a) change in weight (pounds) and (b) change in avoidable risk of death (as measured by the Avoidable Risk of Death Index) [62]. Researchers at the Dartmouth Institute developed and validated a strongly predictive aggregate risk score quantifying an individual's probability of dying over the next 10 years based on 11 major behavioral and biometric risk factors, mortality rates by cause, and estimates of the proportional hazards of risk factor exposure from published systematic reviews. This index has been validated by comparing the predicted risk of death to observed death in 3760 respondents in the National Health and Nutrition Examination Survey

(NHANES) 1999–2004 with linked mortality data to the end of 2006. The risk score predicted observed death by decile of predicted risk with a chi-square statistic of 12.2 for women and 8.1 for men ($p < .05$ for both) [62].

Distal outcomes included the 6-min walk test (6MWT), a measure of exercise capacity [63,64] in which participants walk as far as they can in 6 min, coached not to run. This low-risk test has high test-retest reliability [65–68] and is suitable for sedentary and older individuals with chronic disorders [69–71]. We also took physical measurements including height, resting pulse, waist circumference, and blood pressure. Body mass index (BMI) was calculated from height (measured with a standardized stadiometer) and weight (using a standard medical scale with participants wearing regular clothing, but no shoes).

We measured several proximal outcomes including participation in exercise and diet behaviors. We collected self-reported exercise during the prior 3 months; self-reported physical activity using the International Physical Activity Questionnaire [72], which yields 8 summary scores based on self-report and an activity summary index; and dietary behaviors using the self-reported Weight Loss Behavior-Stage of Change Scale [73], which produces measures of portion control, dietary fat, and intake of fruits and vegetables. We also assessed participation in assigned activities, including gym attendance based on self-report as well as electronic attendance records and sign-in sheets at fitness facilities; and attendance at Weight Watchers based on self-report.

Finally, we used the Colorado Symptom Inventory [74] and the PHQ-9 [75] to measure the impact of psychiatric symptoms on engagement in exercise, and the Self-Rated Abilities for Health Practices Scale [76] to evaluate subjective impression of skill for performing a variety of general health and fitness behaviors.

Participant characteristics and covariates included demographics (e.g., age, gender, education, marital status, living situation), medications (type of all prescribed medications), and medical comorbidity, as measured by the self-reported Katz Comorbidity Scale [77], which evaluates the presence of medical conditions that affect morbidity and mortality. Finally, we used the Mini-Mental State Examination (MMSE) [78] to screen for serious cognitive impairment.

2.7.2. Measures used to evaluate BWLW programs

The primary outcome was biologically confirmed abstinence from smoking based on expired breath CO < 4 ppm and urine cotinine < 100 ng/mL (breath CO only for participants using nicotine replacement therapy). We used the Bedfont Smokerlyzer breath monitor to measure breath CO level and the Accutest NicAlert™ test strip to measure urine cotinine (a metabolite of nicotine). We also used the Timeline Follow-Back [79] to assess smoking behavior over the prior 3 months. With a structured interview, research staff assessed BWLW participants using the Fagerström Test for Nicotine Dependence [80], the Smoking Self-Efficacy Questionnaire [81] (a 17-item self-rating scale assessing motivation to attain and sustain abstinence), the Smoking Attitudes Questionnaire [82] (18-item questionnaire measures attitudes about smoking), the Smoking Effects Questionnaire [83] (33-items that ask about positive and negative effects of smoking), and a 27-item measure of delayed discounting [84]. We also measured weight, blood pressure and pulse. At baseline, 6 and 12 months, participants also completed a brief neuropsychological evaluation including the Wide Range Achievement Test [85], and selected subtests of the Delis-Kaplan Executive Functioning System [86] to assess executive functioning, including the Color-Word Interference Test, the Trail Making Test, and the Verbal Fluency Test.

2.8. Statistical analyses

2.8.1. Planned descriptive analyses

Careful examination of frequency distributions and descriptive statistics for all variables will precede statistical analysis. The data analyses for this study will include many statistical tests of program difference hypotheses, in order to avoid inferential errors (i.e. to control for potential type I error due to multiple contrasts), we will adjust the p-value to account for each contrast using the false discovery rate method [87].

2.8.2. Group equivalence at baseline

Among Weight Management and BWLW participants, we will compare the programs with respect to baseline levels on the primary outcome variables. Continuous variables will be compared using ANOVA and categorical variables compared using chi-square tests. With an equipoise stratified design, random assignment to available treatments within a stratum should produce balance between programs within stratum. If there is a large stratum effect, however, there is a possibility for differences between treatment programs across strata. Prior to any outcome analyses, we will test for stratum effects and for site effects on the outcomes and will adjust for equipoise stratum and site within all analyses. With randomization, we do not expect the programs to differ at baseline, but if we find significant differences, it is likely due to chance. We will adjust for baseline covariates only if the variable is related to both group assignment and the outcomes at follow up.

2.8.3. Participant choice of random assignment (strata)

In the weight loss arm of the study, most participants wanted to be randomized to either In SHAPE or In SHAPE with Weight Watchers ($n = 828$, 60.6%), followed by Gym or In SHAPE ($n = 266$, 19.5%) (See Table 2). Participants chose In SHAPE in the majority of the strata with the exception of Gym or Weight Watchers ($n = 15$, 1.1%).

In the Breathe Well, Live Well (BWLW) arm of the study, participants chose Program 3 (Cognitive Behavioral Therapy phone counseling) or Program 2 (Quitline) over Program 1 (Prescriber Referral alone) ($n = 347$, 52.2%, See Table 3) and many participants preferred Program 2 or Program 1 ($n = 206$, 31%).

2.8.4. Primary outcomes for weight management

The primary outcomes for evaluation of the Weight Management programs are weight loss and reduction in avoidable risk of death. Specifically, we hypothesize (hypothesis 1a) that combined supported exercise (In SHAPE) and weight management (Weight Watchers) will lead to the greatest amount of weight loss and the greatest improvement in avoidable risk of death. We also hypothesize that (hypothesis 1b) receipt of financial incentives will be associated with greater weight loss and greater improvement in avoidable risk of death.

To test hypotheses 1a and b, we will separately analyze a continuous measure of weight and a continuous summary value corresponding to the avoidable risk of death in the next 10 years (avoidable risk of death index). To test hypothesis 1a (superiority of combined supported exercise + weight management), we will fit a mixed-effects linear regression model by including programs (4 intervention conditions), time (baseline plus 4 post-treatment assessment points), and a program by

Table 2
Participant selected equipoise strata for weight loss.

Strata	*N*	%
In SHAPE or In SHAPE with Weight Watchers	828	60.6
Gym or In SHAPE	266	19.5
Weight Watchers or In SHAPE with Weight Watchers	106	7.8
Gym or In SHAPE or In SHAPE with Weight Watchers	67	4.9
Weight Watchers or In SHAPE or In SHAPE with Weight Watchers	35	2.6
Gym or In SHAPE with Weight Watchers	20	1.5
All of the interventions	16	1.2
Gym or Weight Watchers	15	1.1
In SHAPE or Weight Watchers	6	0.4
Gym or In SHAPE or Weight Watchers	5	0.4
Gym or Weight Watchers or In SHAPE with Weight Watchers	2	0.1

Table 3
Participant selected equipoise strata for smoking cessation.

Stratum	*N*	%
CBT with PR or Quitline with PR	347	52.2
Quitline with PR or PR alone	206	31.0
CBT with PR or Quitline with PR or Prescriber Referral alone	79	11.9
CBT with PR or PR alone	33	5.0

PR = Prescriber Referral; CBT = Cognitive Behavioral Therapy.

time interaction, all as fixed effects. The program by time interaction term will test the differential effect of intervention conditions on change in the outcomes over time (improvement). Because hypothesis 1a is about superiority of the combined intervention condition, supported exercise (In SHAPE) + weight management (WW), in comparison with the other 3 intervention conditions alone, our focal point is not to test for the global difference over all programs (intervention conditions), but specific contrasts between the combined intervention condition (In SHAPE + WW) and the other 3 conditions with respect to improvement in the outcomes over time.

To test hypothesis 1b, which states that receipt of financial incentives will be associated with greater weight loss and greater improvement in avoidable risk of death, we will extend the mixed-effects model specified for hypothesis 1a by adding an additional 3-way interaction term (program by incentive by condition by time) to the model. The 3-way interaction term will test whether the effect of incentives on change over time differs by intervention. A significant 3-way interaction will indicate the more intensive and more individually tailored interventions (In SHAPE and Weight Watchers) lead to greater improvements over the less intensive, less tailored interventions (Gym Membership alone, Weight Watchers alone). We will fit the mixed-effects model with the 3-way interaction effect as the first step for testing hypothesis 1b, our main interest is, however, to test specific contrasts for each treatment condition with and without incentives. These specific contrasts will correspond to the hypothesis we intend to test: overall weight loss for all conditions will be superior when incentives for participation are received. These contrasts are pre-specified or planned (not post hoc) tests. For both models we described, we will include a random intercept and slope to account for the correlated nature of the data due to repeated measures. In addition, all analyses will adjust for baseline weight and equipoise stratum.

2.8.5. Primary outcomes for BWLW

The primary outcome for BWLW is biologically verified abstinence from smoking. There are two primary hypotheses. First, we hypothesize (hypothesis 2a) that Program 3 (CBT with Prescriber Referral) will result in the highest rate of cessation, followed by Program 2 (Quitline with Prescriber Referral), followed by Program 1 (Prescriber Referral alone). Second, we hypothesize (hypothesis 2b) that the overall rate of biologically confirmed abstinence for participants who receives financial incentives will be superior to abstinence rates for the non-incentivized participants.

A modeling strategy that is similar to the weight loss model will be used for smoking cessation outcomes except that mixed-effects logistic regression rather than linear regression will be specified because biologically confirmed abstinence is binary. Specifically, the model with intervention condition (3 conditions), time (5 time points) and condition by time interaction as fixed effects will be used to test hypothesis 2a, and the model with the additional 3-way effect (condition by incentive by time) will be used to test hypothesis 2b. Again, our focus will be specific contrasts for the difference between telephone-based CBT and the two other conditions (for hypothesis 2a) and for the difference with and without incentive within each condition (for hypothesis 2b). In addition, all analyses will adjust for severity of nicotine dependence and equipoise stratum.

2.8.6. Sample size and power calculation

2.8.6.1. Sample size description. All participants eligible for inclusion in either the weight management or smoking cessation programs were approached between May 2012 and June 2015. A total of 1348 participants enrolled in the weight management program. After equipoise stratified random assignment in the weight management programs, 164 (12%) were assigned to Gym Membership only, 590 (44%) were assigned to In SHAPE, 508 (38%) were assigned to In SHAPE + Weight Watchers, and 86 (6%) were assigned to Weight Watchers only. Participants in each program were then randomized to receive cash incentives or not. A total of 1432 individuals completed the on-line tobacco education program, with 661 of those enrolling in the BWLW program. A total of 146 (22%) were assigned to Program 1, 303 (46%) were assigned to Program 2, and 212 (32%) were assigned to Program 3. Participants in each program were then randomized to receive cash incentives for biologically confirmed abstinence from smoking or not.

2.8.6.2. Power calculation. Power analyses were conducted for each specific hypothesis (1a, 1b, 2a and 2b), respectively, using Ahn et al.'s [88] power calculation method for both longitudinal continuous outcomes and binary outcomes. For all power analyses, we assumed a two-tailed test, alpha level of 0.05, a cross-time correlation of 0.50 (over 5 assessments), and 20% attrition by end of the study (12 months). Also, to be conservative, all power calculations were based on the contrast between the enhanced (or combination) condition and the smallest comparison condition. Power calculation for hypothesis 1a (superiority of combined supported exercise + weight management) was based on the contrast between the combined condition (In SHAPE + WM, $n = 508$) and the Weight Watchers only condition (the smallest comparison condition, $n = 86$). The study achieves 80% power to detect the slope difference of 0.32 standard deviation units, which is between a small (0.20) and a medium (0.50) effect size in terms of Cohen's [89] standard. Power calculation for hypothesis 1b (enhanced weight loss with incentives: overall weight loss for all conditions will be superior when incentives for participation are received) was based on the smallest condition, Weight Watchers only ($n = 44$ for WW with incentives, and $n = 42$ for WW without incentives). The study has 80% power to detect the minimum effect size of 0.60, slightly higher than a medium effect size of 0.50.

Power calculation for hypothesis 2a was based on abstinence from smoking, a binary outcome. For hypothesis 2a (superiority of Program 3 compared to Program 2, followed by Program 1), power was estimated by comparing the difference in rates of abstinence over time between Program 3 ($n = 212$) and Program 1 ($n = 146$). The study achieves 80% power to detect the minimum 19% difference in abstinence rate, which is equivalent to 0.44 standard effect size [90] in Cohen's metric. Power calculation for hypothesis 2b (enhanced rates of smoking cessation with incentives) was based on the comparison of treatment with and without incentive for the smallest condition, Program 1 ($n = 76$ for Program 1 + incentives, and $n = 72$ for Program 1 without incentives). The study achieves 81% power to detect 28% of difference in abstinence, which is equivalent to Cohen's d of 0.69, between medium (0.50) and large effect (0.80). It is important to note that the effect sizes were computed based on the smallest groups. Because sample sizes for this study differ for different intervention conditions, effect sizes for all other comparisons will be larger than these conservative estimates.

3. Discussion

Individuals receiving public mental health services have higher rates of cardiovascular disease leading to a 25–30 year reduced life expectancy, representing the greatest health disparity among Medicaid beneficiaries, while also accounting for the highest costs [91]. New Hampshire's HCHC program addressed this dramatic health disparity by providing incentivized health promotion programs to overweight and

obese and/or tobacco-smoking Medicaid beneficiaries. Specifically, this innovative program provided: (1) four different fitness and weight management programs to 1348 overweight/obese individuals; and (2) three supported smoking cessation programs to 661 smokers. Using an equipoise stratified randomized (ESR) design to strike a balance between scientific rigor (randomization) and real-world, person-centered choice, participants were able to eliminate intervention options that were not desired. An examination of the ESR strata suggested that the majority of overweight/obese participants (60%) selected the randomization stratum that guaranteed receipt of the InSHAPE program. We speculate that this reflects a strong desire to receive support and/or assistance with health behavior change. By contrast, only 1% of participants chose the stratum that included either a gym membership or Weight Watchers membership alone, with no support from a trainer employed by the mental health center. Similarly, the plurality smokers with mental illness selected the stratum that included either Quitline or Telephone CBT (52%) versus strata that included a single visit with their prescriber alone versus CBT or Quitline (36%). Again, this seems to reflect the desire for more intensive support with behavior change.

Strengths of the ESR model and a typical RCT are well known: the ESR model can reduce attrition and nonadherence while a typical RCT increases internal validity by reducing selection and other bias [92,93]. In this real-world implementation project, acceptability of the treatments by participants was our highest priority and thus we selected the ESR model. Part of the trade-off with using an ESR is we sacrifice internal validity by way of selection bias for external validity by way of its generalizability to real world situations. And in this model, unlike an RCT, we know participants' preferences for treatment, thus, we can control for selection strata to help reduce threats to internal reliability. Further, the incentive randomization was fully randomized and thus we are able to answer questions about this effect without controlling for strata.

This study will assess the effectiveness of incentives in achieving health behavior change in this high-risk, high-cost group of Medicaid beneficiaries by providing accessible health promotion resources in the community, rewards for attendance at fitness facilities (including Weight Watchers), and rewards for smoking abstinence. We will also compare the relative effectiveness of each intervention in achieving primary study outcomes, and we will have the ability to explore outcomes across randomization strata. This program presents an unprecedented opportunity to evaluate an innovative statewide implementation of incentivized health promotion targeting the most at-risk and most costly beneficiaries. If proven effective, it has the potential to provide a national model for widespread implementation and dissemination.

Declarations

This study protocol and consents were reviewed and approved by both Dartmouth College and State of New Hampshire Institution Review Boards.

Consent to publish

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are not currently available as data is still being collected for the study.

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Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

SP, SB, and MB, together with KC, designed the study, hired, trained and supervised the staff who implemented the study and collected the data, directed the analyses of the study data, and wrote the first draft of the paper. ES and RW contributed to the design and analysis of the study data and commented on drafts of the paper. JF provided critical revisions for intellectual content and edited drafts of the paper. All authors read and approved the final manuscript.

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