Nutrition and Exercise for Wellness and Recovery: A Randomized Controlled Trial of a

Community-Based Health Promotion Intervention

(under review)

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Efficacy of Nutrition and Exercise for Wellness and Recovery: A Randomized Controlled Trial of a Community-Based Health Promotion Intervention

ABSTRACT

Objective: The purpose of this study was to examine the efficacy of the Nutrition and Exercise for Wellness and Recovery (NEW-R) intervention for improving competency and behaviors related to healthy eating, physical activity, and weight management.

Methods: Participants with psychiatric disability were recruited from four community mental health agencies and a hospital-based psychiatric outpatient clinic and randomly assigned to the NEW-R intervention (N = 55) or control condition (N = 58). Outcome measures included the Perceived Competence Scale, Health-Promoting Lifestyle Profile (HPLP), and weight loss using random effects regression models. A follow-up analysis examined the interaction of group, time, and site.

Results: 50/55 of the intervention and 57/58 of the control participants completed the study. The two groups did not differ significantly on any measured baseline characteristic. The intervention group had statistically significant improvements greater than the control group on Perceived Competence for exercise and healthy nutrition, total HPLP score, and 2 HPLP subscales (Nutrition and Spirituality). There was no significant difference between groups in weight loss. A study condition by time by site effect was observed: at 3 of the 5 sites where weight loss occurred, there was a significant difference in weight loss in the intervention compared to the control condition.

Conclusions: NEW-R offers promise as an intervention that can initiate changes in healthy lifestyle behaviors and perceived competence towards making these changes. It may also be effective for weight loss when administered in supportive settings.

The prevalence of obesity in the United States is 42.4% (1). Adults with psychiatric disabilities are disproportionately vulnerable to obesity (2,3) due to factors such as poverty (4), low physical activity (5,6), high volume of food intake (7), low fruit and vegetable intake (6), and side-effects of psychotropic medications (8,9). The primary health risks of obesity include premature death, type 2 diabetes, heart disease, stroke, hypertension, hyperlipidemia (1,10), and poor COVID-19 outcomes (11,12). Being overweight or obese is often associated with psychological issues, including increased internal stigma, reduced self-confidence, and persistent social isolation (13). Moreover, research shows that the job discrimination and wage disparities (14,15) experienced by obese individuals is compounded by co-occurring mental illness (16). Together, obesity and psychiatric disability inhibit meaningful, productive community participation beyond the effects of either condition alone.

The term "obesogenic environment" denotes environments that both promote weight gain and interfere with weight loss efforts (17). The ecological model of obesity proposes that people in obesogenic environments struggle against a culture that promotes consumption of high-fat and sugar-laden foods and encourages sedentary behaviors. While the average American lives in an obesogenic environment behaviorally determined by poor diet and lack of exercise, many people with psychiatric disabilities live in obesogenic environments that are both behaviorally *and* pharmacologically determined (18) given their high use of psychotropic medications associated with weight gain (19).

These concerns led to the development of weight management interventions for people with psychiatric disabilities. Research reviewed by Naslund et al (20) identified seventeen randomized controlled trials comparing weight loss interventions with controls or usual care. These were effective for modest weight reduction, with programs of longer duration achieving more consistent results. Despite these promising findings, implementation of complex, long-term interventions can be difficult for many community-based mental health programs with limited financial resources and multiple demands on staff time.

Our primary study aim was to test the effectiveness of Nutrition and Exercise for Wellness and Recovery (NEW-R), an eight-week manualized intervention using a strengths-based approach intended to

circumvent the impact of obesogenic environments. We hypothesized that compared with persons in the control group, NEW-R participants would experience greater increases in: 1) competence for healthy eating, exercise, and weight management; 2) ability to engage in health promoting behaviors and practices; and 3) weight loss.

METHODS

Study procedures

Study participants were recruited from 4 community mental health agencies and a hospital-based psychiatric outpatient clinic in Chicago and the surrounding suburbs by university investigators. Six separate waves of study recruitment followed by delivery of NEW-R classes began in October 2016 and ended in March 2019 (2 waves occurred at 1 site). Inclusion criteria were assessed via self-report and program records. If criteria were met, written informed consent was obtained using human subjects procedures approved by the Institutional Review Board of [name of University]. Randomization occurred at each site and was performed by interviewers at the conclusion of baseline interviews using computer-generated allocation sequences that concealed study condition until assignment (21). Information regarding participant characteristics and outcomes was obtained during in-person interviews at baseline, post-intervention (2 months post-baseline), and follow-up (8 months post-baseline) by researchers blinded to study condition. The study is registered at ClinicalTrials.gov.

Inclusion/exclusion criteria

Participants met all 6 inclusion criteria: 1) psychiatric disability status, defined in Public Law 102–3215 as a documented *Diagnostic and Statistical Manual of Mental Disorders (DSM)* diagnosis (22) accompanied by severe functional impairment (23); 2) enrolled in outpatient mental health services; 3) overweight or obese with a body mass index (BMI) $\geq$ 25; 4) age 18 years or older; 5) able to understand spoken English; and 6) willingness to provide informed written consent. Exclusion criteria mirrored those used in similar studies and included: 1) residing in a nursing home; 2) a terminal illness expected to

result in death within 1 year; 3) pregnancy; 4) history of eating disorder; 5) history of heart disease; 6) diagnosis of dementia; and 7) cognitive impairment severe enough to prohibit informed consent.

Study enrollment and retention

A total of 121 individuals attended study recruitment sessions and 113 individuals consented to participate in the study. Of these, 113 had a baseline interview and were randomized to the experimental (n=55) or control condition (n=58) (see CONSORT diagram in online supplement). Of the 113 interviewed, 95% (107/113) had one or more follow-up interviews, and these proportions did not differ significantly by study condition.

Intervention

NEW-R was designed as an 8-week program to make implementation feasible in community mental health settings, informed by a 12-month weight loss intervention for this population called RENEW (24, 25). The model's foundations include self-determination theory (26), psychiatric rehabilitation theory (27), and the ecological model of obesity (17). Finally, eight experts in weight loss and wellness programming for people with psychiatric disability helped identify salient content for a shorter program. NEW-R applies psychiatric rehabilitation principles including: 1) instruction that compensates for cognitive impairments that co-occur with some types of mental illnesses, 2) skill building and transfer of training to new environments, 3) provision of social and instrumental support, and 4) goal setting. In addition, the focus on intentionality for lifestyle changes promoting weight management was designed to encourage participants to enter more intensive weight loss programs if desired.

Each of the eight 90-minute closed NEW-R sessions involves didactic presentation of session content, followed by activities to personalize and apply the material, then individualized goal setting, and finally 20 minutes of exercise. The first session presents an overview of the intervention, the effects of obesity on physical and mental health, and the value of making a weekly NEW-R plan. The second and third sessions provide a comprehensive overview of healthier eating. The fourth session covers the benefits of exercise and strategies for increasing physical activity. The fifth and sixth sessions focus on

healthy eating in restaurants, meal preparation at home using recipes, and food shopping on a limited budget. Session 7 introduces participants to cooking tools and techniques to reduce carbohydrates and fat when cooking. During the final session, participants reflect on lifestyle changes they have made to promote weight management and described their plan for continued progress towards weight loss goals. Certificates of Completion are presented, and students enjoy a graduation celebration with healthy snacks.

Instructor training and supervision

The same two instructors taught across all study sites: one was an MA-level graduate student and the other had completed a peer certification program. Training included a one-hour webinar, followed by in-person practice of each of the 8 sessions (including exercise segments) observed by study leadership, instruction in procedures for fidelity assessment and attendance tracking, and human subjects education. Instructors were supervised by research staff at weekly meetings held throughout the period of intervention delivery at which they reviewed fidelity and attendance statistics, discussed content of the upcoming session, and resolved logistical issues.

Intervention Fidelity

Fidelity was monitored by researchers via completion of checklists with instructors within 48 hours of each session. Checklists tracked adherence to each session's prescribed topics, time frames, and instructional modalities. Each curriculum component was scored as 1 if the prescribed element occurred and 0 otherwise. Fidelity scores were computed as the proportion of prescribed elements present for that session. We also used direct observation of 2 randomly-selected sessions to validate fidelity reporting.

Control Condition

Participants in the control condition received services as usual in the program from which they were recruited.

Measures

The primary outcome of perceived competence for healthy eating and exercise was assessed by the 4-item Perceived Competence Scale (28) which uses 7-point Likert responses to measure respondents' degree of confidence in their ability to maintain a healthy diet and be physically active (baseline

Cronbach's alpha of .79). A secondary outcome was frequency of engaging in health promoting behaviors and practices as assessed by three subscales from the Health-Promoting Lifestyle Profile (HPLP) (29). We included subscales measuring nutrition, spiritual growth, and physical activity given their consistency with the intervention's targeted behaviors and theoretical underpinnings. Following the scale's authors (29), we also computed a total score summing responses to the 26 subscale items. HPLP total and subscale baseline Cronbach's alphas ranged from .76 to .88. Another secondary outcome was weight loss, with weight measured in pounds using a medical grade digital scale (the Health-O-Meter 498KL Remote Display Medical Weight Scale).

Statistical Analysis

Success of randomization was assessed using chi-square and t-tests. An intent-to-treat approach was used for the main analysis of outcomes (30), in which the effect of study condition was examined using random effects regression models with random intercepts and compound symmetry covariance structure for repeated measures. The study's randomized block design was addressed by inclusion of site as a fixed effect (31,32). Each model included random intercept, study condition, time, and site. The longitudinal intervention effects were modeled with a condition by time interaction term. Following the literature, weight change was reported in terms of standardized mean difference (SMD). To explore site variation found in earlier work (24,25) we used a separate model with a 3-way study condition by time by site interaction. No additional covariates were included in the models given the statistical equivalence of study conditions on baseline characteristics (described below). Data were analyzed in SAS 9.4 and SPSS 25.

RESULTS

Intervention Fidelity and Attendance

Intervention fidelity across all classes in the 6 waves of intervention delivery ranged from a low of 97% to a high of 100%. Program fidelity across all program sites, course sessions, and waves of classes

was 98%. On average, participants attended 6.7±2.8 out of 8 classes, and 84% completed at least 7 of the 8 classes. There were no significant differences in class attendance by study site.

Participant Background Characteristics and Equivalence of Study Conditions.

Table 1 presents characteristics of the study population by randomly assigned study condition. Study conditions did not differ significantly on any measured characteristic.

Primary and Secondary Outcomes for the Intervention Versus Control Condition

The results of random effects regression analyses (Table 2) revealed a significant and positive intervention by time interaction in which scores on the Perceived Competence Scale for healthy diet and exercise increased from baseline to follow-up in the intervention compared to the control group (estimate=1.24, p=0.024). There also was a significant increase over time in the intervention versus control group in the Health Promoting Lifestyle Profile (2.62, p=0.040), total score, as well as the Nutrition (.79, p=0.041) and Spirituality subscales (.95, p=0.019). The effect of intervention on the secondary outcome of weight loss was non-significant over time.

Site Differences in Weight Loss

Investigation of the study condition by time by site effect found a significant three-way interaction associated with weight management (F=3.25, df=5 and 204, p=0.008). Figure 1 displays different patterns of weight management over time among NEW-R participants at the 5 study sites. Table 3 shows differences in weight management over time by study condition and within the intervention condition by time and site. Across sites, the intervention group lost 1.8 pounds during the 2-month course and gained 1.7 pounds in the following 6 months, for an overall negligible net change of -.1 pounds from baseline to follow-up. In contrast, the control group lost 0.7 pounds during the 2-month course and gained 5.6 pounds in the following 6 months, for an overall gain of 4.9 pounds. Intervention sites displayed different patterns of weight change over time, with 3 sites demonstrating weight loss at both post-intervention and follow-up time points and overall (site 2, site 3, and site 5), and 2 sites

demonstrating weight gain at one or both post-baseline time points and overall (site 1 and site 4). We repeated the outcome analysis looking at only the 3 "responder" sites and found a significant decrease in weight over time in the intervention compared to control condition (-4.33, p=0.010) (SMD=-.20), as shown in Table 2.

This pattern of responder and non-responder sites is in keeping with previous studies of weight management (25,33). Figure 2 shows the different patterns of weight management in the intervention condition at the responder and non-responder sites. Together, responder sites lost 5.7 pounds between baseline and follow-up while non-responder sites gained 7.7 pounds in the same period. Statistical analysis revealed no significant differences between responder and non-responder sites in baseline weight, demographic, or clinical characteristics that might account for the differing patterns.

Discussion

Our results indicate NEW-R's effectiveness in increasing perceived competence for exercise and healthy eating. Perceived competence, also known as self-efficacy (34), includes a person's belief in their ability to make the behavioral changes needed to meet life goals, including diet, exercise, and weight loss goals (35). In addition, we found improvements in health promoting lifestyle activities, including nutrition behaviors and health-related spirituality practices for those receiving the intervention, indicating that participants were implementing behavioral changes. These results are consistent with NEW-R's use of an intentional approach to slowly shift health promoting behaviors.

There are reasons why gradual changes are advantageous, including evidence that gradual versus rapid weight loss has benefits for preserving resting metabolic rates (36) and preventing rapid weight regain (37). In fact, some experts advocate for a weight-neutral approach which encourages health promoting behaviors such as physical activity and healthy eating in the absence of weight loss goals (38).

Nevertheless, the nonsignificant finding regarding weight loss for NEW-R participants was disappointing. One explanation is that contamination may have occurred if NEW-R participants shared information from the intervention with controls. This was not reported by any control participants at the

time of the final assessment, and we did not recruit study participants from the same family or household (including group residences) to avoid this kind of contamination. Another possibility is that a more intensive, longer-term intervention may be necessary to achieve significant weight loss. For example, in a large RCT of an 18-month intervention, Daumit et al found increasing amounts of weight loss over the study period, with the intervention group losing 7 more pounds than the control group (41). On the other hand, another long term (12 months) study of 428 participants found that lifestyle coaching was not effective in promoting weight loss or reducing cardiovascular disease risk (42).

Yet, many participants did lose weight. One explanation lies in potential differences between study sites. Three of the five sites in this study were characterized as responder sites because, at these sites, participants lost a total of 5.7 pounds from baseline to follow-up, and NEW-R participants lost significantly more weight than controls. All three responder sites offered comprehensive psychosocial rehabilitation services including health and wellness support, residential services, employment assistance, medication management, peer support, and case management. At the two non-responder sites, participants gained 7.7 pounds from baseline to follow-up, and there were no significant differences in weight loss between NEW-R participants and controls. Services at these 2 sites were more limited, consisting primarily of psychiatric medication management, traditional psychotherapy, and supportive counseling. It is possible that weight management interventions such as NEW-R are more effective when participants are receiving other services than encourage physical activity, healthy eating, and active community participation in work, school, and leisure pursuits.

Our finding of site variation in weight loss is comparable to the site differences identified in research on a precursor to the NEW-R intervention (25). Another study of weight loss in this population also found site differences and attributed these to varying organizational contexts in which the intervention was implemented (43). Authors of a third study of a nurse-led weight management intervention for people with schizophrenia noted that site characteristics such as having a gym on the premises or being located next to parks and other recreation areas was a likely source of variation (44). If environmental factors are indeed contributing to the impact of weight loss interventions, it may be

important to address those factors before implementing new interventions. NEW-R may work best in settings already attuned to the importance of reducing the obesogenic environment where it can "jump start" weight management lifestyle changes that receive continued support from wellness programming. A large systematic review of behavioral weight loss programs found better weight loss outcomes with continued availability of services after the study intervention ended (39). Additional environmental supports may come from so-called "nudge" strategies. A nudge strategy is one in which a modification to the environment allows for choice but influences people to act in a predictable way (45). Nudge strategies for weight loss include listing calorie amounts on menus, interaction with peers who model exercise and good nutrition, making healthy foods conveniently available, and environmental cues such as signs encouraging people to use the stairs. A meta-analysis (46) revealed significant (though small) weight loss in studies examining a variety of nudge approaches.

Limitations of the study include the fact that all participants resided in the Chicago area reducing the generalizability of our findings. The measures of perceived competence and lifestyle behaviors were based on self-report and not verified with more objective measures such as observation. The lack of an active control is another limitation of the study. In addition, we did not collect data about specific services received by study participants that may have affected study outcomes such as nutritional support, exercise classes, and other wellness programming. This information might have helped to elucidate the site differences. The exclusion of participants with a history of heart disease may have prevented these individuals from benefitting from the intervention. Finally, NEW-R's 90-minute session length may not match community programs' 60-minute block schedules, although length can be shortened by moving material into additional sessions.

Conclusions

Significant health and mortality disparities continue to exist for people with psychiatric disabilities and these differences have become even more pronounced during the COVID-19 pandemic (47,48). NEW-R was designed as a practical intervention to address lifestyle behaviors related to healthy eating, physical activity, and weight loss as a means of reducing these disparities. NEW-R offers promise

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as an intervention that can initiate changes in healthy lifestyle behaviors and perceived competence towards making these changes. It may also be effective for weight loss when administered in a supportive setting. Additional research on environmental prerequisites that support NEW-R's success is warranted.

References

1. Centers for Disease Control and Prevention: Adult obesity facts 2021.

2. Keck PE, McElroy SL:Bipolar disorder, obesity, and pharmacotherapy-associated weight gain. J Clin Psychiatry 2003; 64(12): 1426–1435

3. Megna JL, Schwartz TL. Siddiqui UA, et al : Obesity in adults with serious and persistent mental illness: a review of postulated mechanisms and current interventions. Ann Clin Psychiatry 2011; 23(2):131-140

4. Compton MT, Daumit GL, Druss BG: (2006). Cigarette smoking and overweight/obesity among individuals with serious mental illnesses. Harv Rev Psychiatry 2006; 14: 212-222

5. Daumit GL, Goldberg RW, Anthony C, et al: Physical activity patterns in adults with severe mental illness. J Nerv Ment Dis 2005; 193(10): 641-646

6. Martland R, Teasdale S. Murray RM, et al: Dietary intake, physical activity and sedentary behaviour patterns in a sample with established psychosis and associations with mental health symptomatology. Psychol Med 2021; 1–11

7. Teasdale SB, Ward PB, Samara K, et al: Dietary intake of people with severe mental illness: Systematic review and meta-analysis. Br J Psychiatry 2019;,214: 251-259

8. Hirsch L, Yang J, Bresee L, et al: Second-generation antipsychotics and metabolic side effects: A systematic review of population-based studies. Drug Saf 2017; 40:771–781.

9. Nihalani N, Schwartz TL, Siddiqui UA, et al:Weight gain, obesity, and psychotropic prescribing. J Obes 2011; 893629

10. Mariano A, Di Lorenzo G, Jannini TB, et al: Medical comorbidities in 181 patients with bipolar disorder vs schizophrenia and related psychotic disorders: Findings from a single-center, retrospective study from an acute inpatients psychiatric unit., Front Psychiatry 2021; 12: 702789

11. Kompaniyets L, Goodman AB, Belay B, et al: Body mass index and risk for COVID-19-related hospitalization, intensive care unit admission, invasive mechanical ventilation, and death – United States, March-December 2020. MMWR Morb Mortal Wkly Rep 2021; 70(10):355-361

12. Tzur-Bitan D, Krieger I., Kridin K, et al: COVID-19 Prevalence and mortality among schizophrenia patients: A large-scale retrospective cohort study. Schizophrenia Bulletin 2021; 47(5): 1211–1217

13. Puhl RM, Brownell, KD: Psychosocial origins of obesity stigma: toward changing a powerful and pervasive bias. Obes Rev 2003; 4: 213-27

14. Agerström J, Rooth DO: The role of automatic obesity stereotypes in real hiring discrimination. J Appl Psychol 2011; 96: 790-805

15. Campos-Vazquez RM, Gonzalez E: Obesity and hiring discrimination. Econ Hum Bio 2020; 37:100850

16. Honey A: (2003). The impact of mental illness on employment: Consumers' perspectives. Work 2003; 20(3): 267-276.

17. Swinburn B, Egger G, Raza T: Dissecting obesogenic environments: The development and application of a framework for identifying and prioritizing environmental interventions for obesity. Prev Med 1999; 29: 563-570

18. Cook JA, Mueser, KT: The challenge of obesity. Psychiatr Rehabil J 2013: 36(3): 129–132.

19. Correll CU, Detraux J, De Lepeleire J et al: Effects of antipsychotics, antidepressants and mood stabilizers on risk for physical diseases in people with schizophrenia, depression and bipolar disorder. World Psychiatry 2015; *14*: 119-136

20. Naslund JA, Whiteman KL, McHugo GK, et al: Lifestyle interventions for weight loss among overweight and obese adults with serious mental illness: A systematic review and meta-analysis. Gen Hosp Psychiatry 2017; 74: 83-102

21. Viera, AJ, Bangdiwala, SI: Eliminating bias in randomized controlled trials: Importance of allocation concealment and masking. Fam Med 2007; 39(2): 132-137.

22. American Psychiatric Association: Diagnostic and statistical manual of mental disorders (5th ed.). American Psychiatric Publishing, 2013

23. U.S. Department of Health and Human Services: Estimation methodology for adults with serious mental illness (SMI), Federal Register 64, 121 (Thursday, June 24, 1999).

24. Brown C, Goetz, J, Hamera E. Weight loss intervention for people with serious mental illness: a randomized controlled trial of the RENEW program. Psychiatr Serv. 2011; 62(7): 800-802.

25. Brown C, Goetz J, Hamera E et al:Treatment response to the RENEW weight loss intervention: Impact of intervention setting. Schizophr Res 2014; 159: 421-425

26. Deci EL, Ryan RM: Self-determination theory. 2012; In P. A. M. Van Lange, A. W. Kruglanski, & E. T. Higgins (Eds.), Handbook of theories of social psychology (pp. 416–436). Sage Publications Ltd.

27. Farkas MD, Anthony WA: Psychiatric rehabilitation programs: Putting theory into practice. 1989, Johns Hopkins University Press.

28. Williams GC, Deci EL: Internalization of biopsychosocial values by medical students: A test of self-determination theory. J Pers Soc Psychol 1996; 70: 767-779.

29. Walker SN, Sechrist KR, Pender NJ: The Health-Promoting Lifestyle Profile: development and psychometric characterizations. Nursing Research 1987; 36(2): 76-81.

30. McCoy C E: Understanding the intention-to-treat principle in randomized controlled trials. West J Emerg Med 2017; 18(6): 1075.

31. Allison PD (2009) Fixed Effects Regression Models. Sage Publications, 2009

32. Dixon PM: Should blocks be fixed or random? *Statistics Conference Proceedings, Presentations and Posters 2016:* 6

33. Nive N, Cohen AN, Hamilton A et al. Implementation and effectiveness of a psychosocial weight management program for individuals with schizophrenia. J Behav Health Serv Res. 2014; 41(3), 370-380.

34. Bandura A. (2004). Health promotion by social cognitive means. Health Educ Behav 2004; 31: 143-166

35. Nezami BT, Lang W, Jakicic JM et al: The effect of self-efficacy on behavior and weight in a behavioral weight loss intervention. Health Psychol 2017; 35: 714-722

36. Pillinger, McCutcheon, Vano L et al: Comparative effects of 18 antipsychotics on metabolic function in patients with schizophrenia, predictors of metabolic dysregulation, and association with psychopathology: a systematic review and network meta-analysis. Lancet Psychiatry 2020; 7: 64-77.

37. Uguz F, Sahingoz M, Gungor B, et al. Weight gain and associated factors in patients using newer antidepressant drugs. Gen Hosp Psychiatry. 2015;37(1):46-48.

38. Ashtary-Larky D, Bagheri R, Abbasnezhad, A, et al: Effects of gradual weight loss *v.* rapid weight loss on body composition and RMR: A systematic review and meta-analysis. Br J Nutr 2020; 124: 1121–1132

39. Hartmann-Boyce J, Theodoulou A, Oke JL, et al: 2021. Association between characteristics of behavioural weight loss programmes and weight change after programme end: Systematic review and meta-analysis. BMJ 2021; 374

40. Gaesser GA, Angadi SS: Obesity treatment: weight loss versus increasing fitness and physical activity for reducing health risks, iScience 2021; 24

41. Daumit GL, Dickerson FB, Wang NY, et al. A behavioral weight-loss intervention in persons with serious mental illness. *N Engl J Med*. 2013;368(17):1594-1602. doi:10.1056/NEJMoa1214530

42. Speyer, H., Christian Brix Nørgaard, H., Birk, M., et al. (2016). The CHANGE trial: no superiority of lifestyle coaching plus care coordination plus treatment as usual compared to treatment as usual alone in reducing risk of cardiovascular disease in adults with schizophrenia spectrum disorders and abdominal obesity. *World psychiatry (WPA)*, *15*(2), 155–165. https://doi.org/10.1002/wps.20318

43. Heshka, S., Anderson, J. W., Atkinson, R. L., Greenway, F. L., Hill, J. O., Phinney, S. D., ... & Pi-Sunyer, F. X. (2003). Weight loss with self-help compared with a structured commercial program: a randomized trial. JAMA, 289(14), 1792-1798.

44. Usher K, Park T, Foster K, Buettner, P: A randomized controlled trial undertaken to test a nurse-led weight management and exercise intervention designed for people with serious mental illness who take second generation antipsychotics. J Adv Nurs 2013; 69(7): 1539-1548

45. Arno A, Thomas S: The efficacy of nudge theory strategies in influencing adult dietary behaviour: a systematic review and meta-analysis. BMC public health 2016; 16(1): 1-11

46. Li R. Zhang Y, Cai X, et al: The nudge strategies for weight loss in adults with obesity and overweight: A systematic review and meta-analysis. *Health policy 2021; 125*(12): 1527–1535

47. Thornicroft G: Physical health disparities and mental illness: The scandal of premature mortality. Br J Psychiatry 2011; 199:441-441

48. Das-Munshi J, Chang, CK. Bakolis I et al: All-cause and cause-specific mortality in people with mental disorders and intellectual disabilities, before and during the COVID-19 pandemic: cohort study. Lancet Reg Health Eur 2021; 11: 1002

Table 1. Demographic and clinical characteristics at baseline (N=113)

Characteristics	Total Population (N=113)		NEW-R (n=55)		Control (n=58)	
	n	%	n	%	n	%
Gender						
Male	37	33%	15	27%	22	38%
Female	73	65%	39	71%	34	59%
Transgender	3	3%	1	2%	2	3%
Race						
Black/African American	86	76%	42	76%	44	76%
White	24	21%	14	26%	10	17%
Asian	2	2%	0	0%	2	3%
American Indian	8	7%	4	7%	4	7%
Native Hawaiian/Pacific Islander	1	1%	1	2%	0	0%
Alaskan Native	1	1%	0	0%	1	2%
Latinx	9	8%	2	4%	7	12%
Age (M±SD)	47.1±12.4		48.0±12.6		46.2±12.1	
Education						
< High School	28	25%	17	31%	11	19%
High School	31	28%	15	27%	16	28%
Some College	33	30%	12	22%	21	37%
College Graduate	20	18%	11	20%	9	16%
Employed	9	8%	4	7%	5	9%
Marital Status						
Never married	82	73%	41	75%	41	71%
Married/cohabiting	4	4%	1	2%	3	5%
Divorced	20	18%	10	18%	10	17%
Separated	3	3%	1	2%	2	3%
Widowed	4	4%	2	4%	2	3%
Living Situation						
Own home/apartment	83	75%	44	82%	39	68%
Friend/relative home	23	21%	8	15%	15	26%
Agency housing	4	4%	1	2%	3	5%
Shelter/street	1	1%	1	2%	0	0%
Diagnosis						
Schizophrenia/ Schizoaffective Disorder	57	50%	26	47%	31	53%

Characteristics	Total Population (N=113)		NEW-R (n=55)		Control (n=58)	
	n	%	n	%	n	%
Depressive Disorder	43	38%	20	36%	23	40%
Bipolar Disorder	38	34%	20	36%	18	31%
Anxiety Disorder	26	23%	12	22%	14	24%
Substance abuse history	32	28%	16	29%	16	28%
Physical Impairment	62	55%	31	56%	31	53%
Comorbid Disorder	99	88%	47	86%	52	90%
Current cigarette use	30	27%	15	27%	15	26%
Medications with risk for weight gain	20	18%	8	15%	12	21%
Household Income						
<$10,000/year	61	56%	30	57%	31	54%
$10,000-$19,999/year	29	26%	15	28%	14	25%
>=$20,000/year	20	18%	8	15%	12	21%
Insurance						
Medicaid	90	80%	41	75%	49	85%
Medicare	46	41%	20	36%	26	45%
Private	6	5%	4	7%	2	3%
Outcomes						
Perceived Competence for Exercise and Healthy Living (M±SD)	113	18.2±5.6	55	17.8±5.6	58	18.7±5.6
Health Promoting Lifestyle Profile Total Scale (M±SD)	113	64.3±11.6	55	63.8±12.0	58	64.8±11.4
Health Promoting Lifestyle Profile – Nutrition (M±SD)	113	22.3±4.9	55	22.2±5.1	58	22.4±4.7
Health Promoting Lifestyle Profile – Spirituality (M±SD)	113	26.3±5.4	55	25.7±5.6	58	26.8±5.2
Health Promoting Lifestyle Profile - Physical Activity (M±SD)	113	15.7±4.7	55	15.8±4.7	58	15.5±4.7
Weight in pounds (M±SD)	113	232.2±46.5	55	239.1±52.7	58	225.6±39.2

*All differences between NEW-R and control participants were non-significant (all $p > .05$) in chi-square or t-tests.

** Physical impairments included arthritis/joint pain, back pain, vision loss or limitations, diabetes, asthma, high cholesterol, epilepsy, fibromyalgia, hypertension, amputation, dental pain, emphysema, hearing loss, multiple sclerosis, and sarcoidosis.

Table 2. Effect of NEW-R intervention versus control over time by outcome: random effects regression models (N=113).

Outcome	Parameter Estimate	Standard Error	p-value
Perceived Competence for Exercise and Healthy Living			
Intercept	24.44	3.61	<.001
Intervention	-.69	1.09	.527
Time	-.53	.37	.155
Intervention x Time	1.24	.54	.024
Health Promoting Lifestyle Profile Total Scale			
Intercept	74.22	15.46	<.001
Intervention	-.66	2.38	.781
Time	-1.15	.87	.185
Intervention x Time	2.62	1.27	.040
Health Promoting Lifestyle Profile - Nutrition			
Intercept	22.63	1.01	<.001
Intervention	.06	.90	.950
Time	-.40	.26	.130
Intervention x Time	.79	.38	.041
Health Promoting Lifestyle Profile - Spirituality			
Intercept	26.63	1.19	<.001
Intervention	-.74	.98	.450
Time	-.42	.27	.127
Intervention x Time	.95	.40	.019
Health Promoting Lifestyle Profile - Physical Activity			
Intercept	15.42	.60	<.001
Intervention	.66	.86	.446
Time	.30	.27	.280
Intervention x Time	-.05	.40	.907
Weight in pounds			
Intercept	173.24	32.88	<.001
Intervention	14.30	8.88	.110
Time	1.89	.87	.032
Intervention x Time	-1.96	1.28	.128
Weight in pounds, 3 responder sites only			
Intercept	250.89	19.58	<.001
Intervention	9.29	12.51	.461
Time	1.58	1.15	.173
Intervention x Time	-4.33	1.66	.010

Time: baseline, post-intervention, follow-up. Models also control for study site.

Table 3. Changes in Weight at 2- and 6-months post-baseline (N=113).

	Baseline Mean±SD	Post-intervention (2 months post baseline)	Change from Baseline to Post-intervention	Follow-up (8 months post baseline)	Change from Post-intervention to Follow-up	Change from baseline to follow-up
Intervention	239.1±52.7	237.3±56.5	-1.8	239.0±59.1	+1.7	-0.1
Control	225.6±39.2	224.9±40.0	-.7	230.5±40.1	+5.6	+4.9
Intervention only						
Site 1 (Outpatient clinic)	259.2±45.1	262.6±49.0	+3.4	271.0±48.9	+8.4	+11.8
Site 2 (Agency)	237.9±67.7	237.3±73.6	-0.6	234.3±77.0	-3.0	-3.6
Site 3 (Agency)	208.8±46.1	203.6±49.8	-5.2	198.7±42.6	-4.9	-10.1
Site 4 (Agency)	225.0±47.9	220.1±49.6	-4.9	226.7±57.4	+6.6	+1.7
Site 5 (Agency)	254.5±47.7	248.1±46.9	-6.4	247.9±50.0	-0.2	-6.6

Weight measured in pounds.

Figure 1.
   Nutrition and Exercise for Wellness and Recovery (NEW-R) CONSORT Chart

Attended induction session (n=121)

Enrollment

Consented and Enrolled (n=113)

Allocation

Randomized (n=113)

Allocated to intervention (n=55)

Allocated to control (n=58)

Follow-Up

Lost to both post-baseline assessments (intervention) (n=5)
3 unable to locate
2 withdrew

Lost to both post-baseline assessments (control) (n=1)
1 unable to locate

Analysis

Analyzed (intervention) (n=50)

Analyzed (control) (n=57)