EARLY PHASE CLINICAL TRIAL TO TEST THE FEASIBILITY OF AN ACT-BASED PHYSICAL ACTIVITY PROMOTION PROGRAM FOR ADULTS WITH DEPRESSIVE SYMPTOMS

NCT05407935

Study Protocol & Statistical Analysis Plan

8/16/2022

Study Overview and Setting

We will conduct a feasibility RCT comparing ACTivity to the comparison intervention (Relaxercise) among 60 low-active adults (ages 18-65) with elevated symptoms of depression. Participants will be recruited from Rhode Island, and all study procedures will be conducted remotely. Remote data collection procedures reduce several logistical barriers to participation (e.g., finding transportation, childcare), and there is evidence that remote trials have increased racial and ethnic diversity among study participants. The intervention will also be delivered remotely, but within the context of the community-based Greater Providence YMCA setting. Specifically, all participants will receive a 6-month membership to the YMCA, which ensures access to exercise programming (offered both virtually and in-person) and equipment (offered in-person). Community-based settings, like the YMCA, may be a less stigmatizing environment for individuals with depressive symptoms to learn how to increase their PA, in contrast to a traditional mental health setting. In addition, designing the intervention to be delivered in the context of a community-based setting will ultimately allow for widespread dissemination.

Participants

Inclusion Criteria

Participants will include adults with elevated depressive symptoms (score ≥ 10 on the Center for Epidemiologic Studies Depression Scale [CES-D]). While 16 or higher on the CES-D is typically considered the cutoff for a clinical level of depression, there is evidence that even lower levels of depressive symptoms (i.e., subclinical levels) can be predictive of poor PA adherence. For example, in a study of 624 patients with Type 2 diabetes beginning a 6-month exercise program, depressive symptoms of CES-D ≥ 10 were significantly associated with lower exercise session attendance and program dropout. Thus, because the goal of the ACTivity intervention is to increase PA among adults with elevated depressive symptoms who have specific depression-related barriers, we decided to set the CES-D cutoff for the current study at ≥ 10. To capture a wide range in depressive symptomatology, we elected not to have an upper limit cutoff for CES-D scores. To be included in the study, participants must also be low-active (defined as engaging in < 60 minutes per week of moderate or vigorous intensity PA), which will be assessed via self-report. While individuals with elevated depression across the lifespan can benefit from increasing PA, we recognize that there will likely be differential age-related influences on PA engagement that could be challenging for facilitators in the group-based format. Therefore, to balance inclusion across the lifespan with variability in PA barriers across age groups, we

will set a maximum age of 65, consistent with the standard retirement age. Participants must also express ability/willingness to attend weekly virtual video sessions.

Exclusion Criteria

Individuals who endorse a history or presence of any condition that may limit or substantially increase the risks of PA will be excluded. Specifically, we developed a brief self-report screening instrument in consultation with a cardiologist, which asks participants to indicate whether or not they have a current/recent diagnosis and/or have received recent treatment for various conditions that may be contraindicated with moderate intensity PA, such as peripheral vascular disease, cardiovascular disease, seizure disorders, respiratory disease vertigo, or ambulatory problems that interfere with exercise. We will also exclude participants who endorse past-year cardiac, pulmonary, abdominal, joint, or orthopedic surgeries, as well as those who have a pending/scheduled surgery in the next 6 months. Similarly, individuals who report a BMI < 18.5 or ≥ 40 will be excluded given the increased risk of unsupervised PA in these populations. Individuals will also be excluded if they do not speak, read, and/or write fluently in English, or if they endorse: regular mindfulness meditation practice (> once/week), suicidal thoughts/behaviors, current participation in any PA/exercise or weight-loss research study, or having a household member who is already participating in this study. Finally, given that participation in this study is tied to the Greater Providence YMCA and that participants will be mailed study materials/supplies, those who do not have a Rhode Island mailing address, are unable to receive materials in the mail, or do not plan to live in Rhode Island for the next 6 months will also be excluded.

Sample Size

We will randomize 60 participants (30 per condition). This sample size is sufficient for accomplishing our goals of demonstrating feasibility of interventionist training, treatment fidelity, recruitment, retention, randomization, and data collection procedures.

Intervention Conditions

Participants will be randomly assigned to receive ACTivity or the comparison intervention, Relaxercise. Differences between the ACTivity and Relaxercise interventions were minimized to isolate the effects of the ACT-based PA promotion content that is specific to the ACTivity intervention. Both interventions will consist of 8-weekly one-hour treatment sessions conducted virtually (via Zoom), plus a one-on-one virtual booster session with the interventionist at week 12 to reinforce progress, review intervention material, and troubleshoot any obstacles. In addition, both interventions will utilize rolling enrollment,

with participants beginning the intervention at either Session 1 or Session 5, since this approach minimizes wait-times between cohorts. The main objectives introduced during Sessions 1-4 of each intervention will be repeated during Sessions 5-8. However, to reduce redundancy during the second half of the intervention programs, different content will be used to address the intervention objectives in Sessions 5-8. Both the ACTivity and Relaxercise interventions will follow treatment manuals and include a slide presentation and accompanying participant handouts for each session. The interventions are matched on several additional characteristics, including (1) duration, (2) use of media content (e.g., videos), and (3) number of opportunities for participants to interact with each other and/or the interventionist (e.g., open-ended questions for verbal discussion, Zoom chats/polls).

General Intervention Structure

Both the ACTivity and Relaxercise interventions will follow the same general structure. Specifically, videoconferencing sessions will consist of the study interventionist and up to 12 participants. Each session will begin with setting an agenda, a brief stretching routine, an opportunity for participants to discuss their progress towards PA goals over the past week, and a review of the material covered during the previous session. Each session will then focus on intervention-specific objectives/skills (i.e., ACT-based concepts/skills in ACTivity and relaxation training in Relaxercise). Participants will be assigned homework at the end of each session, which provides the opportunity to further consider/practice course content/skills.

PA Promotion Content

Both interventions will include the same standard PA promotion content. Consistent with national guidelines, all participants will be given a prescription to engage in moderate intensity structured exercise for 150-300 minutes per week. We will use a ramp-up approach to frequency and duration consistent with ACSM guidelines, such that all participants will gradually be ramped up to the ultimate goal of 150-300 mins of structured exercise through the first 4 weeks of the program. All participants will be told that they can accumulate these minutes using any form of exercise, as long as the activity is at least of moderate intensity (e.g., brisk walking, cycling, swimming, treadmills, elliptical machines, YMCA classes). All participants will be mailed a formal printed version of their exercise prescription at the start of the program and will be reminded of their prescription at each session.

Although the PA promotion content will focus on engaging in moderate intensity exercise, we will not discourage non-exercise forms of PA. Throughout the program, all participants will also receive psychoeducation regarding the health benefits of PA. Moreover, all

participants will be asked to set a PA goal/plan each week and to self-monitor progress. Weekly goal setting and self-monitoring forms will be provided at each session and collected electronically at the subsequent session. In addition, all participants will be asked to reflect on their goals/progress during a brief check-in portion of each intervention session.

ACTivity

Consistent with the goals of ACT, the ACTivity program is designed to foster willingness to accept discomfort in the service of valued behaviors. As described in more detail below (see *Intervention Development and Preliminary Studies*), the ACTivity treatment protocol was adapted from an acceptance-based PA promotion intervention for adults who recently completed a weight-loss program, based on prior work using ACT as a brief treatment for depression. Specifically, the program aims to promote increased PA behavior by increasing distress tolerance and motivation for PA using several ACT-specific processes/techniques. First, participants are taught to be mindful and accepting of any uncomfortable internal experiences prior to (e.g., low mood, tiredness, urges to skip planed exercise) and during (e.g., negative affect, muscle soreness/fatigue) PA sessions. Participants will be guided through an in-session mindfulness practice and will be invited to practice mindfulness during the stretching portion of each weekly session. Increased mindfulness can help participants increase their distress tolerance, and thereby better cope with the immediate negative affective sensations that can stem from PA. Second, participants will be taught strategies for increasing willingness to engage in PA in the context of unpleasant internal experiences. Although the interventionist will encourage the use of standard behavior change techniques (e.g., goal setting, self-monitoring, problem solving) to make adhering to regular PA as easy as possible, the interventionist will also explain the limitations of these approaches and describe the importance of acceptance. Third, participants will be encouraged to clarify personal values (e.g., health and well-being) that are consistent with adopting and maintaining regular PA, as this can increase autonomous PA motivation. Fourth, participants will be taught several cognitive defusion techniques to further detach from negative thoughts and emotions in order to persist in their values. Throughout the ACTivity program, metaphors, videos, and in-session exercises will be used to demonstrate key concepts. A complete description of the ACTivity treatment content by session is presented in Table 1.

Intervention Development and Preliminary Studies. We used an iterative treatment development process that drew on participant and study team input. Based on preliminary work using ACT as a PA promotion tool and as a brief treatment for depression, the initial treatment prototype was first delivered by a licensed clinical psychologist to 11

participants at a local YMCA. All participants completed an exit/qualitative interview at the end of treatment, which included open-ended questions related to strengths/weaknesses of the intervention, suggested changes/revisions to the program, and reasons for missed sessions, and the treatment protocol was revised accordingly. This refined version was then tested among 19 participants (4 cohorts; roughly 5 participants per group). Again, the intervention was delivered by a licensed clinical psychologist at a local YMCA. Participants attended an average of 5.5 of the 8 weekly sessions, with 9 of 11 participants attending at least 5 sessions, and findings provided initial support for the utility of the ACTivity intervention for increasing both objective and subjective PA. We obtained additional feedback regarding the intervention content/structure from participants at the end of treatment, and overall participants reported being positively inclined towards the intervention with a mean of 4.63 on a scale of 1 to 5 ("highly recommend") in response to the question "to what extent would you recommend ACTivity treatment to someone else to increase well-being." However, participants did note several suggestions for improving the intervention, and we revised the program accordingly. For example, given that several participants expressed a desire for greater emphasis on social support from the group, we incorporated additional opportunities for group discussion to foster group cohesion.

Moreover, several participants reported that they would prefer that the intervention be delivered remotely. In-person delivery limits accessibility to participants and can pose logistical challenges for implementation (e.g., requires availability of a space large enough to conduct group sessions), and recent COVID-related restrictions and safety concerns have posed further barriers to in-person delivery. Therefore, we elected to further refine the intervention to be appropriate for remote delivery. Specifically, we created a slide presentation which provides a useful visual aid as participants progress through the intervention. The presentation includes videos that illustrate key concepts, which also helps to ensure that bachelor's-level non-clinician interventionists are prepared to deliver intervention content. To foster group cohesion in the context of a virtual intervention, we incorporated several interactive components (e.g., open-ended/discussion questions, online polls). Of note, study staff will work with participants prior to beginning the intervention to ensure that they are able to access/use the video conferencing platform and all interactive components (e.g., chat function, online polls).

Relaxercise

Consistent with prior studies evaluating the efficacy of acceptance-based therapies, we elected to use a relaxation training intervention (Relaxercise) as the comparison group. The Relaxercise intervention is designed to help promote relaxation and reduce stress. In addition to the standard PA promotion content, the Relaxercise program covers several

relaxation strategies, including breathing techniques (i.e., diaphragmatic breathing, box breathing), guided imagery, and progressive muscle relaxation. The Relaxercise program also includes tips for creating a personalized relaxation plan. It is explained to participants that both PA and relaxation can be beneficial for stress reduction. Each session will then focus on at least one relaxation strategy/skill. The interventionist will lead in-session exercises to demonstrate each skill. A complete description of the Relaxercise treatment content by session is presented in Table 2.

Ongoing Intervention Refinement

We will further refine the ACTivity and Relaxercise interventions using an iterative process. Specifically, we will revise the intervention based on qualitative feedback collected from the first three intervention cohorts (approximately half of the total sample). The revised intervention programs will then be delivered to the remainder of participants, and, again, we will elicit qualitative feedback upon participants' completion of the program.

Interventionist Training

The interventionists will be bachelor's-level research assistants with some knowledge/background in behavioral health interventions, as this is comparable to staff that would ultimately deliver this intervention within community-based settings like the YMCA. Licensed clinical psychologists with expertise in ACT and PA promotion interventions will provide the interventionists with several training materials, including the intervention protocols and readings on ACT. There will be a series of didactic training workshops, which will involve review of training materials, an overview of techniques and processes central to group therapy and considerations for virtual intervention delivery (e.g., maintaining participant confidentiality, group expectations for teletherapy), discussion of strategies for managing participants who have difficulty using the techniques, and review of the American College of Sports Medicine's guidelines for exercise testing and prescription. A licensed clinical psychologist will demonstrate delivery of intervention content, and interventionists will have the opportunity to role play intervention content and receive feedback. After completion of didactics, interventionists will record "mock" sessions to staff acting as group participants, sessions will be recorded, and fidelity will be assessed by clinical psychologists. Additional training and retests will be conducted until interventionists are able to achieve benchmark performance (<10% deviation from study protocol). Once certified to provide study treatment, interventionists will receive ongoing biweekly supervision by a clinical psychologist to ensure continued fidelity.

Treatment Fidelity

Fidelity checklists for both the ACTivity and Relaxercise interventions were developed based on the treatment manuals. Treatment fidelity checks will be conducted for each of the first 8 treatment sessions. We will then randomly select 20% of subsequent sessions to undergo fidelity checks to prevent protocol drift. Remedial training and practice will be provided if the interventionist does not maintain acceptable fidelity, defined as more than 10% deviation from the written protocol as indicated on the treatment fidelity checklists.

Study Procedures

Study procedures are outlined in Table 3.

Recruitment and Screening

We will recruit 60 adults (ages 18-65) with elevated depressive symptoms through television advertisements, web-based advertisements (e.g., Craigslist, Pandora, Facebook), a web page, brochures in the community, and brochures in primary care and psychiatry practices. We will actively recruit individuals who belong to minoritized groups through targeted recruitment channels, such as through community outreach, through internet-based advertising which aims to specifically recruit minoritized groups, and/or through advertising in newspapers and radio stations that serve these subgroups. Recruitment materials will pitch the study as a "group-based program designed to help people exercise more" and clarify that the study is geared towards adults aged 18-65 who "sometimes feel down or blue and want to exercise more" and will not require any in-person visits. All recruitment materials will include a link to an online screening questionnaire. All participants will be provided with mental health resources upon completion of the online screening questionnaire, and those who indicate elevated depressive symptoms (CES- D score ≥ 10) will be encouraged to follow-up with their primary care provider and/or connect with a licensed mental health provider to discuss the reported symptoms.

Baseline Procedures

Individuals who appear to be eligible following online screening will be asked to attend a virtual initial orientation session. The purpose of this session is to provide additional information and confirm study eligibility. Specifically, participants will be asked to repeat the CES-D, and those who do not report elevated depressive symptoms will no longer be eligible. In addition, participants will be asked a single item to assess suicidal ideation,

with response options ranging from 0 (*I don't have any thoughts of killing myself*) to 3 (*I would kill myself if I had the chance*). Participants who select a response option > 0 will no longer be eligible for participation in this study.

After ensuring eligibility, participants will be invited to provide informed consent and asked to attend a second session prior to randomization. At this session, participants will receive information about objective assessment of PA (via accelerometry; see Measures section), and they will be instructed to set up their study-provided YMCA membership. After completing this session, participants will be invited to a randomization session, during which baseline survey data is collected (see Measures section), and participants are randomly assigned to an intervention condition. Specifically, after completing the online baseline survey, participants will receive a message that informs them of group allocation. Randomization will be stratified by depression severity as assessed during the baseline survey (CES-D score 10-15 vs. ≥ 16). Staff conducting intervention assessments will remain blinded to condition assignment.

Follow-Up Procedures

Participants will be asked to complete follow-up assessments at mid-treatment (week 4), post-treatment (week 8), the booster session (week 12), and 6-month follow-up (week 26). At each of these time points, participants will complete additional self-report questionnaires. Moreover, objective PA data (accelerometry) will be collected at post-treatment and 6-month follow-up.

Measures

Credibility and Acceptability.

We will assess credibility and acceptability of the two intervention conditions using two different self-report measures. The Credibility and Expectancy Questionnaire (CEQ) is a reliable and valid self-report measure of patients' initial expectancies for improvement from treatment that has been used in numerous previous clinical trials. Participants will complete the CEQ at the end of their first intervention session. The Client Satisfaction Questionnaire (CSQ) is an 8-item questionnaire assessing participant satisfaction with the treatment (e.g., "How would you are the quality of service you received? 4=excellent, 3=good, 2=fair, 1=poor"). Participants will complete the CSQ at the end of the 8-week treatment. We will also assess knowledge of intervention content at the end of the 8-week treatment using a questionnaire developed based on the ACTivity and Relaxercise manuals. Finally, we will elicit qualitative feedback from participants to assess various facets of acceptability (e.g., intervention coherence, perceived effectiveness, burden,

affective attitude), the strengths/weaknesses of the program, and suggestions for improvement.

Measures Administered for Feasibility.

The primary goal of this study is to establish feasibility of study procedures, and, therefore, the study is not adequately powered for hypothesis testing. However, we will administer several measures, including measures of primary and secondary outcomes, putative mediators, and potential covariates, to assess feasibility of data collection methods to be used in a subsequent efficacy trial.

Primary Outcome: Moderate-to-Vigorous Physical Activity (MVPA).

To assess total minutes per week of MVPA, participants will wear Actigraph wGT3x-BT monitors during one-week periods at baseline (prior to randomization), immediate post-treatment (week 8), and 6-month follow-up (6 months post-randomization). Accelerometers will be worn on the right hip at the anterior axillary line using an elastic belt, consistent with standard practices. We will use ActiLife software to determine PA intensity. Data will be considered valid if the monitor was worn for ≥ 10 hours on ≥ 4 days (including ≥ 1 weekend day). Intensity will be assessed as average counts per minute (cpm) and previously validated cut points will be used to identify bout-related moderate-to-vigorous intensity PA (≥1952 cpm accumulated in bouts ≥10 min). We will also be collecting raw accelerometry output data thus allowing for analysis of the count-level data (using more intensive statistical techniques including raw signal analytic approaches). Leisure-time MVPA will also be self-reported at each assessment timepoint using a modified version of the Godin leisure-time exercise questionnaire.

Secondary Outcome: Depression Symptoms.

Depressive symptoms will be assessed with the Center for Epidemiological Studies-Depression (CES-D). The CES-D is a 20-item measure that has demonstrated good sensitivity and specificity for identifying individuals at risk for clinical depression.

Putative Mediators.

Distress tolerance will be assessed using the Discomfort Intolerance Scale (DIS), which is a 5-item measure of perceived capacity to tolerate uncomfortable sensations. The DIS has demonstrated good test-retest reliability in prior studies. Motivation for PA will be assessed with the 15-item Treatment Self-Regulation Questionnaire-Exercise Version which measures the extent to which motivation for exercise is autonomous and self-determined. Construct validity, factor structure, and reliability of this measure are established. The Valuing Questionnaire (VQ) is a 10-item self-report instrument that measures the extent to

which individuals are engaging in behaviors that are consistent with their self-determined values. Items assess progress toward chosen values as well as the degree to which avoidance behaviors disrupt valued living. Research shows that clinical samples have lower scores than nonclinical samples on the VQ, and that the VQ is associated with other established scales pertaining to life satisfaction, values clarification, and experiential avoidance. The Physical Activity Acceptance Questionnaire is a 10-item measure that will be used to assess acceptance of psychological and physical discomfort related to PA. This measure has shown high internal validity, convergent validity, and predictive validity in clinical samples.

***Potential Covariates*.**

We will assess various participant characteristics to be considered for inclusion as potential covariates. First, we will assess sociodemographic factors including gender, ethnicity/race, education, relationship status, income, and employment. Second, body weight will be measured on a Tanita HD-662 Digital Bathroom Scale. Third, we will assess for the presence of substance use/disorders using the Alcohol Use Disorders Identification Test, the Drug Use Disorders Identification Test, and the Heaviness of Smoking Index. Fourth, we will assess for symptoms of mania (Altman Self-Rating Mania Scale), psychosis (Community Assessment of Psychic Experiences - 15), and eating disorders (SCOFF Eating Disorder Screening Questionnaire). Fifth, we will assess participants' use of physical fitness centers, in-home exercise equipment, and/or mobile application- and internet-based fitness programs. Finally, group cohesion will be assessed at mid-treatment (week 4) and end of the 8-week treatment with the 40-item Group Questionnaire (GQ), which assesses perceived group structure and quality and has shown adequate reliability and predictive validity of treatment outcomes.

Benchmarks and Data Analysis

Several a priori benchmarks will be used to evaluate the feasibility of the study procedures and the ACTivity and Relaxercise intervention programs, as well as the credibility/acceptability of the intervention programs.

To address Benchmark 1, we will assess interventionists' adherence to the treatment protocols using treatment fidelity scales. First, prior to participant recruitment, we will evaluate training and intervention fidelity procedures by assessing whether interventionists score ≥ 80% on treatment fidelity scales when delivering the intervention to mock participants. Second, we will calculate percent of treatment delivery objectives met (via the fidelity checklist) by study interventionists on a randomly selected sub-sample of 20%

of recorded sessions. Third, although not a primary aim of this study, we will explore receipt of treatment and enactment of treatment skills (which are two additional domains of intervention fidelity) by examining scores on the post-treatment knowledge check and completion of homework assignments, respectively.

Second, we will evaluate feasibility of recruitment, randomization, retention, and data collection procedures. Specific benchmarks are as follows: Benchmark 2 – we will recruit at a pace of 10 participants over 2-month periods, including 20% racial/ethnic minorities; Benchmark 3 – we will retain ≥ 80% of participants per condition through post-treatment and at the 6-month follow-up; Benchmark 4 – we will obtain usable data from accelerometry and self-report questionnaires from ≥ 80% of participants at post-treatment and 6-month follow-up.

Third, we will assess credibility and acceptability of the intervention conditions. Specific benchmarks include Benchmark 5 – 80% of participants will score > 6 (scale of 1-9) on the Credibility Rating Scale; Benchmark 6 – 80% of participants will score > 3 (scale of 1-4) on the Client Satisfaction Questionnaire; Benchmark 7 – 80% of participants will attend > 5 out of 8 treatment sessions. Average acceptability scores and mean attendance scores will be compared between conditions using two-sample confidence intervals.

Table 1 ***Overview of ACTivity Content***

Session	Objectives	Content
1/5	▪ To provide an overview of ACT	▪ Provide brief introduction to empirical- and theoretical-basis for ACT ▪ Describe psychological flexibility o **Session 1**: display brief video about psychological flexibility o **Session 5**: use "The Hockey Goalie" metaphor to illustrate the concept of psychological flexibility
	▪ To provide psychoeducation regarding the benefits of physical activity (PA)	▪ Introduce the benefits of PA, including effects on physical health, mental health, and quality of life
	▪ To build awareness of internal experiences	▪ Define "hooks" (i.e., internal experiences) as unhelpful/unwanted thoughts, feelings, physical sensations, and urges that can interfere with values-directed action ▪ Provide/elicit examples of hooks that occur prior to and during PA o **Session 1**: provide examples of thoughts, feelings, sensations, and urges that may occur prior to or during PA o **Session 5**: elicit examples of thoughts, feelings, sensations, and urges that participants have experienced before or during PA
	▪ To introduce mindfulness as a skill that increases awareness of hooks	▪ Provide overview of mindfulness ▪ Complete brief mindfulness practice o **Session 1**: mindfulness of breath practice o **Session 5**: body scan meditation
2/6	▪ To describe the importance of controlling what you can in terms of PA	▪ Provide overview of strategies for making adhering to PA as easy, rewarding, and automatic as possible (e.g., goal setting, self-monitoring, problem solving) ▪ Discuss the limitations of these standard behavior change strategies
	▪ To introduce acceptance/willingness skills	▪ Define willingness as moving towards what is important, despite unwanted/unpleasant internal experiences o **Session 2**: describe the costs of low levels of willingness o **Session 6:** use "The Unwanted Party Guest" metaphor to illustrate the concept of willingness ▪ Provide the opportunity to practice willingness o **Session 2**: introduce "only if" vs. "even if" skill and provide participants with the opportunity to practice applying this strategy to hooks o **Session 6**: practice willingness using an experiential exercise
3/7	▪ To define values and discuss importance of values clarification	▪ Introduce values as the ideas, principles, or areas in our lives that are most important to us o **Session 3**: provide participants with the opportunity to reflect on their values and relate these to their PA goals o **Session 7**: display brief video explaining how values differ from goals and explain how awareness of values can help to increase motivation to engage in PA
	▪ To describe the importance of using values to guide behavior	▪ Describe the importance of and strategies for sticking to values o **Session 3**: use the "Passengers on the Bus" metaphor to illustrate the importance of sticking to values o **Session 7**: provide overview of challenges to sticking to values as well as potential solutions to overcome these barriers
4/8	▪ To introduce cognitive defusion strategies	▪ Define cognitive defusion and introduce skills/strategies to aid in cognitive defusion o **Session 4**: display two brief videos describing cognitive defusion strategies, including "I'm having a thought that…" and thanking your thoughts o **Session 8**: use the "Sushi Train" metaphor to illustrate the concept of cognitive defusion, provide participants with the opportunity to practice cognitive defusion using an experiential exercise, and introduce the "just do it" strategy
	▪ To provide a summary of ACTivity content	▪ Revisit concept of psychological flexibility and explain how all of the content throughout this program ties together to increase psychological flexibility

Note. The intervention will utilize rolling enrollment, with participants beginning the intervention at either Session 1 or 5. Although the objectives of Sessions 1-4 are identical to those of Sessions 5-8, the content used to accomplish these objectives will differ in each half of the program (see above).

Table 2 ***Overview of Relaxercise Content***

Session	Objectives	Content
1/5	▪ To provide an overview of relaxation training	▪ Provide brief introduction to relaxation training, including empirical-basis and overview of types of relaxation o **Session 1**: display brief video describing three different types of relaxation (i.e., physical, breathing, visualizing) o **Session 5**: display brief video describing the importance of using relaxation strategies to manage stress
	▪ To provide psychoeducation regarding the benefits of physical activity (PA)	▪ Introduce the benefits of PA, including effects on physical health, mental health, and quality of life
	▪ To introduce breathing techniques	▪ Introduce a breathing strategy o **Session 1**: display brief video introducing diaphragmatic breathing o **Session 5**: display brief video introducing box breathing ▪ Complete in-session breathing practice o **Session 1**: diaphragmatic breathing practice o **Session 5**: box breathing practice
2/6	▪ To introduce guided imagery	▪ Introduce guided imagery o **Session 2**: provide overview of the benefits of guided imagery o **Session 6**: display brief video introducing guided imagery ▪ Complete in-session guided imagery practice o **Session 2**: read guided imagery script about a garden o **Session 6**: read guided imagery script about a beach
3/7	▪ To introduce progressive muscle relaxation	▪ Introduce progression muscle relaxation o **Session 3**: explain the importance of physical relaxation and display brief video describing the benefits of progressive muscle relaxation o **Session 7**: display brief video describing how to de-stress using progressive muscle relaxation ▪ Complete in-session progressive muscle relaxation practice
4/8	▪ To create a personalized relaxation plan	▪ Discuss the steps for creating a personalized relaxation plan, including identifying signs of stress and planning relaxation and self-care strategies for reducing stress o **Session 4:** display brief video defining self-care and discuss the importance of engaging in pleasant/enjoyable activities and hobbies as part of self-care routine o **Session 8**: display brief video explaining how self-care can be used to cope with stress and discuss the importance of engaging in healthful behavior as part of self-care routine
	▪ To provide a summary of Relaxercise content	▪ Explain how all of the content throughout this program ties together to increase relaxation

Note. The intervention will utilize rolling enrollment, with participants beginning the intervention at either Session 1 or 5. Although the objectives of Sessions 1-4 are identical to those of Sessions 5-8, the content used to accomplish these objectives will differ in each half of the program (see above).

Table 3 ***Participant Timeline***

Timepoint		*Baseline*	*Allocation*	*Post-Allocation*											*Close-Out*
				Session 1	*Session 2*	*Session 3*	*Session 4*	*Mid-Treatment Assessment*	*Session 5*	*Session 6*	*Session 7*	*Session 8*	*Post-Treatment Assessment*	*Booster Session*	*6-Month Follow-Up*
ENROLLMENT:															
Eligibility Screen		X													
Informed Consent		X													
Allocation			X												
INTERVENTIONS:															
ACTivity				♦	—	—	—	—	—	—	—	♦		♦	
Relaxercise				♦	—	—	—	—	—	—	—	♦		♦	
ASSESSMENTS:															
Credibility/ Acceptability	CEQ[1]			X											
	CSQ[2]												X		
Primary Outcome: MVPA[3]	Accelerometry	X											X		X
	Self-Reported MVPA	X						X					X	X	X
Secondary Outcome: Depression Symptoms	CES-D[4]	X						X					X	X	X
Putative Mediators	VQ[5]	X						X					X	X	X
	PAAQ[6]	X						X					X	X	X
	TSRQ[7]	X						X					X	X	X
	DIS[8]	X						X					X		
Potential Covariates	Demographic Factors	X													
	Substance Use[9]	X													
	Psychopathology [10]	X													
	PA Facilities, Equipment, Apps	X						X					X	X	X
	BMI[11]	X											X		X
	GQ[12]							X					X		

[1]Credibility and Expectancy Questionnaire, [2]Client Satisfaction Questionnaire, [3]Moderate-to-Vigorous Intensity Physical Activity, [4] Center for Epidemiological Studies – Depression Scale, [5]Valuing Questionnaire, [6]Physical Activity Acceptance Questionnaire, [7]Treatment Self-Regulation Questionnaire – Exercise Version, [8]Discomfort Intolerance Scale, [9]Alcohol Use Disorders Identification Test, Drug Use Disorders Identification Test, Heaviness of Smoking Index; [10]Altman Self-Rating Mania Scale, Community Assessment of Psychic Experiences, SCOFF Eating Disorder Questionnaire, [11]Body Mass Index, [12]Group Questionnaire.

Figure 1

Conceptual Model of ACTivity