

HEALTH PROMOTION RESOURCE GUIDE

Choosing Evidence-Based Practices for Reducing
Obesity and Improving Fitness for People with
Serious Mental Illness



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Center for Integrated Health Solutions

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TABLE OF CONTENTS

HOW TO USE THIS RESOURCE GUIDE	3
SECTION I: Overview and Background	4
SECTION II: Weighing the Evidence	4
SECTION III: Selecting Programs Based on the Evidence	5
SECTION IV: What are Implementation-Ready Health Promotion Practices?	5
SECTION V: Evidence-Based Practices At-A-Glance	6
SECTION VI: Evaluating Health Promotion Programs for Persons with Serious Mental Illness: What Works?	9
SECTION VII: A Checklist for Evaluating Your Organization’s Readiness to Adopt a Health Promotion Program for Persons with Serious Mental Illness	11
SECTION VIII: Description of Different Evidence-Based Implementation Ready Practices	12
APPENDICES	
APPENDIX I: Search Methods	18
APPENDIX II: Search Results	20
APPENDIX III: Evidence-Based Health Promotion Programs Not Available for Implementation	20
REFERENCES	21

HOW TO USE THIS RESOURCE GUIDE

The purpose of this guide is to help behavioral health administrators, program directors, state agencies, clinicians, practitioners, families and consumers to select evidence-based practices. This Resource Guide provides a detailed overview of health promotion practices for reducing obesity and improving fitness among persons with serious mental illness that have been evaluated using rigorous scientific methods. Each of the practices described in this guide have been implemented in diverse settings and have materials and manuals available for training purposes. The key results and additional information necessary for selection are provided for each evidence-based health promotion practice.



This guide is organized into the following eight sections:

- I. Overview and Background: Evidence-Based Practices Aimed at Reducing Obesity and Improving Fitness for People with Serious Mental Illness
- II. Weighing the Evidence
- III. Selecting Programs Based on the Evidence
- IV. What are Implementation Ready Health Promotion Practices?
- V. Current Selected Evidence Practices – At-A-Glance
- VI. A Checklist for Evaluating Health Promotion Programs for Persons with Serious Mental Illness: What Works?
- VII. A Checklist for Evaluating Your Organization’s Readiness to Adopt a Health Promotion Program for Persons with Serious Mental Illness
- VIII. Description of Different Evidence-Based Implementation Ready Practices

This guide is not intended to deliver training in any of these practices, but rather it is designed to inform others about practices that work, and offer assistance with selecting and evaluating these practices.

SECTION I: Overview and Background

The prevalence of obesity is double among persons with serious mental illness (SMI) when compared to the general population^{1,2} and contributes to the severity of health problems and shortened lifespan observed within this population group.³ Many antipsychotic medications are known to cause significant weight gain in persons with SMI,^{2,4-13} and some are associated with hyperlipidemia and decreased glucose tolerance, both of which are known risk factors for cardiovascular disease.^{14,15} Behaviors associated with poor health outcomes, such as a sedentary lifestyle and poor eating habits, are also more common in persons with SMI than the general population.^{16,17} Fewer than 20 percent of individuals with schizophrenia engage in one or more periods of moderate exercise on a weekly basis and nearly 40 percent are physically inactive.¹⁸ Poor diet, which is characterized by lower consumption of fruits, vegetables and fiber, and greater consumption of calories, nutrients and saturated fats, is more prevalent among these individuals compared to the general population.¹⁸⁻²¹ All of these factors combined are largely responsible for the high rates of diabetes, heart disease, and obesity found in persons with SMI.

Although poor physical health and obesity are common in people with SMI, few programs delivered through publicly-funded mental health facilities target physical fitness and wellness.^{7,22,23} Despite the elevated healthcare costs and adverse outcomes associated with the combination of mental illness and poor physical health,²⁴⁻²⁶ relatively little attention has been given towards developing health promotion interventions designed to address the needs of this high-risk group.

Implementing effective health promotion programs in settings where adults with SMI seek and receive services is critical to lowering the risk associated with preventable medical conditions such as cardiovascular disease and obesity. Implementation of these programs requires both an understanding of the evidence behind the programs as well as having an appropriate and appropriately trained workforce in place. Despite the growing body of research highlighting the effectiveness of health promotion programs for persons with SMI, fitness and nutrition initiatives are rarely included as a component of routine mental health services. The types of programs that have proven successful predominantly include interventions focused on a combination of diet and exercise, though some programs have placed greater emphasis on one or the other. These health promotion programs are delivered across diverse settings and rely on varying formats including group-based programs, individualized sessions, and combined group and individual sessions.

SECTION II: Weighing the Evidence

For purposes of this guide, evidence-based practices represent treatments and services with well-documented effectiveness. These practices have been evaluated in mental health settings using rigorous scientific methods. Even when reviewing these different practices, it is important to realize that there are differing levels of evidence, where some practices have characteristics associated with greater improvements in patient outcomes than others.

It is important to distinguish between health promotion practices that contribute to statistically significant changes as opposed to those that result in a clinically significant impact. For example, a statistically significant improvement means that the practice resulted in observed changes that were not due to chance. These changes, however, could in fact be very small. For example, in a large sample a 2-point change on a 100-point scale could be highly statistically significant, even though such a change is not clinically significant.

In contrast, a clinically significant improvement means that the practice contributed to a big enough change that it is associated with decreased risk of disease and improved health. When considering two important outcomes of health promotion practices, such as weight-loss and physical fitness, very small changes in weight could be observed as statistically significant, however a weight-loss of 5% bodyweight or greater would be judged as clinically significant and is more meaningful in terms of the person's health. For example, if an individual weighing 350lbs loses 5lbs of weight, this may be a statistically significant result but would not be considered clinically significant because this represents a less than 1.5% reduction in body weight. This distinction between statistical and clinical significance emphasizes the need to look at how big the change is in order to determine the potential impact of a practice.

Another way to consider the evidence is to identify which outcomes are reported. Many studies focus exclusively on weight loss or body mass index (BMI), a reliable measure of body fatness for most people calculated as weight (kg) divided by height squared (m^2), even though there are other important outcomes relevant to health promotion. For example, improved physical fitness is an important outcome of many health promotion programs and contributes to well-documented health benefits including decreased cardiovascular risk. Studies that report both weight and physical fitness outcomes offer more robust findings.

Section IV of this guide provides a critical overview of each of the evidence-based health promotion practices, with consideration of the impact of each.

SECTION III: Selecting Programs Based on the Evidence

There are a number of studies that offer compelling evidence regarding the benefits of health promotion programs for use among individuals with SMI. The high participation rates, significant reductions in weight and BMI, as well as improvements in quality of life and self-efficacy all support the feasibility of using these programs in community-based or clinical settings for people with SMI. However, only a handful of these programs have been implemented in real-world settings following validation through evidence-based research. Insufficient funding is a key reason for the discontinued use of some health promotion programs. For instance, many grant-funded interventions were no longer viable following the end of the grant. In addition, many of the studies identified in the literature review were of varying methodological quality and were limited by potential risks of bias. These included conflicts of interest among study authors as well as a substantial number of studies funded through pharmaceutical industry grants.



Despite these diverse challenges, Section V of this guide identifies nine important health promotion programs that have demonstrated effectiveness and training materials or instruction manuals and training curriculums in development. These programs are implementation ready, and they may be appropriate for dissemination across a number of settings.

Among all of the interventions described in Section V (see Table 1), it is apparent that by combining an education and activity-based approach, with emphasis on both nutrition and physical exercise, it is possible to achieve greater success in effectively reducing weight among individuals with SMI. Research studies demonstrate that health promotion programs need to be intensive and based in the science of fitness and weight loss, with special adaptations to meet the needs and challenges of those with SMI, to have any real impact for a significant number of people.

SECTION IV: What are Implementation-Ready Health Promotion Practices?

Implementation-ready health promotion practices are supported by evidence-based research, and have the materials necessary to successfully implement these practices readily available. A small number of studies were not included in this guide because they were not implemented beyond the initial research settings and did not have available training materials. These studies were excluded because they are not relevant to practitioners or program directors. For a list of the excluded practices, refer to the table in Appendix 3.

For each of the practices described in this guide, there are training manuals available or in preparation and available from the program developers, and the practices have been implemented following the completion of their respective research studies. This guide includes details on how to access the training materials and contact the program developers to schedule training.

SECTION V: Evidence-Based Practices At-A-Glance

This section includes a summary of each evidence-based health promotion practice for persons with SMI. The purpose is 1) to highlight the various settings in which these practices have been implemented following completion of their respective research studies; and 2) to identify the characteristics that have contributed to their success. This section also provides an overview of the factors important for the implementation of these practices, such as accessing training materials and determining personnel requirements.

Evidence-Based Implementation-Ready Models

Standard Framework for Levels of Integrated Care²⁰ offers a point of reference and reflection for providers planning, implementing, and sustaining integration projects.

A total of nine evidence-based interventions have been implemented in different settings following completion of their respective studies. These evidence-based interventions are arranged from the most recent peer-reviewed publication of primary outcome data supporting the program's effectiveness:

- 1) In SHAPE^{27,28}
- 2) Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)²⁹
- 3) Healthy Eating and Activity in Latinos Treated in the Heights (HEALTH)³⁰
- 4) Recovering through Nutrition and Exercise for Weight Loss (RENEW)³¹
- 5) Solutions for Wellness (SFW) Manualized Wellness Program
- 6) Lifestyle Intervention³²
- 7) Simplified Intervention to Modify Physical activity, Lifestyle, and Eating behavior (SIMPLE)³³
- 8) Diabetes Awareness and Rehabilitation Training (DART)³⁴
- 9) Behavioral Group-Based Treatment for Weight Reduction in Schizophrenia and Other Severe Mental Illnesses (BT)³⁵

Evidence-Based Practices At-A-Glance

Tables 1-4 provide an overview of the nine evidence-based practices. **Table 1** provides a summary of the key research results and evidence for each of these practices. It is helpful to consider if the programs report both statistically and *clinically significant* evidence of effectiveness.

Table 1. Summary of the evidence base for health promotion programs with training materials for persons with serious mental illness

Intervention	Report Weight Loss or BMI	Report Clinically Significant Findings	Report Weight Loss and Fitness	Key Findings
In SHAPE	✓	✓	✓	50% with ≥5% weight loss or clinically significant increased fitness 24% improved fitness and ≥5% weight loss
ACHIEVE	✓	✓		37.8% with ≥5% weight loss
HEALTH	✓	✓		24% with ≥5% weight loss
RENEW	✓			4.4 lbs weight loss
SFW	✓			0.1-8.7 lbs weight loss
Lifestyle Intervention	✓			3-10 lbs weight loss
SIMPLE	✓	✓		6.4 lbs weight loss
DART	✓			5 lbs weight loss
Behavioral Therapy (BT)	✓	✓		27% with ≥5% weight loss 41% who completed BT with ≥5% weight loss

Table 2 highlights the different components of each of the nine evidence-based practices. As shown, all of the practices target either nutrition or physical activity, or both. In general, programs that provide both nutrition and physical activity are more effective. In addition, these practices consist of either education-based or active real-world training within community settings. It is important to make the distinction between the more passive didactic or classroom training and involvement in active training as this affects the potential impact of each health promotion practice. Education-based training consists of classroom education, instruction, or demonstrations in nutrition or fitness. In contrast, the active training in physical fitness can be comprised of one-on-one personal training sessions at community fitness centers or participation in group exercise classes. Similarly, nutrition practices with active training consist of hands-on cooking classes or visits to local grocery stores to select healthier food options.

Table 2. Components of the evidence-based health promotion programs: Educational vs. Active; Nutrition and/or Physical Activity

Intervention	Duration	Education-based Training		Active Training	
		Nutrition	Physical Activity	Nutrition	Physical Activity
In SHAPE	12 months	✓	✓	✓	✓
ACHIEVE	18 months	✓	✓	✓	✓
HEALTH	14 weeks	✓	✓		
RENEW	6 months	✓	✓		
SFW	12 weeks	✓	✓		
Lifestyle Intervention	12 weeks	✓	✓		✓
SIMPLE	16 weeks	✓	✓	✓	
DART	24 weeks	✓	✓		
Behavioral Therapy (BT)	14 weeks	✓	✓		

It is also important to consider what the organizational requirements are in order to provide these different practices. This information is summarized in **Table 3**, by types of provider needed to implement the program.

Table 3. Overview of personnel requirements for evidence-based health promotion programs for persons with serious mental illness

Intervention	Personnel Requirements				
	Nurse	Dietitian	Fitness Trainer	Basic Training	Other
In SHAPE		✓	✓	✓	
ACHIEVE			✓	✓	✓
HEALTH		✓			
RENEW	✓	✓	✓		
SFW	✓	✓	✓		
Lifestyle Intervention	✓	✓	✓		
SIMPLE				✓	
DART					✓
Behavioral Therapy (BT)				✓	

Table 4 contains additional background information about the research supporting each of the practices, including the research design, location of the research, the funding agency who supported the research, and the duration of the study. **Table 4** also provides a summary of the “implementation-readiness” of each of these practices in terms of the personnel requirements and whether training is available from the program developers.

Table 4. Implementation Readiness: Evidence-based interventions that have been implemented or are in preparation for implementation

Intervention	Authors	Design	Region	Funding	Duration	Personnel	Available Training	Manual
In SHAPE	Bartels (2013) ^{27,28}	RCT	US (NH)	NIMH	12 months	Health Mentor	Yes	Yes
ACHIEVE	Daumit (2013) ²⁹	RCT	US (MD)	NIMH	18 months	Trained for intervention, exercise instructor	Yes	Yes
HEALTH	Mangurian (2012) ³⁰	Non-randomized Comparison	US (NY)	Janssen, Eli Lilly, NARSAD	14 weeks	Dietitian	Yes	Yes
RENEW	Brown (2011) ³¹	RCT	US (AZ)	NIMH Grant	6 months	No specific requirements	Yes	Yes
Eli Lilly Solutions For Wellness and related programs	Porsdal (2010) ³⁶	Non-randomized Comparison	Denmark	Eli Lilly	12 weeks	Nurse or therapist	Yes	Yes
	Vreeland (2010) ³⁷	Non-randomized Comparison	US (NJ)	Not reported	10 weeks	No specific requirements	Yes	Yes
	Chen (2009) ³⁸	Single Arm	Taiwan	Eli Lilly	10 weeks	Psychiatrist, psychiatric nurse, dietitian, fitness coach	Yes	Yes
	Lee (2008) ³⁹	Single Arm	Korea	Eli Lilly	12 weeks	Nurse Practitioner	Yes	Yes
	Kwon (2006) ⁴⁰	RCT	Korea	Eli Lilly	12 weeks	Nurse Practitioner	Yes	Yes
	Skrinar (2005) ⁴¹	RCT	US (MA)	Eli Lilly	12 weeks	Fitness coach	Yes	Yes
	Menza (2004) ⁴²	Non-randomized Comparison	US (NJ)	Eli Lilly	12 months	Advanced practice nurse, nurse, dietitian	Yes	Yes
	Littrell (2003) ⁴³	RCT	US (GA)	Not reported	16 weeks	Advanced practice nurse, nurse, dietitian	Yes	Yes
Lifestyle Intervention	Wu (2008) ³²	RCT	China	Ministry of Science and Tech., PRC	12 weeks	Nurse, dietitian, exercise therapist	Yes	Yes
SIMPLE	Jean-Baptiste (2007) ³³	Randomized Controlled Pilot	US (CT)	CMHC	16 weeks	Providers at mental health settings	Yes	Yes
DART	McKibbin (2006) ³⁴	RCT	US (CA)	NIMH & DVA	24 weeks		Yes	Yes
Behavioral Therapy (BT)	Brar (2005) ³⁵	RCT	US (PA)	Janssen	14 weeks	Experience with SMI	Yes	Yes

To obtain training materials such as manuals and pamphlets, or to inquire about scheduling training sessions for the different programs, see **Table 5**.

Table 5. Training materials and contact information for implementation ready health promotion practices

Practice	Manual Available	Training Available	Contact
In SHAPE	✓	✓	Ken Jue: ken@kenjue.com
ACHIEVE	✓	✓	Joseph Gennusa: jgennus1@jhmi.edu
HEALTH	✓		Dr. Christina Mangurian: Christina.Mangurian@ucsf.edu
RENEW	✓	✓	www.cmhsrp.uic.edu/health/weight-wellbeing.asp Dr. Catana Brown: cbrown2@midwestern.edu
SFW	✓	✓	Betty Vreeland: vreelaeb@umdnj.edu
Lifestyle Intervention	✓	✓	Dr. Ren-Rong Wu: wurenrong2005@yahoo.com.cn
SIMPLE	✓	✓	www.simpleprogram.org Dr. Cenk Tek: cenk.tek@yale.edu.
DART	✓		Dr. Christine McKibbin: cmckibbi@uwyo.edu
BT	✓		Rohan Ganguli: Rohan.Ganguli@camh.ca

SECTION VI: Evaluating Health Promotion Programs for Persons with Serious Mental Illness: What Works?

This section provides a checklist that can be used in evaluating and comparing health promotion programs (exercise and nutrition programs) for persons with SMI. Each of these features is important to consider in evaluating programs that are a) most effective and b) ready for implementation in real-world settings. This checklist can be used to evaluate the practices described in this implementation guide and can also be used to evaluate new practices or “promising practices” that have not been reviewed in this guide. A greater number of checked items in either category will be associated with greater confidence in the effectiveness of the intervention and the implementation readiness of the program.

A practice that is effective, but does not have adequate implementation materials, may be difficult to implement in real world settings. There may be substantive differences between a manual designed for a carefully planned research study, and a manual intended to guide providers in the practical issues associated with real-world implementation. In contrast, a program that has clear and appealing manuals, attractively produced implementation materials, and/or easy to implement and inexpensive implementation requirements, but lacks well-documented evidence of effectiveness, should be considered with significant skepticism and caution. Programs that are enthusiastically promoted based on anecdotal evidence, general reports of “satisfaction,” or pre-post outcomes collected by those who provided the intervention, may be practical and popular, but ineffective when provided in a larger scale implementation or program. The following checklist can be used as a helpful guide to evaluating and choosing an appropriate health promotion program.

Checklist for Evaluating Health Promotion Programs for Persons with Serious Mental Illness: What Works?

This checklist can be used for comparing health promotion programs. Check all that apply. Each of these features is important to consider in evaluating programs that are a) effective and b) ready for implementation in real-world settings.

Features Associated with Greater Health Promotion Program Effectiveness

- Program has been specifically designed, evaluated, and proven effective for persons with mental illness
- Program has been proven effective in a randomized controlled trial (RCT) consistent with establishing an “evidence-based practice”
- Outcomes are reported as clinically significant, not just statistically significant (i.e. outcomes include % or total sample weight loss of at least 5% or more and/or reports on clinically significant change in fitness)
- Program consists of active participation in physical activity and nutrition (not just education, classroom, or passive learning)
- Program includes both physical activity and nutrition components (not just one or the other)
- Program includes a component of physical activity/and or nutrition with coaching or supervision by a person with training in fitness and/or nutrition coaching
- Program includes ongoing self-monitoring by the participant and review by the coach or provider of goals and outcomes (e.g., weight, amount of regular physical activity or exercise, nutrition, etc.)
- Duration of program participation is at least 6 months

Features of Programs Associated with Greater Implementation Readiness

- The program has been implemented at least once outside of the research setting
- The program has been implemented in multiple settings by different agencies outside of the initial research setting
- The program has been implemented and provided without relying on grant funding
- There is an instruction manual for implementing the program designed for providers in real-world settings (not just a research manual)
- Technical assistance for training and implementation of the program is available

SECTION VII: Evaluating Your Organization's Readiness to Adopt a Health Promotion Program for Persons with Serious Mental Illness

This section can be used to evaluate your organization's readiness to implement a health promotion program (exercise and nutrition programs) for persons with serious mental illness. The questions in this checklist cover four key domains related to organizational readiness: 1) Defined Need; 2) Readiness for Change in Culture; 3) Time, Resources, Personnel; and 4) Sustainment of the Change. This 10-item checklist will help your institution understand its level of readiness to initiate a health promotion program. A greater number of checked items will be associated with greater organizational readiness to implement a health promotion program. However, a higher score on this checklist does not guarantee successful implementation.



Organizational readiness is a complex multi-factorial part of successful implementation, and this checklist is not comprehensive and is intended only to provide a preliminary assessment of your organization's readiness. Staff members and senior leaders at your institution should complete the checklist independently, and then responses should be compared as a group in order to stimulate discussion and to help with determining the necessary steps toward implementing a health promotion program. This checklist may also be helpful for identifying areas of weakness or disagreement that require further attention.

This checklist is adapted from the Agency for Healthcare Research and Quality (AHRQ) Organizational Readiness Assessment Checklist. The AHRQ checklist can be found at: teamstepps.ahrq.gov/readiness/

Checklist for Evaluating Your Organization's Readiness to Adopt a Health Promotion Program for Persons with Serious Mental Illness

This checklist can be used to help your institution understand its level of readiness to initiate a health promotion program targeting obesity and fitness among individuals with serious mental illness. Check all that apply.

Defined Need

-Have you clearly defined the need that is driving your institution to consider implementing a health promotion program?
-Is building a stronger culture that embraces wellness and health promotion as a key element an appropriate strategy to address your institution's need?

Readiness for Change in Culture – Adopting a Culture that Promotes Wellness and Health Promotion

-Is now the right time for implementing a culture change (i.e., it will not compete with other major changes currently being made at your institution)?
-Is a culture change that emphasizes the importance of wellness and health promotion feasible and acceptable?
-Will your institution's leaders support a culture change and the effort required to implement and sustain a health promotion program?

Time, Resources, Personnel

..... Will your institution provide sufficient resources, materials, and staff with the necessary characteristics and attitudes to lead the implementation and delivery of a health promotion program?

..... Will your institution allow time to secure necessary materials and resources, and prepare the staff for their role in leading a health promotion program?

..... Will your institution allow time for personnel to attend training?

Sustainment of the Change

..... Will your institution be willing to measure and assess progress of implementing a health promotion program and continuously improve program reach and delivery?

..... Will your institution be able to reinforce and reward staff for engaging and retaining consumers with SMI into a health promotion program?

SECTION VIII: Individual Descriptions of Evidence-Based Implementation Ready Practices

This section of the Health Promotion Resource Guide provides individual descriptions of the nine selected evidence-based interventions implemented in different settings following completion of their respective studies:

- 1) In SHAPE^{27,28}
- 2) Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)²⁹
- 3) Healthy Eating and Activity in Latinos Treated in the Heights (HEALTH)³⁰
- 4) Recovering Through Nutrition and Exercise for Weight Loss (RENEW)³¹
- 5) Solutions for Wellness (SFW) Manualized Wellness Program
- 6) Lifestyle Intervention³²
- 7) Simplified Intervention to Modify Physical activity, Lifestyle, and Eating behavior (SIMPLE)³³
- 8) Diabetes Awareness and Rehabilitation Training (DART)³⁴
- 9) Behavioral Group-Based Treatment for Weight Reduction in Schizophrenia and Other Severe Mental Illnesses (BT)³⁵

1) In SHAPE

In SHAPE is an individualized health promotion program designed to be delivered in community settings, with the goal of improving health behaviors related to diet and exercise among individuals with SMI.⁴⁴ A certified fitness trainer delivers the program to participants, and assists them in identifying personal fitness goals and developing an exercise and diet plan. In this program, the plan is tailored according to each participant's fitness abilities, dietary behaviors, goals, and preferences, and participants are provided with a gym membership to a community fitness facility. The trainers are certified in fitness training and CPR, and have received additional training from dietitians, as well as instruction in motivational interviewing, goal setting, and the symptoms and treatments of mental illnesses. The caseload for the fitness trainers is typically 30 participants per one full-time equivalent. For one hour each week, fitness trainers meet with participants to review progress, and provide instruction and education about exercise and nutrition. In addition, there are monthly weight-management group sessions, where 6-8 participants can meet with a fitness trainer at a community setting to receive healthy eating education and participate in group discussions.

A 2013 randomized controlled trial conducted in Concord, New Hampshire compared the In SHAPE program to fitness club membership alone. In this study, 49% of In SHAPE participants achieved *either* clinically significant increased cardiorespiratory fitness, measured as >50 meter increase on the 6-minute Walk Test, *or* clinically significant weight loss of 5% of body weight or greater. Most notably, 24% In SHAPE participants achieved *both* improved fitness *and* weight loss.²⁷ This study was supported by a grant from the Centers for Disease Control (CDC). A subsequent randomized controlled trial compared the 12-month In SHAPE program to fitness club membership within an ethnically diverse sample of 210 individuals with serious mental illness from Boston, Massachusetts.²⁸ In this trial, In SHAPE participants lost significantly more weight compared to fitness club membership participants ($p=0.029$). Additionally, 51% of In SHAPE participants achieved *either* clinically significant increased cardiorespiratory fitness, measured as >50 meter increase on the 6-minute Walk Test, *or* clinically significant weight loss of 5% of body weight or greater. These weight loss outcomes were maintained at 18-month follow-up. This larger randomized control trial was supported by a grant from the National Institute of Mental Health (NIMH).

The effectiveness of the In SHAPE program has been demonstrated in a randomized controlled trial and then replicated in a subsequent randomized controlled trial conducted in an entirely different setting, representing a high level of evidence to support this program. In SHAPE has since been implemented across numerous mental health facilities in New Hampshire and elsewhere. Formal training for In SHAPE is available, and an abbreviated instruction manual is available free of charge from the program coordinator. For enquiries contact Ken Jue at ken@kenjue.com.



2) Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)

This 18-month weight loss intervention consists of three contact types: group weight management sessions, individual weight management sessions, and group exercise sessions.²⁹ The intervention is divided into two phases, the initial 6-month intervention phase (intensive phase), followed by the maintenance phase from months 7-18. During the initial intervention phase, participants attend three monthly 45-minute group weight management sessions led by an interventionist, one monthly 15-20 minute individual visit with an interventionist, three weekly 45-minute group exercise sessions, and weekly weigh-ins. During the maintenance phase, participants attend one 45-minute group weight-management session each month, one 15-20 minute individual visit with an interventionist each month, three 45-minute group exercise sessions each week, and semi-monthly weigh-ins.

The group exercise sessions are 45 minutes and place emphasis on moderate intensity physical activity. The weight management sessions are 45-minute group sessions that cover diet education, self-monitoring, and include hands-on activities such as measuring portions and grocery shopping. Interventionists deliver both the group exercise and weight management sessions either alone or in pairs. Typically, 1-2 interventionists facilitate classes for 20-30 participants. The individual weight loss consultations are delivered one-on-one, which allows for a personalized treatment plan and flexibility of scheduling. The interventionists are specifically trained to deliver the intervention, and typically have bachelor degrees in health education, dietetics, or kinesiology, as well as relevant experience working with individuals with SMI. Those leading the group exercise classes are certified exercise instructors from the community, and are specifically trained for this intervention.

The feasibility of implementing this program was previously demonstrated in a 2011 pilot study conducted through two psychiatric rehabilitation programs in Maryland, and supported by a grant from NIMH.⁴⁵ A 2013 randomized controlled trial compared this intervention to a control group that received standard nutrition and physical-activity information among 291 individuals with SMI.²⁹ The ACHIEVE program contributed to significant weight loss of 7.0lbs on average ($p=0.002$) for 10 psychiatric rehabilitation outpatient programs in Maryland.²⁹ Additionally, 37.8% of participants in the intervention group achieved clinically significant weight loss (5% or greater) compared to 22% of participants in the control group. The researchers are developing a standardized manual and training curriculum that will be made available to psychiatric rehabilitation programs and other mental health organizations. Inquiries can be addressed by contacting the study director Joseph Gennusa at jgennus1@jhmi.edu.

3) Healthy Eating and Activity in Latinos Treated in the Heights (HEALTH)

The description for the HEALTH intervention is brief because this program is modeled after the Behavioral Therapy (BT) approach developed by Brar et al (2005)³⁵ and described in item number 10 in this section. This intervention was culturally adapted for Latinos with SMI, is taught by a bilingual dietitian, and consists of 20 classes spanning 14 weeks.³⁰ During each class, participants weigh-in, provide the number of steps taken daily as measured using a pedometer, followed by instruction on how to incorporate exercise into daily routine. A quasi-experimental study of program implementation involved a clinic in Northern Manhattan in New York who provides mental health services to a predominantly Hispanic (75%), low-income population.³⁰ There were no significant differences for weight loss between the HEALTH group and a control group receiving basic nutrition education. However, 88% of participants completed follow-up for the intervention group, and 24% achieved clinically significant weight loss of 5% or greater. The manual is available for this program free of charge. For enquiries, contact Dr. Christina Mangurian at Christina.Mangurian@ucsf.edu.

4) Recovering Through Nutrition and Exercise for Weight Loss (RENEW)

RENEW is a 12-month intervention focused around nutrition and physical activity, and it is delivered in three separate phases: 1) a 3-month intensive phase with weekly 3-hour sessions to learn about nutrition, participate in physical activity, set individualized goals, and eat meals together; 2) a 3-month maintenance phase with monthly 3-hour meetings and weekly phone support; and 3) a 6-month intermittent support phase.³¹ During the intensive phase, participants are provided with two meal replacements each day, and are encouraged to reduce their daily calorie intake by 500 calories and to participate in a minimum of 30 minutes of daily physical activity.

The initial randomized controlled trial was funded by NIMH and demonstrated significant improvement with respect to weight loss. Participants in the RENEW program lost an average of 5.3 and 4.4 pounds at three and six months compared to an average weight gain of 0.1 and 0.9 pounds among participants in the control group ($p=0.005$).³¹ The RENEW program is targeted toward community-dwelling individuals with SMI with a BMI greater than or equal to 25. The program was developed by a nurse, dietitian, occupational therapist, and certified fitness trainer, however specific qualifications are not required for its implementation. It is recommended that a minimum of two group leaders deliver the program.

The manual for the RENEW program is available free of charge. In addition, the manual for an abbreviated version of the RENEW program, called Nutrition and Exercise for Wellness and Recovery (NEW-R), is available for download free of charge at: www.cmhsrp.uic.edu/health/weight-wellbeing.asp. The primary expenses associated with both the RENEW and NEW-R programs are the staffing requirements, as well as the meal costs for participants during the first 12 weeks. For additional details regarding either model, and for inquiries regarding the formal training curriculum, contact Dr. Catana Brown at cbrown2@midwestern.edu.

5) Solutions for Wellness (SFW) Manualized Wellness Program

SFW is a copyrighted manualized psychoeducational program developed, published, and distributed by Eli Lilly and Company. The program was first released in 1998, and while the format varies somewhat between settings, it is intended for persons with SMI who use psychotropic medications and have weight problems. The program typically consists of a 10-12 week curriculum focused around education to promote healthier diet and increased physical activity, and is based on written materials for both patients and program coordinators available to download free of charge. Within these materials, there are 18 subjects related to diet and 14 subjects related to exercise. The program coordinator or lesson facilitator - usually a nurse or therapist - can choose which subjects to include to tailor each lesson to meet the participants' needs.³⁶ Groups range in size from 4-12 participants.

SFW has been implemented and evaluated across numerous settings both nationally and internationally. There are several published studies evaluating SFW and prior versions of the program, though all of this research has been funded fully or in part by Eli Lilly or has been completed by researchers who are funded or have previously received funding from Eli Lilly in their research work. As such, the results from these studies must be interpreted with caution due to potential industry biases.

In general, the results have been mixed, with the SFW program and its variants contributing to a range of average weight losses from less than 0.1 pounds⁴³ to over 8.6 pounds.⁴⁰ Nevertheless, these studies provide important evidence when considering evidence-based health promotion practices for individuals with SMI. Specifically, a 2010 non-randomized comparison study from New Jersey found significant improvements in weight and BMI among SFW participants compared to controls, although the control group was considerably unmatched on demographic and health status variables, including race and psychiatric diagnosis.³⁷ Prior versions of SFW were evaluated in a 2003 mixed methods study in Georgia,⁴³ where the control group experienced significant weight gain compared to the experimental group, and also in a 2004 non-randomized comparison study from New Jersey⁴² that demonstrated significant improvements in weight and BMI in pre-post analyses as well as compared to usual care controls. A different version of the intervention was also evaluated in a Massachusetts randomized controlled trial where greater, though non-significant, weight loss was observed in program participants compared to the control group.⁴¹

Internationally, SFW and variations of this Eli Lilly funded program have been tested across diverse settings. From South Korea, participation in this 12-week program showed significant improvements in weight and BMI in a 2006 randomized controlled-trial,⁴⁰ and in follow up, a 2008 multi-center pre-post evaluation of the same intervention demonstrated significant reductions in BMI (-0.98 +/-1.01 kg/m², p<0.001) and weight (-2.64 +/- 2.75 kg, p<0.001).³⁹ A variation of the SFW program tested in Taiwan found significant decreases in weight (-2.7 +/-2.2, p<0.001) and BMI (-1.1 +/-1.0, p<0.001) after 48 weeks.³⁸ The Scandinavian SFW study was associated with maintaining or decreasing weight among participants.³⁶

Manuals for the SFW program are available for download from www.treatmentteam.com/Pages/solutionsForWellness.aspx and international versions from www.solutions-forwellness.org/. For additional inquiries, contact Eli Lilly's Neuroscience Information Line at 1-888-354-8326. For enquiries regarding evaluation, implementation, and training in relation to the SFW program in the United States contact Betty Vreeland at vreelael@umdnj.edu.



6) Lifestyle Intervention

The 12-week lifestyle intervention was developed and validated among patients with schizophrenia through a randomized controlled trial in Changsha, China.³² The program consists of a nutrition component that is based on the American Heart Association (AHA) diet plan that places emphasis on a reduction in calories from fats and carbohydrates, and an increase in fiber intake. A dietitian assisted program participants with diet recording, and adjusting dietary intake according to the AHA program. The second component of the intervention was comprised of intensive daily exercise sessions directed by an exercise physiologist for the first week, followed by home-based exercises for the remainder of the program. The therapists helped participants develop an individualized exercise plan consisting of a variety of light, moderate and vigorous activities to be completed at home. Participants were instructed to keep a log of their activities. Follow-up sessions to assess exercise adherence and offer advice were held after 4, 8 and 12-weeks, in conjunction with psychoeducational sessions focused on managing weight and describing the benefits of healthy diet and physical activity.

This intervention was evaluated in a four-arm randomized controlled trial comparing the lifestyle intervention and metformin to metformin alone, lifestyle intervention and placebo, and a placebo alone.³² A total of 32 participants were in each arm. Significant decreases in weight and BMI were observed in the lifestyle intervention and metformin group, the metformin alone group, and the lifestyle intervention and placebo group, while the same measures increased in the placebo group over time. The lifestyle intervention and metformin group experienced a decrease in weight of 7.3% (mean, 4.7 kg; 95% CI, 3.4-5.7 kg) and a decrease in BMI of 1.8 (95% CI, 1.3-2.3). The lifestyle intervention and placebo group experienced a decrease in weight of 2.2% (1.4 kg; 95% CI, 0.7-2.0 kg) and a decrease in BMI of 0.5 (95% CI, 0.3-0.8). Between group comparison revealed significant reductions in weight and BMI in the lifestyle intervention and metformin group compared to all other groups. The lifestyle intervention and placebo group lost significantly more weight (p<0.001) and lowered BMI (p<0.001) compared to the placebo alone group. This study was completed as part of the lead author's doctoral dissertation, and was funded through a grant from the Ministry of Science and Technology of the People's Republic of China.

This lifestyle intervention has been implemented for use among patients with schizophrenia within other hospitals in China. A manual describing the intervention in Chinese is available free of charge. To obtain the manual, contact Dr. Ren-Rong Wu by email at wurenrong2005@yahoo.com.cn.

7) Simplified Intervention to Modify Physical activity, Lifestyle, and Eating behavior (SIMPLE)



SIMPLE is a lifestyle program focused broadly on nutrition and physical activity that consists of one-hour group sessions with 8-12 attendees held weekly over a 16-week period. The program places emphasis on providing weight loss support and teaching healthy eating habits including important skills such as shopping, label reading, food preparation and portion control. This program involves active real-world training in nutrition where persons with SMI are taken to local grocery stores to do shopping and receive assistance with selecting healthier food choices. Through the program, participants also receive financial reimbursement for healthy foods for a total of \$25 each week. A 2007 pilot study (n=18), funded by the Connecticut Mental Health Center Foundation, highlighted the potential efficacy of this program, as participants with SMI lost an average of 6.4 pounds compared to a 5.9-pound weight gain on average among controls (p=0.026). Weight loss continued following completion of the intervention among participants who completed a 6-month follow-up. This intervention has since been evaluated as part of a larger randomized controlled trial, to which the results are not yet available. This program will be implemented clinically for use among patients at community mental health centers in New Haven, CT. Training is available at cost to all non-profit entities. The manual describing this intervention as well as participant handouts are available free of charge at www.simpleprogram.org. For additional inquiries, contact Dr. Cenk Tek at cenk.tek@yale.edu.

8) Diabetes Awareness and Rehabilitation Training (DART)

DART is a 24 week manualized intervention consisting of three primary components: 1) diabetes education; 2) nutrition; and 3) lifestyle exercise.³⁴ The education component covers several topics related to diabetes and diabetes management, including basic symptoms, complications, medications, how to use a glucose meter, and how to talk with your doctor. During the nutrition component, participants learn about food groups, portion sizes, selecting healthy meals, how to read labels, and how to replace sugar with fat and fiber. Lastly, the lifestyle exercise component reviews different types of exercise, the relationship between blood sugar and exercise, how to track exercise using pedometers, and the importance of foot care during exercise.

The intervention is designed for middle-aged and older adults with serious mental illness (Schizophrenia or schizoaffective disorder) and type-2 diabetes mellitus who are taking a second-generation antipsychotic medication. The program has been implemented in community mental health centers and delivered by counselors with master's level training and experience working with persons with serious mental illness.

In a 2006 randomized controlled trial with 64 participants, those receiving DART (N=32) achieved significantly greater weight loss when compared to the usual care control group (5 lbs loss vs. 6 lbs gain, p<0.001).³⁴ Additionally, 38% of DART participants achieved clinically significant weight loss of 5% bodyweight or greater compared to 12% in the control group.³⁴ This study was supported by grants from NIMH and the Department of Veterans Affairs.

Currently, this program is being expanded to include people with bipolar disorder and major depression. The manual is available by contacting the program developer, Dr. Christine McKibbin at cmckibbi@uwoyo.edu.

9) A Behavioral Group-Based Treatment for Weight Reduction in Schizophrenia and Other Severe Mental Illnesses (BT)

In this 14-week behavioral treatment program, the primary focus is around diet and nutrition, and working through incremental steps towards developing an understanding of caloric content of foods, self-monitoring, and portion control among program participants.³⁵ The program consists of 20 sessions separated into seven steps, where two sessions are held each week for the first six weeks, and one weekly session for the remaining eight weeks. In the later sessions, there is some emphasis on exercise participation and calorie burning activities, though the program predominantly focuses on developing healthy eating habits.³⁵ Sessions are typically one hour in length and have 3-6 participants. Anyone with experience working with persons with SMI in group-based settings can deliver the program.

This program was evaluated in a 2005 randomized controlled trial in Pennsylvania. This study formed part of a larger trial that examined the effects of changing antipsychotics, from olanzapine to risperidone, on body weight among participants with SMI.⁴⁶ Both of these trials were funded by Janssen Pharmaceutica, the developer and manufacturer of risperidone (Risperdal), therefore the results should be interpreted with caution given potential conflicts of interest and industry bias. Out of 72 patients with SMI and BMI >26 kg/m², significant weight loss and reductions in BMI were observed in both the behavioral therapy group (n=34; -2.0 +/- 3.79 kg, p=0.005; -0.9 +/- 1.38, p=0.003 respectively) and the usual care group (n=37; -1.1 +/- 3.11 kg, p=0.042; -0.5 +/- 1.19, p=0.029, respectively). While the behavioral therapy group lost more weight and experienced greater reduction in BMI when compared to controls, the between group differences were not significant.

Among participants who attended at least one behavioral therapy session, significantly more participants in the behavioral therapy group reported clinically significant reductions in weight ($\geq 5\%$ of body weight) compared to the control group (32.1% vs. 10.8%, p=0.038). And for participants who completed the 14-week intervention, 40.9% achieved clinically significant weight loss. This behavioral therapy program has subsequently been evaluated in a larger randomized controlled trial funded by a NIMH R01 grant, to which the results are in preparation. The manual for the behavioral therapy program is available free of charge by contacting the study authors, Dr. Rohan Ganguli at Rohan.Ganguli@camh.ca.

APPENDIX I: Search Methods

Literature Review

The research team updated a previous review of the literature completed for SAMHSA in 2011 by Bartels & Desilets (refer to Box 1 for full description). Consistent with the methods used in the prior review, the research team conducted a comprehensive search of published systematic reviews and research studies indexed in the following electronic databases in August 2012: PubMed (MEDLINE), PsycINFO, The Cochrane Library and CINAHL. Search terms included a combination of keywords and medical subject headings (MeSH) relating to persons with SMI, physical health related co-morbidities and health promotion interventions. Specifically, the following search parameters were used: (“Schizophrenia”[MeSH] or “Psychotic Disorders”[MeSH] or “Bipolar Disorder”[MeSH] or “Depressive Disorder, Major”[MeSH] or “serious mental illness”) AND (“Obesity”[MeSH] or “Diabetes Mellitus”[MeSH] or “Hypertension”[MeSH] or “Heart Failure”[MeSH] or “Hyperlipidemias”[MeSH] or “Myocardial Infarction”[MeSH] or “Comorbidity”[MeSH] or “physical health” or “co-existing” or “co-occurring” or “comorbid”) AND (“Health Promotion”[MeSH] or “Diet”[MeSH] or “Diet Therapy”[MeSH] or “Exercise”[MeSH] or “Exercise Therapy”[MeSH] or “Health Behavior”[MeSH] or “Life Style”[MeSH]). Searches were limited to clinical trials, meta-analyses, randomized controlled trials (RCT) and reviews published in the past 20 years, written in the English language and with adult (aged 18+) subjects. In addition, the research team hand-selected and retrieved relevant articles from the review articles, from the reference lists of relevant articles, and following full text examination.

Box 1. Summary of Systematic Review

Title: Physical Activity and Nutrition Health Promotion Programs for Overweight People with Serious Mental Illness: What Works?

A 2011 Systematic Review and Analysis of the Evidence Base in the Published Research Literature by the Dartmouth Health Promotion Research Team

Stephen J. Bartels, MD, MS & Rebecca Desilets

In early 2011, a Dartmouth research team reviewed the published research literature addressing non-pharmacological lifestyle interventions aimed at reducing obesity and improving fitness for persons with SMI. An electronic database search was conducted to identify high quality research studies based on pre-designated inclusion and exclusion criteria. The initial search identified 728 articles that were screened for content, resulting in 52 articles specifically addressing the topic area. From this set, 6 systematic review articles and 24 research trials met predetermined criteria for quality, including 12 randomized controlled trials (RCTs), 6 comparison studies and 6 pre-post outcome studies. The majority of the trials incorporated both nutritional and exercise components into their interventions, although several studies focused on either nutrition or exercise. Interventions were characterized according to whether they provided an educational approach, an activity-based approach or combined education and activity.

Weight loss achieved for the interventions studied in the RCT studies consisted of a median 2.5 kg (5.5 lbs). All of the controlled studies reported differences in weight and/or BMI change between the intervention and control groups, and those differences were statistically significant in 10 of the controlled studies. Intervention group participants achieved a mean weight loss or reduction in BMI in 22 of the 24 studies selected for this review. Percentage weight loss was reported in 19 of the research trials, with a median of 2.6%. Only one study achieved a clinically significant median weight loss of 5% or greater (5.4%), although one other study reported that a significant proportion of participants (38%) lost at least 5% of their baseline weight. Clinically significant increases in physical fitness (as measured by the 6-minute walk test) were achieved in several of the trials. Statistically significant health benefits were reported more frequently among the interventions that utilized a combined educational- and activity-based approach than among those that used one or the other alone. Finally, lifestyle interventions demonstrated improved psychological functioning among people with SMI: over half of the studies that measured depression symptoms reported statistically significant symptomatic improvement from the beginning until the end of the intervention among program participants.

Using these search terms, and combining the results of the prior review, a total of 1,541 articles were retrieved, screened, and evaluated for relevance, of which the majority (n = 1,450) were not relevant or did not meet inclusion criteria (n = 61) following full-text review. The remaining 30 studies represented evidence-based practices that satisfied the following inclusion criteria:

- ▶▶ Trials including a behavioral or educational (non-pharmacological) health promotion intervention
- ▶▶ Reported results that used standard measures of physical health outcomes, such as weight, body mass index (BMI), waist circumference, or other measures of physical fitness
- ▶▶ Study participants were primarily adults diagnosed with SMI, including schizophrenia, schizoaffective disorder, bipolar disorder, or severe depression
- ▶▶ Minimum of 30 participants in the study

Among these 30 peer-reviewed studies, some interventions were described more than once by the same study authors, leaving a total of 27 unique evaluations of evidence-based practices aimed at reducing obesity and improving physical fitness for people with serious mental illness. These 27 trials consisted of 15 randomized controlled trials (RCTs), 6 non-randomized comparison studies, and 6 single arm trials. Results were not limited to studies conducted in the U.S., and of the 27 trials identified, 11 were from 9 countries abroad: Canada (n=1); China (n=1); Denmark (n=1); Israel (n = 1); Italy (n = 1); Korea (n=2); Switzerland (n=1); Taiwan (n=2); and Thailand (n=1).

Follow-up with Study Authors

The next step was to expand upon the information collected through the literature review, and to determine the extent to which each of the 27 evidence-based programs were “implementation-ready” for use by usual care providers, and to determine the resources and costs associated with their implementation. To address these questions, the research team contacted each of the study authors and program developers to obtain responses to the detailed questions described in Box 2.

Box 2. Survey Questions

- 1) Was your program and research study grant funded? If so, did the program continue following the end of the grant?
 - 2) Has your program been disseminated or implemented in other settings following the initial research study?
- If you answered ‘yes’ to this question, please proceed to the following questions (3-12). If you answered ‘no’, then it is not necessary to answer the following questions. Thank you for your time.*
- 3) What is the target population of your program? Are there specific BMI or weight criteria? Are there pre-specified psychiatric or medical conditions?
 - 4) What qualifications must the providers have in order to implement and deliver your program? (eg: Nutritionist, nurse, physician, certified fitness trainer etc.)
 - 5) What are the staffing requirements, and the ratio of full-time providers to the number of participants necessary to deliver your program?
 - 6) Has your program been used or implemented in clinical or other settings outside of the original study? If so, in what settings? (Not including any follow up research)
 - 7) Is there an instruction manual available for clinicians, providers and health care systems for your program? Are there additional materials describing your program, such as video or web-based content?
 - 8) Are the manuals or other materials proprietary or are they available in the public domain? Is there a cost in order to obtain the instruction manual or other materials?
 - 9) Is there a formal training curriculum available in order to learn how to implement your program? If so, do you offer training?
 - 10) What is the estimated cost for an agency or provider group to receive training in order to implement your program?
 - 11) Has the overall cost (eg. training, staffing, supervisions, materials, etc.) of implementing your program in a usual care setting been estimated? (Yes/No) If so, what is the approximate cost per person or per 100 persons?
 - 12) Where can someone go to learn more about your program? (eg. website, email or phone number of contact person, pamphlet, etc.) Please provide details.

APPENDIX II: Search Results

Over a 6-week period from mid-September to late November 2012, a total of 20 out of the 27 study authors (74%) responded with completed questionnaires. There were 14 respondents for studies conducted in the United States (Seven RCTs, three comparison studies, and four single arm studies), and six respondents for studies conducted at international sites (Three RCTs, one comparison study, and two single arm studies). The majority of these interventions consisted of combined nutrition and fitness education, but with varying formats and intensities, while some programs focused either on exercise or diet only. The results are organized according to whether the interventions are implementation ready or not. In the first section, a detailed description is provided of each intervention that has been implemented outside of the research setting and for which manuals and training are available or are in preparation. In the second section, an overview of all the other models is provided.

APPENDIX III: Evidence-Based Health Promotion Programs Not Available for Implementation

There were also several models that have been evaluated and validated in studies, but that have not been implemented elsewhere. Most often, these interventions were discontinued due to lack of funding. The table below provides an overview of these models.

Evidence-based interventions that discontinued after completion of the study

Study	Region	Design	Funding	Duration	Description	Reason to Discontinue
Zhang (2012) ⁴⁷	US (NY)	Single arm	Health System	12 months	Weekly group or individual cognitive-behavioral weight management.	Lack of funding.
Methapatara (2011) ⁴⁸	Thailand	RCT	Internal	12 weeks	Pedometer walking program with goal setting, group education on nutrition and exercise.	Research study only.
Melamed (2008) ⁴⁹	Israel	Non-Randomized Comparison	Eli Lilly in part	12 weeks	Facility-based combination of nutritional counseling, group behavioral therapy, mealtimes overseen by supervisor, and walking sessions multiple times per week.	Program was not continued.
Wu (2007) ⁵⁰	Taiwan	RCT	China Medical University Grant	24 weeks	Facility-based intervention consisting of reduced calorie diet and exercise program	Research study only.
Beebe (2005) ⁵¹	US (TN)	RCT	NIMH Grant	16 weeks	Exercise-based intervention consisting of 3 weekly treadmill-walking sessions.	Research study only.
Kalarchian (2005) ⁵²	US (PA)	Single arm	NARSAD Grant	12 weeks	Diet intervention based on the Stoplight Diet with 12 hour-long educational sessions	End of funding.
Richardson (2005) ⁵³	US (MI)	Single arm	Internal – University of Michigan	12 weeks	Lifestyle intervention program consisting of nutrition and exercise education sessions plus a group walk at the end of each session.	End of funding.

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