

HealthMatters@24/7 eLearning for People Supporting Adults with Intellectual and Developmental Disabilities

ClinicalTrials.gov ID: NCT03206164
Study Protocol and Statistical Analysis Plan
Document Date: June 24, 2020

Study Protocol

Objectives and Hypotheses:

The *HealthMatters @ 24/7* eLearning project has three objectives:

Objective: Test the effectiveness of an on demand e-Learning platform (HealthMatters@24-7) for staff in CBOs in one state.

HO1. **More CBOs** in the asynchronous training program will have developed Strategic Action Plans for Health and Wellness, established Wellness Committees, and have equal or more resources and improved culture for health promotion at 3 months compared to CBOS participating in the current live *HealthMatters TtT Workshop* webinar.

HO2. **Staff** in the asynchronous training group will have improved level of learner/instructor satisfaction toward the training immediately after completing the enhanced mode of training, *HM@24/7* compared to staff trained using the current live *HealthMatters TtT Workshop* webinar.

Design. We will utilize two groups (Table 1), random selection, pre-test/post test experimental design where Experimental Group receives *HealthMatters@24/7* training and Control Group receives the usual real-time (live) webinar training (*HealthMatters Train the Trainer Workshop*).

Table 1. Two groups, Random Selection, Pre-test, Post-test experimental design

Group	Pre-test	Treatment	Post-test
HealthMatters@24/7 synchronous group	O	X	O
HealthMatters Train the Trainer Workshop (real-time synchronous webinar training) asynchronous group	O		O

Methods. We will convert the evidence based *HealthMatters Train the Trainer Workshop for Instructors*, real-time synchronous webinar training into *HealthMatters@24/7*, a continuous, e-learning environment to train staff to plan, conduct, and evaluate a *12-Week HealthMatters Program* for people with IDD in residential and day/employment community-based organizations.

HealthMatters™ Train the Trainer (TtT). is an evidence-based 6-hour training (synchronous and asynchronous) provides structured information on how to organize and start a tailored physical activity and health education program for people with intellectual and/or developmental disabilities (IDD) in community-based residential and day/vocational organizations. The training can enhance staff's skills, knowledge, and abilities to work with persons who have disabilities to become more physically active, make healthy food choices, and incorporate healthy lifestyle into daily living. Support staff will be given the following strategies and resources to **improve health behaviors and health status of people with IDD:**

- Asynchronous Virtual Coach: HealthMatters™ Program using Google Classroom;
- paper-based Health Matters Curriculum; and,
- Program Plan for your Virtual Coach: HealthMatters™ Program.

Participants. A minimum of 20 CBOs with at least 3-member team totaling 60 staff will be recruited. CBOs enrolled in either synchronous or asynchronous group. Both groups will receive a form of training with an estimated reach of 160 individuals with IDD (not research participants).

Measures. HO1, HO2, and HO4 Measures. *Process Evaluation* (assessment of changes in policy and fiscal strategic plans). Throughout the program, process evaluation will be used to continuously provide data for program improvement efforts and communicate new information through as many channels as possible to reach target audience. Process evaluation questions are in **Appendix B. HO3 Measures** will be collected using an online organizational HealthMatters Assessments (oHMA) via Qualtrics. oHMA evaluates organizational **needs** and **capacity** for developing a health promotion plan including programs, services, environmental support, resources, culture, and employee knowledge and skills to do health promoting activities. Please see **Table 2** for reliability and validity information. Data will be collected from CBO staff before at baseline and at 1 year. Staff outcome expectations, barriers to exercise and nutrition, self-efficacy for health promotion and health promotion knowledge, and health advocacy will also be assessed via online HMAs. The data will be collected before HMP at baseline, 3, 12, and 24 months after implementation of the *HMP* intervention.

Table 2. Reliability and Validity of HealthMatters Assessments

<i>Organizational Capacity Checklist</i>	Reliability coefficients for the <i>Organizational Capacity Checklist</i> subscales (e.g., organization commitment, supportive health promotion policies, policies supporting staff to do health promotion, and organizational resources) ranged from .92 - .81. Test/retest correlations ranged from .83 - .74.	
<i>Employee Capacity Checklist</i>	Reliability coefficients for the <i>Employee Capacity Checklist</i> subscales (e.g., confidence doing health promotion, agency policies, agency resources, and health promotion knowledge) ranged from a= .90 - .67. Test/retest ranged from .74 - .58.	
<i>Exercise and Nutrition Outcome Expectations (OE); Barriers to Exercising and Nutrition</i>	OE: Exercise: a=.81; test/retest =.60; Nutrition: a=.81; test/retest =.59 Barriers: Exercise: a= .88; test/retest = .54; Nutrition: a= .80; test/retest = .57	
<i>Self-Efficacy for Teaching Exercise Activities</i>	(a= .94; test/retest = .68)	

Statistical Analysis Plan

Data Analysis. With a minimum of 20 CBOs, 60 employees (30 in each group) and 160 individuals with IDD (80 in each group) participating in the *12-week HealthMatters Program*, the proposed project will have a 95% power to detect a small effect size of 0.08 between the *HealthMatters@24/7* intervention and the *HealthMatters* Live webinar control groups using a 2-sided alpha 0.05 and an estimated intraclass correlation (ICC) of 0.5. While the actual effect size

is unknown due to its novel nature, the proposed sample size should be adequate to detect a minimum meaningful difference in study outcomes between the two experimental groups as we anticipate a small to moderate effect size resulting from the *HealthMatters @ 24/7 e-Learning*.

Data were electronically collected throughout the project. Descriptive statistics will be obtained for all study variables. Tests of significance will be based on an alpha level of .05. Repeated measures analysis of variance (RM-ANOVA) will be employed to examine whether outcome measures of self-efficacy, barriers, outcome expectations, and health advocacy for DSP will be more favorable for the *HealthMatters asynchrononous group* compared to *synchrononous* group. Multi-level hierarchical liner modeling (HLM) analysis will be done to estimate separately the variance between DSPs within the same CBO, and the variance between CBOs. We will examine group-level and individual-level factors with multilevel analysis to allow for variance in outcome variables that can be analyzed at multiple hierarchical levels.

Informed Consent Form. No informed consent form was needed. Per “Study IRB Protocol #2020-0754 Exempt Research” was determined under **exemption category under 45 CFR 46.101(b) in that** information obtained was recorded in such a manner that no human subjects could be identified, directly or through identifiers linked to the study participants.