

Can we predict who will be successful in a weight loss intervention tailored for individuals with severe mental illness? The ACHIEVE Study

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Outline

- Background: Obesity is epidemic in persons with severe mental illness (SMI), and intervention adapted to persons with SMI are needed.
- Achieving Healthy Lifestyles in Psych Rehab (ACHIEVE) Study (NIMH-R34MH070368)
 - Piloted weight loss intervention tailored to persons with SMI.
 - Present baseline characteristics as possible predictors of success.
 - Present final results of pilot intervention.
- Future directions: Randomized controlled trial

Health behavior change interventions for weight loss in the general population

- Trial of Nonpharmacologic Interventions in the Elderly (TONE) maintained weight loss 5kg for 30 months
 - Trials of Hypertension Prevention II 2kg difference from control at 3 years (even with some regained)
 - Diabetes Prevention Program 4kg at 4 years (↓ diabetes by 58%)
 - Finnish Diabetes Prevention Study (↓ diabetes by 58%)
 - Cochrane 2004 Review (2.8 kg 95%CI[1.0-4.7]) weight loss in non-pharm weight loss interventions > 1 year for adults with pre-diabetes
- Relatively small weight changes can prevent diabetes, hypertension
 - With some weight regain, benefit on diabetes, hypertension is still preserved
 - Weight changes can be sustained, but we need to know more about how to do this best
 - Weight Loss Maintenance Study

Challenges in Behavioral Lifestyle Interventions in SMI

- Cognitive limitations
- Socioeconomic
 - Access to healthy food
 - Access to place to exercise
- Competing demands
 - Mental health
 - Medical
 - Social, housing

Rationale for Healthy Lifestyles Intervention in Psych Rehab Setting

- Psychiatric rehabilitation framework fits well with behavioral change theories
 - Self-efficacy
 - Skill modeling and development
- Opportunity for environmental components
 - Physical activity
 - Food served
- Location, location, location – already attending
- Potential for sustainability

Achieving Healthy Lifestyles in Psych Rehabilitation: ACHIEVE Study



- National Institute of Mental Health R34MH070368: Clinical Trial Planning Grant
- Goal: To design and pilot test a multifaceted weight loss intervention appropriately adapted for persons with SMI in a psychiatric rehabilitation program.
- Study design: Pre-post with two sequential cohorts of 25 participants
- Study population: Overweight or obese adults with SMI attending Alliance, Inc., a psychiatric rehabilitation program in Baltimore City and Baltimore County
- Intervention: Individual and group education and counseling by trained nutritionists, on-site physical activity classes, healthy modification of on-site meals, 6 month duration
- Primary outcome: Weight change at 6 months

Eligibility Criteria



Inclusion criteria

- Age 18 or older
- Body Mass Index at least 25.0 kg/m²
- Plan to be in rehab program for at least 8 months
- Able and willing to give informed consent and participate.
- No change in psychotropic medications within 90 days

Exclusion criteria

- Contraindication to weight loss
 - cancer in past 2 years, liver failure or anorexia
- Pregnant or planning a pregnancy
- Inability to walk to participate in exercise class
- Consumption of more than 14 drinks per week
- Symptoms of angina or cardiovascular event within 6 months

ACHIEVE Study Intervention

- Healthy modification of on-site meals and vending machine offerings
- Group and individual nutrition classes
- On-site group physical activity classes

Developed and delivered by nutritionists experienced in behavioral interventions in general population trained to work with SMI



ACHIEVE: Healthy Modification of On-site Meals

- Intervention directed toward kitchen staff
 - ↓ Portion size, ↓ sugar,
↑ lean meats/ cheeses,
↑ fresh fruit /vegetables,
↑ baking ↓ frying
- Healthy modification of vending machine offerings



Kitchen staff and study interventionists evaluating menus



ACHIEVE Nutrition Intervention

- Weigh-in three times a week
 - Self-monitoring, feedback
 - Incentives for number of times weighed in
- Group nutrition classes
 - 45 minutes twice weekly
- Individual nutrition visit 15 minutes every month



Nutrition class

ACHIEVE: Physical Activity Intervention

On-site group physical activity

- 3 times/week for 45 minutes
- Exercise trainer with experience in community
- Participant involvement in leading

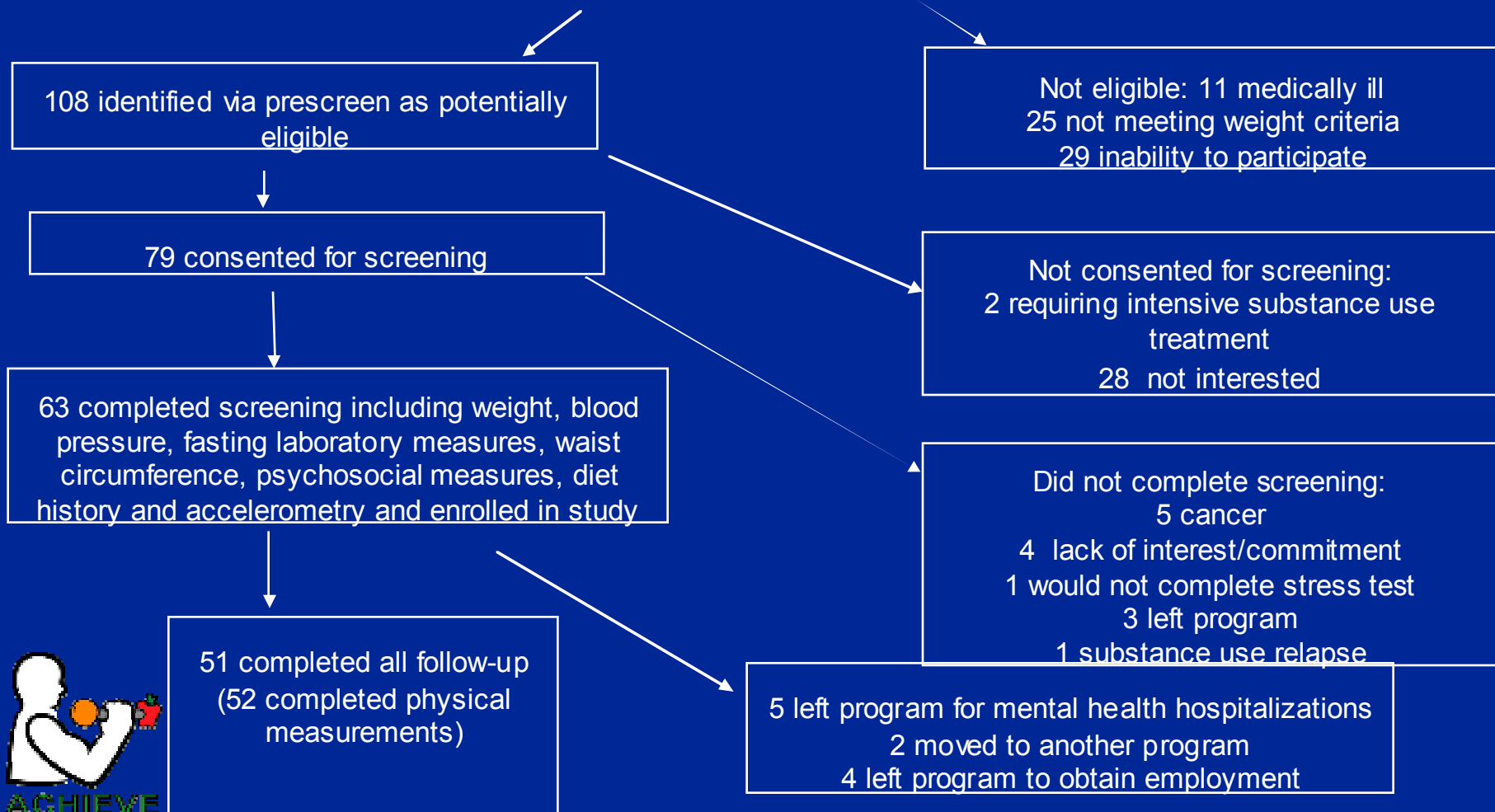


Participants exercising



ACHIEVE: Recruitment, Screening, Enrollment

173 consumers at 2 day programs
-community meetings
-flyers



ACHIEVE Enrolled Participant Characteristics

	Cohort 1 (N=32)	Cohort 2 (N=31)
	%	%
Mean age (years)	45	42
Men	42	48
Women	59	52
African-American	88	13
Schizophrenia	42	26
Schizoaffective	9	32
Other psychotic	3	6
Bipolar disorder	18	29
Depression	24	16
Anxiety disorder	3	3
Mental retardation	36	10
Alcohol/substance abuse	21	48
Mean RBANS	59.9	68.7



ACHIEVE Participant Characteristics



	Cohort 1 (n=32) (%)	Cohort 2 (n=31) (%)
Current smoker	55	63
Hypertension	36	32
Diabetes mellitus	27	13
Mean Body Mass Index (kg/m ²) Men	34.6	34.7
Women	33.6	36.8
Mean waist circumference (cm) Men	117.5 (SD 12.3)	115.8 (SD 13.6)
Women	110.5 (SD 15.4)	116.3 (SD 19.5)
Mean Blood pressure (mm/Hg) Systolic	120.1 (SD 14.8)	117.2 (SD 11.0)
Diastolic	70.6 (SD 10.9)	69.9 (SD 9.0)
Total cholesterol (mg/dl)	178.2 (SD 33.9)	179.1 (SD 38.9)
Triglycerides (mg/dl)	134.1 (SD 69.9)	165.8 (SD 88.3)
HDL (mg/dl)	46.3 (SD 18.6)	42.0 (SD 13.7)
LDL (mg/dl)	105.0 (SD 28.6)	105.0 (SD 34.4)
Glucose (mg/dl)	109.5 (SD 55.7)	105.5 (SD 41.1)
Insulin (μU/ml)	22.0 (SD 18.0)	13.0 (SD 6.1)
C-reactive protein (mg/L)	7.6 (SD 8.6)	6.8 (SD 6.2)

ACHIEVE Results: Participation

- Average percentage of nutrition classes attended
 - 73%
- Average exercise class attendance
 - 73% when at rehab center
- Average overall attendance
 - 72%





ACHIEVE Participant Physical Measurements (n=52)

Mean characteristics	Baseline Mean (SD)	Follow-up Mean (SD)	Change Mean (SD)	P-value
Weight (lbs)	210.9 (43.9)	206.4 (42.3)	-4.5 (12.8)	0.01
Waist circumference (cm)	113.3 (15.1)	110.0 (15.9)	-3.1 (5.6)	<0.01
BMI (kg/m ²)	34.1 (7.2)	33.5 (7.2)	-0.6 (2.0)	0.03
6 minute fitness walk (feet)	1358 (297)	1463 (311)	+104 (180)	<0.01
Systolic blood pressure (mmHg)	117.1 (11.7)	117.3 (12.7)	+0.2 (11.9)	NS
Diastolic blood pressure (mmHg)	69.8 (9.9)	72.0 (11.3)	+2.2 (9.3)	NS

*52 participants completed weight measurements

Psychosocial Measures

- SF-36 (baseline and follow-up)
- SCL-90 (baseline)
- Depression symptoms-CES-D (baseline and follow-up)
- RBANS cognitive function (baseline)
- Lehman quality of life short form (baseline and follow-up)
- General perceived self-efficacy (baseline and follow-up)
- Binge eating assessment (baseline and follow-up)
- Eating / exercise habits confidence (baseline and follow-up)





ACHIEVE Participant Psychological Measurements (n=51)

Mean characteristics	Baseline Mean (SD)	Follow-up Mean (SD)	Change Mean (SD)	P-value
SCL-90 General Severity Index	1.0 (0.8)	not measured		
CES-D Depression Score	21.0 (12.4)	22.5 (12.2)	+1.9 (9.3)	0.25
SF-36 General Health	61.5 (24.2)	60.1 (27.8)	-1.4 (19.0)	0.60
RBANS	63.9 (14.0)	not measured		
Lehman Quality of Life General Life Satisfaction	4.9 (1.4)	4.9 (1.7)	-0.3 (2.0)	0.62
General Self Efficacy	29.8 (5.9)	29.5 (7.1)	-0.2 (5.7)	0.77

*51 participants completed all of follow-up

ACHIEVE Lost Weight (n=32) vs Did Not Lose Weight (n=19)



Mean characteristics	Lost Weight (SD)	Did Not Lose Weight (SD)	P-value
Overall Participation (%)	72.8 (19.1)	71.5 (19.2)	0.81
Exercise Participation (%)	74.3 (20.8)	70.0 (25.3)	0.54
Nutrition Attendance (%)	72.0 (23.0)	75.2 (12.1)	0.58
Baseline Weight (lbs)	208.9 (45.8)	207.1 (42.7)	0.89
Baseline Waist circumference (cm)	112.1 (13.2)	114.3 (18.1)	0.63
Baseline BMI (kg/m ²)	34.0 (7.0)	34.3 (7.7)	0.90
Baseline 6 minute fitness walk (feet)	1390.2 (312.5)	1332.8 (250.7)	0.50
Baseline Systolic blood pressure (mmHg)	116.8 (10.8)	117.5 (13.4)	0.85
Baseline Diastolic blood pressure (mmHg)	68.6 (9.4)	71.7 (10.8)	0.29

ACHIEVE Lost Weight (n=32) vs Did Not Lose Weight (n=19)



Mean characteristics	Lost Weight (SD)	Did Not Lose Weight (SD)	P-value
SCL-90 General Severity Index	1.1 (0.8)	0.7 (0.5)	0.05
Baseline CES-D Depression Score	22.8 (12.8)	17.8 (11.3)	0.17
Baseline SF-36 General Health	60.0 (26.1)	64.1 (21.1)	0.57
RBANS	62.9 (13.5)	65.6 (15.1)	0.52
Baseline Lehman Quality of Life General Life Satisfaction	4.6 (1.4)	5.3 (1.3)	0.10
Baseline General Self Efficacy	29.1 (6.7)	31.0 (4.4)	0.26

ACHIEVE Overall Participation by Category



Mean characteristics	Mean Participation (%) (SD)-Category 0	Mean Participation (%) (SD)-Category 1	P-value
Substance abuse (25% yes) (0=no,1=yes)	75.5 (17.2)	63.0 (21.5)	0.04
Alcohol abuse (29% yes) (0=no,1=yes)	74.2 (17.5)	67.8 (22.2)	0.27
Atypical antipsychotic use (73% yes) (0=no,1=yes)	69.8 (17.4)	73.3 (19.7)	0.57
Mental retardation (27% yes) (0=no,1=yes)	69.7 (21.1)	79.1 (9.2)	0.12
Sex (53% female) (0=female,1=male)	68.8 (20.4)	76.4 (16.8)	0.16

Summary

- Successful recruitment, enrollment
- High levels of participation in intervention
- Results show weight loss, waist circumference decrease, increased fitness
- While psychiatric symptoms were severe and health status was low, these characteristics were not related to intervention success.
- Weight loss interventions can be performed across a wide spectrum of persons with SMI.

Limitations:

- Pre/post study, no control group

Next step: R-01 for Randomized Clinical Trial

- Objective: To test a practical behavioral intervention to accomplish and sustain weight loss in overweight and obese consumers with severe mental illness attending psychiatric rehabilitation programs

Randomized Clinical Trial of ACHIEVE

- Study population: Overweight or obese adult consumers attending psychiatric rehabilitation programs
- Setting: Ten psychiatric rehabilitation programs throughout Maryland
- Intervention group: Individuals randomized to nutritional intervention and group physical activity six months intensive, 12 months maintenance or control
- Primary Outcome: weight change at 6 months, 18 months
- Secondary Outcomes: menus/dietary intake, physical activity/physical fitness, waist circumference, depression, quality of life, health status

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- Background: Obesity is epidemic in persons with severe mental illness (SMI), and interventions adapted to persons with SMI are needed. The ACHIEVE Study piloted a weight loss intervention tailored to persons with SMI. We examined whether baseline participant characteristics were associated with program attendance and weight loss, and hypothesized that less severe psychiatric symptoms and better health status would be associated with high attendance and weight loss.
- Methods: We performed a pre/post 6 month intervention consisting of nutrition and exercise classes at two psychiatric rehabilitation centers. T-tests and linear regression were performed.
- Results: Fifty one (81% of enrolled) participants completed the study. Mean age was 45 years, 53% were women, 53% African American, 57% had schizophrenia, 20% bipolar disorder, 20% depression, 27% mental retardation, 35% substance use, 73% used atypical antipsychotics. Mean BMI was 34.5 kg/m². The mean SCL-90 General Severity Index was 1.0; CES-D depression score was 21; SF-36 General Health was 61.5. Participants completing the study attended 72% of sessions and lost an average of 4.1 pounds (p=0.02); 63% lost weight. Most baseline characteristics including psychiatric symptoms and health status were not significantly related to attendance or weight loss; participants with substance use had lower attendance (65% vs 76%, p=0.05).
- Conclusion: Intervention attendance was high and most lost weight. While psychiatric symptoms were severe and health status was low, these characteristics were not related to intervention success. This pilot study illustrates that an effective weight loss intervention can be performed across a wide spectrum of persons with SMI.