



Adaptation of tele-behavioral activation to increase physical activity in depression: Protocol for iterative development and evaluation

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ABSTRACT

Background: Poor treatment outcomes, disease recurrence, and medical co-morbidities contribute to the significant burden caused by depressive disorders. Increasing physical activity in persons with depression has the potential to improve both depression treatment outcomes and physical health. However, evidence for physical activity interventions that can be delivered as part of depression treatment remains limited. This study will examine a Behavioral Activation teletherapy intervention adapted to include a specific focus on increasing physical activity.

Methods: The two-phase study will include a preliminary pilot study ($n = 15$) to evaluate and refine the manualized intervention using a mixed-methods approach followed by a single-arm study to evaluate feasibility and preliminary efficacy of the adapted BA teletherapy. Participants will be adults, age 18–64, with moderate to severe depressive symptoms (defined as a PHQ-9 score ≥ 10) and who currently engage in 90 min or less of moderate-to-vigorous physical activity. Individuals will be excluded if they have a current or past manic or hypomanic episode, psychosis, schizophrenia or schizophreniform disorder, or active suicidal ideation, or if not medically-cleared to exercise. The BA intervention will consist of 8 weekly sessions, followed by 2 bi-weekly booster sessions. Feasibility outcomes will include metrics of screening, enrollment, intervention adherence and fidelity, and participant retention. Intervention preliminary efficacy will be evaluated through assessment of changes in depressive symptoms and moderate-to-vigorous physical activity.

Conclusion: Data from this trial will be used to support the conduct of a randomized controlled trial to evaluate the efficacy of the adapted BA intervention.

1. Introduction

1.1. Background

Depressive disorders are chronic, recurrent disorders with significant disease burden. Approximately 10% of the population in the United States is affected by a depressive disorder annually and the lifetime prevalence of depression is 20% [1,2]. The annual economic burden of depression is estimated at \$83 billion [3] and depressive disorders are predicted to be the greatest contributor to global health burden by the year 2030 [4]. Several factors contribute to the significant burden

associated with depressive disorders, including poor treatment outcomes [5–7], disease recurrence [8], and medical co-morbidities [9–13]. These data underscore the substantial public health burden of depression and highlight the need for innovative interventions to reduce disease recurrence inherent in current treatments and improve the physical health of persons with depressive symptoms.

Depression has been consistently associated with low levels of physical activity and poor cardiorespiratory fitness [14–17]. Analysis of the National Health and Nutrition Survey data indicates those with depression engage in approximately 50% less moderate-to-vigorous physical activity (median 9.8 min of moderate-to-vigorous physical

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activity per week) compared to those without depression [18]. Increasing physical activity among those with depression has the potential to alleviate depressive symptoms, reduce disease recurrence, and address medical co-morbidities to relieve the burden experienced by those with depression. Exercise is an efficacious stand-alone treatment for MDD [19,20]. Results from randomized controlled trials and meta-analyses indicate the treatment effect of exercise is comparable to that of antidepressant medication [21–23]. Exercise is also efficacious as an augmentation treatment [21,24,25]. Furthermore, physical activity improves long-term treatment outcomes for MDD by reducing disease recurrence. Successful maintenance treatment for depression would avert nearly half of the disease burden during the 5 years following a depressive episode [26]. In a one-year follow-up to a trial comparing exercise and antidepressant medication, patients who engaged in regular physical activity during the follow-up period were less likely to be depressed [27]. Finally, medical co-morbidities can be addressed through physical activity, as improved cardiorespiratory fitness is associated with a reduced mortality risk in persons with a history of depression [28].

An intervention that increases physical activity among persons with depression has the potential to substantially improve public health. There is a high level of interest amongst those with depression in an exercise treatment program [29]. However, clinicians rarely use exercise as a treatment for MDD in real-world clinical settings [30]. The low usage of exercise as a treatment despite demonstrated efficacy and patient interest highlights the presence of several barriers to optimal implementation of exercise for persons with depression within clinical settings. Clinicians indicate a primary reason for not prescribing exercise is a lack of training in exercise prescription; rather, they prefer referring patients to community exercise resources [31–33]. Many of these existing resources are regimented group classes or supervised exercise sessions, which are not necessarily tailored to an individual's interests or skill level and may therefore not be maintained, especially after supervision ends. A lack of resources available through healthcare system further impacts clinicians use of exercise. For example, in the United States, insurance coverage for exercise programming is limited [34]. Finally, poor adherence to exercise may limit its utility in clinical settings. Depression has been associated with poor adherence to health behaviors generally [35], and elevated depressive symptoms results in poor adherence to exercise [36–38]. Poor adherence rates also occur in exercise trials evaluating exercise as a treatment for depression [51,52, 54–56]. Acknowledging these barriers, a physical activity treatment that can be tailored to an individual's interests or skill level, financially accessible, and designed to maintain engagement is needed.

1.2. Rationale

This paper presents the study protocol for a trial that will examine a manualized Behavioral Activation intervention that has been adapted to include specific physical activity emphasis and support. We hypothesize that Behavioral Activation's structured approach to scheduling and problem-solving barriers to physical activity engagement through the support and accountability of a therapist will facilitate physical activity engagement and ultimately improve depression treatment outcomes. Furthermore, Behavioral Activation explicitly targets depressive symptoms cognitions and behaviors (anhedonia; withdrawal; reduced motivation, interest, energy) that especially limit physical activity initiation and maintenance among depressed, sedentary individuals. This approach contrasts with supervised exercise sessions that focus solely on modeling and supervising exercise rather than problem-solving the cognitive, behavioral, and depressive-symptom-related features that are barriers to activity completion and engagement. Furthermore, Behavioral Activation relies on participants completing activities outside of session while supervised exercise does so in session and may therefore not be able to be maintained once this supervision ends.

The proposed study addresses these barriers described above in

several ways. First, by manualizing the intervention while personalizing its content to the individual participant, we overcome lack of training concerns; create a scalable intervention to improve dissemination; personalize such intervention to increase its relevance, adherence, and long-term maintenance; and place the burden of care on specifically trained and less-expensive interventionists rather than primary care physicians. Related to this point, licensed therapists are trained in the behavior change techniques that we use to target physical activity in this intervention. Second, the integration of a physical activity intervention within a reimbursable treatment regimen (BA delivered by a licensed therapist) addresses the barrier of financial resources. Finally, it is clear that depressive symptoms, and behaviors, such as anhedonia, withdrawal, poor self-esteem, and fatigue limit successful initiation and engagement in physical activity. Behavioral Activation is empirically-supported to reduce depressive symptoms by promoting engagement in activities that enhance pleasure and joy, as well as mastery and accomplishment [39,40], even in a very brief, four-session protocol [41, 42]. Given these findings, we propose to adapt and deliver a brief BA treatment for depression with a focus on increasing physical activity.

Other researchers have conducted projects based on similar rationale, combining Behavioral Activation or other psychotherapy approaches with either structured exercise programs or interventions that target increases in physical activity. However, many of these interventions resulted in poor adherence, with participants attending 50% or less of the intended intervention sessions [43–45]. Program length presents a potential barrier for adherence; these interventions were typically of a longer duration (16+ weeks) and required a significant number of intervention sessions. Related to this issue, the resources required to deliver in-person exercise sessions or longer psychotherapy interventions limit the potential for real-world use within clinical settings. These barriers limit the conclusions drawn from these studies and suggest different intervention approaches are required. We propose that our Behavioral Activation intervention specifically focusing on promoting physical activity, of limited duration (only 8 core sessions), and delivered through teletherapy will ameliorate such logistical and methodological concerns that have posed barriers to participant recruitment, retention, and intervention adherence.

2. Methods

2.1. Overview

In Phase 1 of this project, we will use an iterative process to evaluate and refine the manualized intervention using a mixed-methods approach to conduct a preliminary assessment of the feasibility of telehealth delivery by conducting an intervention with a small number of individuals ($n = 15$), utilizing a preliminary manual developed with specific session-by-session content. We will refine the intervention and/or study procedures based on data from Phase 1. In Phase 2, we will conduct a single-arm trial ($n = 50$) of the refined intervention to evaluate the feasibility of intervention delivery and conduct a preliminary evaluation of intervention efficacy.

2.2. Participants

2.2.1. Inclusion criteria:

- Be 18–64 years old
- Able and willing to provide informed consent
- Have moderate to severe depressive symptoms, with a PHQ-9 score ≥ 10 .
- Insufficient current moderate to vigorous physical activity (< 90 min a week)
- Demonstrated interest in increasing physical activity
- Have a smartphone

2.2.2. Exclusion criteria:

- Have any current, past, or lifetime manic or hypomanic episode, psychosis, schizophrenia or schizophreniform disorder (as seminal prior BA literature (Dimidjian et al., 2006; Dobson et al., 2008) focused on this treatment in persons with unipolar depression and specifically excluded participants with a history of schizophrenia, psychosis, or bipolar disorder, we sought to be consistent with this literature in the current study).
- Be currently experiencing active suicidal ideation (i.e. with suicidal thoughts, plan, and intent) or at a high risk for suicide during the course of the study, as designated by the PI
- Be medically prohibited to exercise by PCP/OB/GYN or study MD

Be in current, active psychotherapy, as assessed through a single item: “Are you currently attending any sort of therapy or mental health counseling” conducted at pre-screening.

2.3. Recruitment

Participants will be recruited from the Center for Depression Research and Clinical Care at UT Southwestern (CDRC) ongoing longitudinal cohort study (D2K) as well as the Mood Disorders Network, a network of mainly primary care clinics partnering with the CDRC to facilitate depression screening and care. Following informed consent, screening and baseline data will be collected regarding depressive symptoms, physical activity readiness, and medical and treatment history.

2.4. Screening

All potential participants will undergo a screening visit. Informed consent will be obtained before any study procedures begin. All participants who provide informed consent will be asked about basic demographic and medical information (including disease history, medications, and/or other treatments for depression). The screening visit will also include brief self-report and clinician-rated measures required for eligibility (including MINI modules and PHQ-9). All participants will need medical clearance from their PCP, OB/GYN, or the study physician before engaging in physical activity by obtaining signature on the Medical Eligibility Checklist.

2.5. Eligibility measures

Demographics. A basic demographic questionnaire will be employed that captures age, race, ethnicity, gender, biological sex, education level, marital status, occupational status, and household income.

Patient Health Questionnaire (PHQ-9). The PHQ-9 is a self-administered assessment that reflects DSM-IV criteria for depression [46]. A score of ≥ 10 indicates moderate-to-severe depressive symptoms (and high likelihood of Major Depressive Disorder) and will serve as the cut-off point for study entry.

MINI – Suicidality and Bipolar and Psychosis Modules. The Suicidality, Bipolar and Psychosis Modules from the MINI-International Neuropsychiatric Interview [47] (MINI) will be employed to rule out current active suicidal ideation with plan and intent, current or lifetime manic or hypomanic episode, a psychotic disorder, or depression with psychotic features.

Physical Activity Readiness Questionnaire (PAR-Q). The PAR-Q asks 7 yes/no questions about contraindications to exercise and will be utilized in the completion of the Medical Eligibility Checklist Form.

Medical Eligibility Checklist Form. This form will be employed and signed by a participant’s PCP or study physician before randomization to confirm safety and medical clearance to engage in physical activity.

Physical Activity Readiness Questionnaire (PAR-Q). The PAR-Q asks 7 yes/no questions about contraindications to exercise.

Physical Activity Vital Sign (PAVS). To gauge self-reported physical activity before the intervention, we will also utilize the two-item Physical Activity “Vital Sign” (PAVS) which asks about level and intensity of physical activity on a weekly basis. This measure’s utility has been well-established and will also be used to confirm eligibility criteria [48,49].

2.6. Outcome measures

A comprehensive list and schedule of measures is presented in Table 1.

2.6.1. Primary outcome measures

Leon et al. [50] suggests the primary goal of pilot studies is to determine the feasibility for an approach to be used in a subsequent larger clinical trial. As such, Leon et al. propose that evaluations of efficacy or safety should not be the primary outcome in a pilot study and that estimation of the intervention effect size from a pilot study is not appropriate. We have identified five feasibility metrics and for each metric, we have pre-determined a goal that will indicate feasibility of intervention delivery and evaluation in a subsequent clinical trial (Table 2). As previously mentioned, metrics for intervention fidelity come from the 14-item Quality of Behavioral Activation Scale (QBAS) [51], with an overall average score of 3 or higher (range: 0–6) per item (Total score 42 out of 84) as the cutoff for intervention fidelity, comparable to an intervention fidelity metric from a widely-used measure in CBT, the Cognitive Therapy Rating Scale [52].

2.6.2. Secondary outcome measures

Patient Health Questionnaire (PHQ-9). The PHQ-9 is a self-administered assessment that reflects DSM-IV criteria for depression. A score of >4 indicates depressive symptoms and/or depressive disorder. Participants will complete the PHQ-9 weekly during the 14-week intervention period and at follow-up.

Physical Activity. Upon enrollment, participants will be provided a Fitbit Inspire HR and asked to wear the device for the duration of their participation, removing it only for charging. Wrist-worn Fitbit devices have demonstrated acceptable reliability and validity for “Active Minutes” compared to moderate-to-vigorous activity measured by Actigraph [53]. We will utilize Fitabase, a comprehensive data management platform to acquire near real-time physical activity data from the Fitbit devices including steps, activity intensity, METs, energy expenditure, floors, sleep, and heart rate. We will also utilize the PAVS throughout the intervention to monitor physical activity changes via self-report. Finally, at selected visits, we will use the Short Form of the International Physical Activity Questionnaire (IPAQ-S) [54].

2.6.3. Additional symptom measures to assess potential mediators

We propose increasing physical activity will impact potential mediators of the intervention such as positive affect, interest, energy, and self-esteem to promote continued and even enhanced activity completion which will ultimately reduce depressive symptoms. Under Aim 1, we discuss specific measures to assess these variables and conduct formal statistical tests in Aim 2. All of these measures will be completed at baseline visit (i.e., first therapy session, week 0), and after the mid-point (4th intervention session) and endpoint (8th intervention session).

Positive and Negative Affect Schedule (PANAS). The 20-item PANAS¹⁰⁴ assesses for changes in positive and negative affect, which is a potential mediator for depressive symptoms.

Emotion Regulation Questionnaire (ERQ). The 10-item self-report questionnaire assesses one’s ability to regulate emotions with items tapping two distinct constructs: cognitive reappraisal and suppression [54]. All items are measured using a 1 to 7 Likert scale, from “strongly disagree” to “strongly agree”.

Dimensional Anhedonia Rating Scale (DARS). Participants will complete the 17-item DARS, a measure that assesses anhedonia, and better differentiates MDD subgroups compared to the traditional Snaith-

Table 1
Schedule of assessments and procedures.

Visit/Session	—	1	2	3	4	5	6	7	8	9	10	11	12
Week	−1	0	1	2	3	4	5	6	7	9	11 ^c	15	19 ^d
Informed Consent	X												
Inclusion/Exclusion Criteria Reviewed	X												
Demographics	X												
Physical Activity Readiness Questionnaire (PARQ)	X												
Medical Eligibility Checklist Form	X												
Self-Administered Comorbidity Questionnaire (SCQ)	X												
Concomitant Meds	X	X	X	X	X	X	X	X	X	X	X	X	X
MINI – Suicide, Psychosis and Mania/Hypomania modules	X												
Primary Outcomes													
PHQ-9 ^{g, h}	X	X	X	X	X	X	X	X	X	X	X	X	X
Fitabase/Fitbit ^m	X	X	X	X	X	X	X	X	X	X	X	X	X
International Physical Activity Questionnaire- Short Form (IPAQ-SF) ^b	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical Activity Vital Signs (PAVS) ^{g, h}	X	X	X	X	X	X	X	X	X	X	X	X	X
Visit/Session		1	2	3	4	5	6	7	8	9	10	11	12
Week	−1	0	1	2	3	4	5	6	7	9	11 ^c	15	19 ^d
Intervention													
BAT form- Session completion		X	X	X	X	X	X	X	X	X	X		
Weekly Activity Sheet		X	X	X	X	X	X	X	X	X	X		
Post-initial session questionnaire ^e		X											
Mid-point session questionnaire ^e					X								
Final Session Feedback ^{e, j, k}											(X)		(X)
Mediating Variables^f													
Positive and Negative Affect Schedule (PANAS)		X			X				X				
Dimensional Anhedonia Rating Scale (DARS)		X			X				X				
Multidimensional Fatigue Inventory (MFI-20)		X			X				X				
Rosenberg Self-Esteem Scale (RSES)		X			X				X				
Inventory of Depressive Symptomatology (IDS-SR)		X			X				X		X	X	X
Emotion Regulation Questionnaire (ERQ)		X			X				X				
Covariates													
Generalized Anxiety Disorder Scale (GAD-7) ^{g, h}	X	X	X	X	X	X	X	X	X	X	X	X	X
BMI (height/weight)	X										X ^l		X ^l
Patient Adherence Questionnaire (PAQ) ^{g, h}	X	X	X	X	X	X	X	X	X	X	X	X	X
Safety and Tolerability													
Serious Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Reporting		X	X	X	X	X	X	X	X	X	X	X	X
Validity													
Behavioral Activation for Depression - Short Form (BAD-SF) ^{g, h}		X	X	X	X	X	X	X	X	X	X	X	X

a: In-person visit.

b: Phase 2 only.

c: Core intervention sessions cannot be completed within the same week; allowed up to 2 weeks in between sessions if necessary.

d: Final visit in Phase 1 - in person/Visit 10 in Phase 2 - remote.

e: Final visit for Phase 2 - in person.

f: To be completed post-intervention.

g: To be completed post-intervention at weeks 0, 3, and 7.

h: To be completed weekly regardless of when intervention scheduled.

i: To be completed pre-intervention, same day.

j: Exit/Early withdrawal form to be completed after participant has finished study participation.

k: Fitbit returned and final visit procedures to be completed at early withdrawal visits.

l: Final BMI to be collected at final in-person visit; For phase 1- Visit/Session 10; For phase 2- Visit/Session 12.

m: Fitbit dispensed at screening after eligibility is confirmed. Fitbit should be worn for entirety of study, except when charging. Data must be synced with participant smart device.

Table 2
Pre-determined feasibility metrics.

Metric	Definition	Feasibility Goal
Screening	number of participants screened per month	6/month
Enrollment	percentage of screened participants enrolled	50%
Intervention Adherence	percentage of intervention sessions attended	75%
Intervention Fidelity	average item score on the QBA-SF	>3
Retention	percentage of PHQ-9 assessments completed	80%
	percentage of valid Fitbit wear days (>12 h)	80%

Hamilton Pleasure Scale [55].

Multidimensional Fatigue Inventory (MFI-20). The 20-item MFI will be used to assess fatigue.*Rosenberg Self-Esteem Inventory (RSES)*. The 10-item RSES will be utilized to measure self-esteem [56].*Inventory of Depressive Symptomatology (IDS-SR)*. The 30-item self-report Inventory of Depressive Symptomatology will be used to track a wide variety of depressive and anxiety-related symptoms, including symptoms such as irritable mood, loss of libido, and facets of atypical and melancholic depression generally not captured by other depression inventories. Psychometrics have been well-established [57,58].

2.6.4. Covariate measures

BMI. Body Mass Index will be assessed through measurement of height and weight at in-person visits (baseline and final visit/session).*Concomitant Medications*. Participants will complete a Concomitant

Medication Log at each study visit, therapy session, and follow-up visit to track all medications taken, including antidepressants. Participants will be instructed to bring in pharmacy records to assist with this process.

Patient Adherence Questionnaire (PAQ). For individuals on antidepressant medication, we will include the two-item Patient Adherence Questionnaire [59], which asks about the number of days participants have missed taking their antidepressant medication over the last week alongside common reasons for non-adherence. This will occur at each study visit, therapy session, and follow-up visit.

Generalized Anxiety Disorder Scale (GAD-7). Anxiety symptoms will be measured weekly through the 7-item Generalized Anxiety Disorder Scale [60], given the high degree of comorbidity between depression and anxiety [61], and the impact of comorbid anxiety on depression treatment outcomes [62].

2.6.5. Intervention development

This intervention was adapted from prior 8-session manualized BA-for-depression interventions by this research group, previously determined to reduce depressive symptoms, with a majority of participants achieving depression remission and/or a clinically-significant response [63,64]. The manual was created from prior seminal writings on BA therapy, including the 10-year revision to the BA manual [65], and a guide for clinicians [64]. The intervention will utilize the Behavioral Activation framework to help participants schedule, execute, and problem-solve barriers to activity completion, with a focus on activities that related to a sense of mastery/accomplishment and joy/pleasure. At least 2 activities per week will be required to be physical activity, tailored to a participant's interests, skill level, and physical health. Therefore, both physical and non-physical valued activities will be scheduled and completed.

Additional standardized Behavioral Activation interventions will be employed, including values identification, psychoeducation about the Behavioral Activation model and linkage between mood and activity completion/accomplishment, self-monitoring, and activity tracking. All participants will receive a comprehensive packet before beginning therapy, with a number of psychoeducational and experiential handouts to track activity scheduling, completion, exertion of physical activities, and mood before and after activity completion. Homework (i.e., reading psychoeducational materials, tracking one's current schedule, tracking activity identification and completion and rating mood before and after) was assigned at the end of each session and reviewed at the beginning of the subsequent session. Problem-solving interventions will be employed when previously-scheduled activities are not successfully completed. The exertion, intensity, and duration of physical activity will be gradually increased. Additional details about content by session can be found in Table 3.

2.6.6. Interventionist training and validity

Interventionists will be, master's level providers (i.e., LPC or LPC-Intern, LMSW, LCSW) with current and/or prior psychotherapy provision experience. Initial training will consist of a combination of didactic and experiential exercises, including reading of the study manual, which includes a review of physical activity concepts relevant to the intervention, reading seminal articles in the field, and BA-related training videos. Therapists will complete a recorded full mock therapy session and must be scored at a total score of 42 or higher (average of 3 or higher across all 14 items) on the Quality of Behavioral Activation Scale [66] in order to pass initial certification. Training will be overseen by a licensed psychologist. Ongoing, regular weekly supervision between study therapists and the psychologist will occur, and 10% of therapy sessions will be reviewed in full and rated using the Quality of Behavioral Activation Scale to monitor the ongoing quality and fidelity of the study interventionists and intervention.

Table 3

Description of intervention session objectives and activities.

Sessions 1-2	<p>Assessment – Assess patient's depressive symptoms, risk/safety, and goals for treatment. Discuss prior experience with physical activity, specific activities previously enjoyed and not enjoyed, and barriers to regular physical activity. Discuss physical activity goals and limitations.</p> <p>Psychoeducation – Discuss how depression and chronic physical conditions are associated with a decline in pleasurable and/or accomplishment-building activities that exacerbates symptoms; discuss how physical activity can improve mood and energy; discuss common barriers and solutions to physical activity initiation and maintenance; discuss physical activity guidelines and goals to increase physical activity to at least 150 min/week by intervention end.</p> <p>Behavioral Activation – Introduce rationale for BA; complete activity scheduling to determine how a patient generally occupies time; complete values work to identify important domains in work, social relationships, health and wellness and leisure activity, with a specific focus on values tapping into physical health/wellness and increasing activity.</p>
Sessions 3-5	<p>Behavioral Activation – Schedule activities that promote increases in physical activity; review completion of physical activity homework; problem-solve barriers to activity completion. Activities at each session must include at least 2-3 days a week of scheduled moderate-intensity physical activity. Engage in self-monitoring and mood tracking before and after activity completion, and ratings of exertion of physical activities completed.</p>
Session 6	<p>Limited Cognitive Work to Promote Behavioral Activation – Discuss relationship between thoughts, feelings, and behaviors (Cognitive Model). Discuss that motivation need not come before beginning an activity, and to follow a plan, not one's mood, when progressing through activities.</p>
Sessions 7-8	<p>Summarization and relapse prevention – Review newly-learned skills and practice behavioral and cognitive strategies; introduce plan for termination of weekly therapy; identify which interventions were helpful and which were not; focus on relapse prevention.</p>
Sessions 9-10	<p>Continued review – Review/revise relapse prevention plan; reinforce behavioral and cognitive skills; problem-solve barriers to physical activity maintenance; set new activities.</p>

2.7. Satisfaction/acceptability

Post-initial session questionnaire. A brief questionnaire after the initial intake session will gauge logistics and satisfaction. We will ask questions including if the participant was glad they came to the visit, if they plan to return next week, one aspect they liked and disliked about their visit, any barriers to regular attendance, any aspects that might make continued attendance easier, and skills learned from the intervention to help increase physical activity.

Mid-point session questionnaire. After the 4th session, participants will again receive a brief questionnaire, focused more on satisfaction and improvement. We will use a 5-point Likert scale, from "strongly disagree" to "strongly agree" to ask such items as "the intervention helped me increase my physical activity", "the intervention helped me decrease my depressive symptoms", "I am feeling better overall", and "I have experienced problems using video technology". We will also ask for free responses about the most helpful and most frustrating aspects of the intervention so far, as well as general feedback to promote continued satisfaction and session attendance.

Exit survey. We will administer an exit survey for all participants at the completion of the intervention. This survey will include both quantitative and open-ended questions regarding the timing, frequency, and length of the intervention, the perceived usefulness of the intervention for increasing physical activity, and the likelihood that patients would choose such an intervention to increase physical activity. The questionnaire will include same questions as mid-point survey, as well as additional questions on same 5-point Likert scale including, "Participating in these intervention sessions was important to me", "As a result of the intervention sessions, I believe I will be able to successfully increase my physical activity on my own", "I enjoyed meeting with my

therapist using the video technology". Two questions on a 3-point Likert scale, from "too short" to "too long" will be included to assess number of sessions and length of time between sessions. Free response questions from mid-point session will be included, as well as questions about barriers to completing intervention and ways to reduce such barriers, and things that could have been done in intervention to help increase physical activity. Finally, the participant will complete 2 questions, checking all options that apply, about what kind of interventionists could be used to complete intervention and types of settings for the intervention, and will also mark preferred setting for completing intervention.

Phase 1 focus groups. Two to three focus groups (to reach a total of 15 participants) will be conducted with enrolled participants from Phase 1. Each focus group will be ideally comprised of 4–6 patients (large enough to achieve diversity of perspectives but small enough to allow all members to participate), enabling us to obtain a large amount of qualitative data in a relatively short time [67,68]. The focus groups will be audio-recorded to ensure accuracy of data collected. The groups will be semi-structured, driven by a guide but open to discussion on related topics. The guides will gather data on participants' experiences and opinions of the intervention, the message type, the intensity of completed exercise, barriers to and facilitators of intervention engagement, and perceived benefits of the intervention to increase physical activity. We will also seek to elicit participants' receptiveness to the intervention, learn how and in what ways the intervention has influenced their adherence practices, and gauge their opinions about conducting the intervention via teletherapy. We will also hold a focus group near the end of intervention completion (after having completed at least 8 of the 10 available sessions) to capture their opinions about all aspects of intervention satisfaction, suggestions for improvement, and the manual and intervention, including a discussion of potential mediators.

Phase 1 semi-structured interviews. We will also target recruitment of 3–5 participants who do not initiate or who do not complete the intervention to assess their perspectives and reasons for non-engagement or partial completion. We anticipate that such participants may be more challenging to recruit and engage in a group format; thus, the one-on-one interview provides an opportunity to understand the unique circumstances of an individual's decision as it relates to feasibility, acceptability, and interest. Participants who consented at the beginning of the study will be audio-recorded during the interview to ensure accuracy of data collected. Similar to the focus group, the interview will be semi-structured, driven by a guide but flexible enough to allow for the participant to engage in related topics. Interview topics will include reasons for and barriers to intervention non-engagement and non-completion, opinions regarding the intervention for partial completers, and suggestions on how the intervention may be modified (in terms of content, delivery, timeframe, etc.) to enhance engagement and completion.

2.8. Intervention

Once a participant has been deemed eligible for the study via screening, they will have 8 weekly teletherapy intervention sessions to be delivered over a 10-week period to allow for missed appointments/scheduling issues), plus two biweekly booster sessions. Total participation in this intervention will therefore be up to 14 weeks. In Phase 1, participants will complete an exit survey and may also be invited to participate in a focus group. In Phase 2, participants will complete two follow-up assessments, 4 and 8 weeks following the final booster session.

2.8.1. Baseline visit and first therapy session (Week 0)

The baseline visit will include the baseline and covariate assessments (described below), a brief orientation to the intervention and the video teletherapy system, and the intake therapy session.

2.8.2. Intervention sessions (Weeks 1–7, 9 and 11)

Participants will have weekly 45–50 min scheduled video teletherapy sessions and complete the PHQ-9, GAD-7, BAD-SF, PAVS, and PAQ remotely, pre-intervention, on a weekly basis. Table 3 describes the objectives and activities for each Behavioral Activation session. The interventionist will work with the participants to schedule sessions at a convenient time for the participant, including after regular business hours and during lunch to accommodate working participants. The interventionist will also send appointment reminders to the participant the day prior to their scheduled session. The 8 sessions including the baseline visit will be delivered within a 10-week window to allow for rescheduling due to any participant scheduling conflicts, with two additional biweekly sessions offered, for a total intervention period of up to 14 weeks (but may be as few as 12, if the initial 8 sessions are indeed attended weekly).

2.8.3. Analysis

2.8.3.1. Preliminary efficacy. We will evaluate the within-subjects effect of the intervention on physical activity and depressive symptoms. Linear mixed-effects analysis will be conducted with the two outcomes (physical activity and depressive symptoms) with time as a within-subjects factor. The baseline measurement of the outcome will be included as a covariate. Any following measures: PHQ-9, GAD-7, BMI, and antidepressant use (yes/no) will also be included as covariates if it is determined that they improve the fit of the final model (using the Akaike Information Criteria). The mixed-effects model will allow for the inclusion of participants with missing data and will provide unbiased estimates as long as the missing at random assumption holds. Given the limited sample size we do not consider it feasible to do an adjusted analysis to account for missing data.

Qualitative analysis. We will conduct basic descriptive analysis of quantitative data to summarize participants' characteristics, assess process measures regarding the intervention, and examine correlations among selected variables for participants in the first phase of the project. Audio recordings of focus groups and semi-structured interviews will be transcribed verbatim and, along with qualitative text from the surveys, will be uploaded into Nvivo 12 (QSR International) for data management, coding, and analysis. The research team will use an iterative coding strategy to develop a codebook that relates qualitative data to behavioral theory and clinical practice [69–71]. Coding will include thematic analysis of actual utterances, expressions, and concepts alongside participant characteristics, such as medication use [72]. Joint coding by multiple team members will enhance rigor by strengthening coding consistency and inter-rater reliability.

3. Discussion

At the completion of this project, we will have evaluated the feasibility of conducting a trial to evaluate the efficacy of the proposed Behavioral Activation + physical activity intervention to improve depression treatment outcomes by targeting physical activity. The data collected will inform the recruitment and retention strategies required to ensure successful completion of a subsequent efficacy trial. We will use data on adherence, retention, and acceptability to make any necessary revisions to intervention delivery or assessment procedures to ensure the subsequent trial can definitively evaluate the efficacy of the Behavioral Activation + physical activity intervention. We do note potential limitations to the study design. First, the small sample size and single-group design will limit interpretation of intervention efficacy data. Second, while the incorporation of the Fitbit is meant to assist with participant self-monitoring, it is possible that providing the Fitbit may have an effect on participant physical activity above and beyond the BA intervention. Finally, we are not capturing data on goal content or goal completion, which may be important mediators for intervention

efficacy. Collecting such data in future trials will be essential to understand the mechanisms by which the intervention influences physical activity and depressive symptoms.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Joseph Trombello is a shareholder in Merck, unrelated to the current project. Within the past 36 months, Dr. Trivedi has provided consulting services to ACADIA Pharmaceuticals, Allergan, Alkermes Inc., Alto Neuroscience Inc, Applied Clinical Intelligence, LLC, Axsome Therapeutics, Biogen MA Inc, Boehringer Ingelheim, Cerebral Inc., Circular Genomics Inc., Compass Pathfinder Limited, GH Research, GreenLight VitalSign6 Inc, Heading Health, Health Care Global Village, Janssen Pharmaceutical, Jazz Pharmaceutical, Legion Health, Lundbeck Research USA, Merck Sharp & Dohme Corp., Mind Medicine Inc., Myriad Neuroscience, Naki Health Ltd, Navitor, Neurocrine Biosciences Inc., Noema Pharma AG, Orexo US Inc., Otsuka America Pharmaceutical Inc, Perception Neuroscience Holdings, Pharmerit International, Policy Analysis Inc., Praxis Precision Medicines Inc, Rexahn Pharmaceuticals, Inc., SAGE Therapeutics, Signant Health, Sparian Biosciences, Titan Pharmaceuticals, Takeda Pharmaceuticals Inc, WebMD. He has received grant/research funding from NIMH, NIDA, NCATS, American Foundation for Suicide Prevention, Patient-Centered Outcomes Research Institute (PCORI), and Blue Cross Blue Shield of Texas. Additionally, he has received editorial compensation from Engage Health Media, and Oxford University Press. All other authors have no competing interests to report.

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