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The Positive Affect, Promoting Positive Engagement, and Adherence for Life (APPEAL) Feasibility Trial: Design and Rationale

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Abstract

Objective: To describe development of the Positive Affect, Promoting Positive Engagement, and Adherence for Life (APPEAL) program.

Method: APPEAL is intended to increase HIV medication adherence through promotion of positive affect, and was developed through an iterative process involving 6 focus groups ($N = 34$) that elicited feedback on intervention content, followed by an individually administered prepilot of the entire intervention ($N = 7$).

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Results: Participants provided feedback on important potential moderator variables, including depression, on mode of intervention administration, and on anticipated barriers and benefits to participation. Insights gained were used to finalize study procedures in preparation for a feasibility trial. For the feasibility trial, a total of 80 participants who, in the past 6 months have had at least one plasma HIV RNA >200 copies/mL, will be randomized to receive APPEAL or standard of care (N = 40 per group). Intervention group participants will receive 3 monthly, individually administered sessions, and all participants will have their medication adherence monitored and complete structured interviews at baseline and at 3 and 6 months.

Conclusion: The APPEAL program is innovative in that it focuses on promoting self-regulation of positive emotions, an understudied approach to promoting chronic disease self-management behaviors such as HIV medication adherence. Findings from the feasibility trial will gauge suitability of the APPEAL intervention and evaluation methods for subsequent testing in a confirmatory trial and will examine changes in positive affect, the primary mechanism of change targeted in the intervention.

Keywords

positive affect; adherence; HIV; feasibility; intervention

Chronic diseases are the leading causes of death and disability in the United States (Best et al., 2018; Johnson, Hayes, Brown, Hoo, Ethier, & the Centers for Disease Control and Prevention 2014); approximately 60% of adults live with at least one chronic condition, and over 40% have multiple chronic conditions (Buttorff, Ruder, & Bauman, 2017). Patients are typically the primary managers of their health, responsible for a range of behaviors, which include adherence to medication regimens. Adherence is an ongoing challenge, as it is estimated that 40% to 60% of people living with a chronic disease take their medications as prescribed (Stirratt et al., 2018). There is a continuing need to strengthen the evidence base for adherence promotion interventions that are potent and feasible to implement (Conn & Ruppar, 2017; Stirratt et al., 2018).

For HIV infection, which impacts approximately 1.1 million people in the United States and 38.8 million globally (Centers for Disease Control and Prevention, 2019; The Global Burden of Disease 2015 HIV Collaborators, 2016), adherence has always been a significant barrier to individual patient health and public health control efforts. A systematic review and network meta-analysis of 85 experimental trials, which included over 16,000 patients, revealed that interventions to improve adherence to HIV antiretroviral therapy (ART) have yielded modest effect sizes (Kanters et al., 2017). Additionally, ART adherence gains that are made in interventions are typically not sustained over time (Kanters et al., 2017; Locher, Messerli, Gaab, & Gerger, 2019). Thus, there is a continuing need for innovations in effective, acceptable, and potent interventions that can support adherence to ART medication over time.

One underexplored area for supporting ART adherence is that of positive affect promotion. Positive affect refers to a group of pleasurable emotions such as joy, awe, amusement, and contentment. The broaden-and-build theory (Fredrickson, 2001, 2013) posits that while negative emotions, such as anger, help humans respond to specific perceived threats by

narrowing attention and physiologic responses, positive emotions generate thoughts and actions that build psychological and social resources which can support and motivate health protective behaviors (Van Cappellen, Rice, Catalino, & Fredrickson, 2018). These resources include greater resilience to stressful life events (i.e., positive affect may moderate, or buffer, the impact of experienced stressors by reducing the likelihood that they will result in impaired adherence), along with greater proactive coping and lower perceived stress (i.e., positive affect may be linked to better adherence through its influence on coping and stress; Okely, Weiss, & Gale, 2017; Pressman, Jenkins, & Moskowitz, 2019). Greater positive affect has been associated with improved health outcomes and decreased mortality in older community-dwelling populations and across several chronic diseases (Pressman et al., 2019; Steptoe, 2019). In the context of HIV infection, greater positive affect is associated with an increased likelihood of HIV RNA viral control among women (Wilson et al., 2017) and reduced HIV/AIDS-related mortality among men (Moskowitz, 2003).

Positive affect is modifiable, in that emotion regulation intervention techniques that focus on supporting individual habits of positive affect production can increase psychological well-being, may reduce symptoms of depression, are acceptable to diverse populations, and are relatively low cost to implement (Bolier et al., 2013; Quoidbach, Mikolajczak, & Gross, 2015; Weiss et al., 2016; White, Uttl, & Holder, 2019). Emotion regulation interventions focused on positive affect can influence the type, timing, and intensity of emotional experiences. Strategies to regulate emotions can occur prior to emotion generation, through situation selection (involving approaching or avoiding a situation that will produce an emotion), through situation modification (involving changing a situation in order to modify emotion), by attention deployment and cognitive change (involving moving attention toward or away from a situation that evokes emotion or by modifying the interpretation of a situation in order to influence emotions associated with that situation), and by response modulation (involving modifying an emotion after it has been generated; Peña-Sarrionandia, Mikolajczak, & Gross, 2015). Interventions utilizing behavior change techniques centered on situation selection and attentional deployment, in particular, have demonstrated empirical support for generating increased positive emotions over time (Quoidbach et al., 2015). Although methodologically rigorous intervention studies are needed in the area of positive affect and chronic disease management, initial findings support these connections in interventions targeting cardiovascular disease and diabetes outcomes (Pressman et al., 2019). In addition, a positive affect-focused intervention, including patients newly diagnosed with HIV, revealed lower utilization of antidepressants 15 months postdiagnosis among those receiving the intervention versus a control group (Moskowitz et al., 2017).

The Positive Affect, Promoting Positive Engagement, and Adherence for Life (APPEAL) program was developed to examine whether positive affect interventions can support medication adherence among men and women living with HIV infection. APPEAL is an individually administered intervention, theoretically grounded in concepts of emotion regulation, which translates evidence-based positive affect building strategies to the domain of ART adherence. APPEAL involves three individually administered sessions, each grounded in a character strengths perspective (Peterson & Seligman, 2004), which engage evidence-informed behavioral change techniques primarily in the emotional regulation domains of situation selection and attention deployment. APPEAL is culturally and

linguistically tailored for a population of urban, minority men and women of low socioeconomic status living with HIV infection. In order to prepare APPEAL intervention and evaluation procedures for a trial that will examine whether positive affect is a causal, modifiable, and meaningful determinant of adherence behavior, a parallel-group randomized controlled feasibility trial is first being conducted with a 1:1 randomization scheme among 80 participants, with blinding at the level of the statistical analyst. Participants complete self-report assessments at baseline, and at 3 and 6 months from baseline, and agree to chart review to monitor HIV RNA viral load measurements and related clinical parameters, and to medication adherence monitoring (Wisepill Technologies, Cape Town, South Africa) throughout trial participation. The randomized feasibility study described herein leverages the experimental medicine approach espoused by the Science of Behavior Change (SOBC) Research Network and supported by the National Institutes of Health (NIH) Common Fund Program (Nielsen et al., 2018). The SOBC seeks to strengthen evidence for social and psychological mechanisms associated with health behavior, and to identify interventions that actively engage those mechanisms.

Utilizing this experimental medicine approach, the study objectives are to translate evidence-based emotional regulation techniques focused on increasing positive affect to the context of HIV medication adherence, to verify feasibility of proposed methods for implementation and evaluation when applied to the priority population, and to describe whether receipt of APPEAL program activities results in short-term changes in positive affect that can serve as proof of concept for planning a definitive trial. The objective of this article is to provide details regarding the APPEAL study protocol, including rationale, methods, and details regarding dissemination and data sharing plans.

Method

Intervention Description and Development

Development of APPEAL began with a search for evidence-based positive affect exercises, and assessment of fit with organizational resources and consumer characteristics, in partnership with an advisory group of clinicians and patient advocates. The APPEAL intervention involves several distinct emotion regulation strategies, including character strengths identification, strengths-based activity scheduling, and approaches to savoring behaviors and experiences linked to strengths of character. Medication adherence considerations are built into several of the positive affect components. The following paragraphs briefly describe the positive affect promotion approaches used. Accompanying session objectives are described in Table 1.

Character strengths identification.—Identification of strengths of character and aligning thoughts and behaviors with these strengths may improve well-being (Schutte & Malouff, 2019) and is an approach to situation selection when paired with strengths-consistent behavioral goals. In Session 1, participants complete the 72-item version of the Values in Action Inventory (Niemiec, 2013), work with the interventionist to define core strengths of character, and describe personal stories or examples that demonstrates those strengths. The theme of character strengths is carried through all intervention sessions.

Strengths-based activity scheduling.—In activity scheduling, individuals identify and schedule activities that are enjoyable and meaningful. As a core element of behavioral activation interventions, these types of situation selection activities have been found to promote well-being and reduce symptoms of depression (Cuijpers, van Straten, & Warmerdam, 2007; Mazzucchelli, Kane, & Rees, 2010). In each session, participants are encouraged to identify activities that engage their top strengths in an enjoyable way. They then set realistic and achievable goals for these activities, identify potential barriers to activities, and develop strategies to overcome those barriers.

Imagining a positive future and building habits of health behaviors in support of that future.—Interventions focused on attentional deployment can be utilized to support development of a positive future or vision for oneself or someone else and the "preexperience" of that future. Several variations of this approach have been shown to promote improved positive affect over time (Quoidbach et al., 2015). Participants are encouraged to think about where they want to be in the next year or two, and to describe that situation, place, event, or mental, social, or physical state. Participants are then asked to identify how to get there, with regard to their own health. Participants engage in a discussion of self-care, with probes focused on medication adherence, and with integration of discussion of how personal strengths can support these goals. Subsequent discussion focuses on methods to remember to take medication, specifically with regard to building habits of medication use into daily routine (Conn & Ruppar, 2017).

Savoring strengths-centered behaviors and experiences.—The ability to create awareness and cultivation of responses of positive emotions is an attentional deployment approach that is associated with increases in positive affect, in the form of activities such as communicating, sharing, and celebrating positive events with others, expressing positive emotional reactions to events, increasing mindful attention to positive emotions as they arise, and reminiscing about positive emotional experiences or events (Quoidbach, Berry, Hansenne, & Mikolajczak, 2010). Participants are introduced to different savoring approaches, practice skills related to these approaches, and set goals for integrating them into their activity scheduling.

Formative Intervention Activities

The APPEAL intervention went through several modifications in preparation for the feasibility testing trial. Once the core elements of each of the APPEAL sessions were defined, a series of six focus groups was conducted (2 per APPEAL session), composed of four to eight participants each, for a total of 34 participants (19 women, 15 men). Participants aged 18 or older and currently on an HIV ART regimen and receiving HIV primary care were eligible. Focus group members participated in one group only. For each focus group, the intervention was first described and the exercises demonstrated. Once this was complete, a facilitator led the group through a semistructured interview designed to elicit feedback on language, graphics, exercises, and other elements of the session.

The resulting program was modified based on focus group feedback and then implemented in a prepilot of the intervention, conducted in an individually administered format. In

addition to the inclusion criteria for the focus groups, participants for the prepilot had to have had an HIV RNA viral load greater than 200 copies/ml in the previous 6 months and could not have participated in the initial focus groups. For all formative activities, participants provided informed written consent and were remunerated for completion of the qualitative data, in amounts ranging from $30 to $40, and including round-trip transportation fare. Of 12 participants who consented to participate in the prepilot, three did not present for any intervention sessions, two completed Session 1 only, and seven completed all sessions. At the conclusion of the final intervention session, a facilitator led the seven participants through a semistructured interview to assess important areas for modification prior to feasibility testing.

Overall, participants' assessment of the intervention was positive. Most found it to be straightforward, simple, and understandable. For some, the overall effect of the program was strongly linked to the character-building activity ("self-awareness," or "getting to know who you are"). Several participants were able to articulate their understanding of how identifying and then building on character strengths can enhance the quality of their lives. Participants also identified potential intervention moderators which were built into the evaluation for the feasibility trial. These included depression and substance abuse, but also a suggestion that the program might work best with older participants. Two of the proposed moderators that were suggested were also supported in the literature, in that positive affect and related interventions focused on promoting psychosocial assets may have a greater influence on well-being among older populations and among those with depression (Sin & Lyubomirsky, 2009).

Randomized Feasibility Trial Design

Timeline.—Each participant engages with the study for approximately 6 months (Figure 1). Enrolled participants complete an initial practice phase with the Wisepill for approximately two weeks (range, 1–4 weeks) prior to their baseline evaluation, to ensure that there are no technical issues and that participants are comfortable with the device. After completion of the baseline assessment, participants are randomized to either receive the individually administered APPEAL sessions or to standard of care. Participants complete follow-up evaluation assessments at 3 and 6 months following baseline. Adherence is monitored throughout participation, and a retrospective chart review is conducted for all participants, regardless of completion status, at 6 months.

Participants.—Participants are recruited from an HIV primary care clinic located in Brooklyn, New York. The clinic provides HIV care to over 1,200 patients annually, and primarily serves the neighborhoods of East Flatbush, Flatbush, Crown Heights, Brownsville, and Bedford-Stuyvesant. These neighborhoods are characterized by high poverty rates, a vast majority of residents who identify as Black or African American, and a disproportionate burden of HIV as compared with the rest of New York City (New York City Department of Health and Mental Hygiene, 2019).

Inclusion criteria for the study are (a) men and women aged 18 and older, who are (b) currently prescribed HIV antiretroviral medication, and who (c) have an HIV RNA viral load

greater than 200 copies/ml in the previous 6 months. Excluded participants are those who (a) are unable to communicate in English (generally <5% of patients), (b) participated in focus groups or prepilot interviews during the intervention development phase, (c) are planning to move outside of New York City in the ensuing 6 months, or (d) demonstrate an impairment that limits their ability to provide informed consent. To identify eligible participants, clinical staff produced a list of patients with detectable viral load in the past 6 months. This list is generated as necessary during the study recruitment phase. Research staff work closely with clinical staff to identify scheduled and walk-in patients during periods of recruitment based on this list, and conduct an in-person screen to ascertain other study inclusion criteria. Research staff describe the study to eligible participants who express interest and obtain written informed consent.

Intervention implementation.—Each APPEAL session lasts for approximately 1 hr, and is designed for administration by personnel with health education experience. Sessions are spaced at 1-month intervals. For each attended session, participants are provided round-trip transportation fare and receive a study-related gift (e.g., a certificate outlining top identified participant strengths with the participant name listed, a mug, tote bag, or other small item with the project logo on it), of a value not exceeding $10.00. In addition, participants consent to weekly text messages from a predefined menu. In total, there are seven standardized text messages, beginning the week after Session 1 and ending 6 weeks after Session 3. Text messages contain no identifying information, and no information about the participant's health. The one-way text messages are sent through a HIPAA-compliant data management system that is connected to the participant study ID number. Sample text messages include, "Using your strengths can improve your mood and help reduce stress. What can you do this week to use your character strengths?" and "Looking forward to seeing you soon and learning more about how you have used your strengths!"

Standard of care.—Both the experimental and control groups receive the standard of care at the clinical care site throughout study participation. A PharmD at the clinic provides adherence education to patients as indicated, advises on drug/drug interactions, and assesses for adverse medication effects. Behavioral health services for comorbid conditions are available, and all staff are trained in motivational interviewing techniques. For some patients, patient navigators provide patient reminders about appointments, accompany patients to appointments, and may also provide directly observed therapy.

Data collection.—Study data are generated from surveys, electronic medical and laboratory records, and from medication monitoring devices, and linked by a nonidentifiable unique study identification number. Survey data are administered through an audio computer-assisted structured interview (ACASI) with a privacy screen attached to the tablet or computer; details of survey measures are included in Table 2. Participants are remunerated $30 for completion of the ACASI baseline interview and $40 for completion of each follow-up ACASI interview; public transport fares are provided for interviews. Interventionists do not collect evaluation data, and all intervention and evaluation activities are conducted in a private space.

Adherence.: The outcome of adherence is assessed in the ACASI with three self-report items: (a) how often medication was taken over the past few days (100%, 95%-99% 75%-94%, <75%), (b) how well a participant did at taking medication in the way prescribed (very poor, poor, fair, good, very good, excellent), and (c) the number of days in the previous 30 days that the participant missed at least one dose of medication. Adherence is also monitored with the Wisepill pillbox, which provides real-time information on medication adherence, assuming that opening the box equates to medication-taking behavior. Wisepill transmits data via a cellular network. The Wisepill has been shown to be an acceptable and feasible approach to objective adherence measurement (Stringer et al., 2019).

Positive affect.: Two common measures of positive affect include the Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988) and the Modified Differential Emotions Scale (mDES: Fredrickson, Tugade, Waugh, & Larkin, 2003). The PANAS is included, given that it is one of the most widely used measures of positive affect in intervention studies to date. The mDES is also included, in that it allows for examination of a broader range of emotions than the PANAS, and may be useful for further describing the intervention in terms of the types and degree of emotional experience resulting from intervention exposure.

Additional measures.: A number of other variables are included that may influence the relationship between APPEAL exposure, changes in positive affect, and changes in adherence. Although the randomized feasibility trial is not powered to detect the impact of these variables, they are included in order to describe changes in hypothesized relationships and to test the psychometric properties of variables in preparation for a confirmatory trial. In line with this reasoning, we include measures of stressful life events, which would be used to test the buffering relationship of positive affect, measures of perceived stress and coping, in relation to their proposed mediating relationship between positive affect and health behavior, and measures that may moderate the impact of APPEAL exposure on positive affect changes, including depression, age, and substance use. Finally, we include measures to examine competing potential targets of the APPEAL intervention, including reductions in negative affect and increases in optimism.

All participants also consent to medical chart abstraction. Data elements collected from medical charts include month and year of birth, date of first visit to the clinic, and presence of chronic comorbid conditions, including hepatitis C, diabetes, and hypertension. In addition, date of visit, CD4 count, HIV RNA viral load and laboratory testing date closest to the study visit date are abstracted each time a patient presents for HIV primary care. Receipt of patient navigation, behavioral health services, and other adherence supports offered at the clinical setting are detailed in the patient's medical chart and are abstracted for each study participant.

Allocation and blinding.—Randomization was conducted by a study data analyst using a computerized number generator with 1:1 allocation. Assignments were placed in secured opaque envelopes, numbered sequentially, and are maintained securely by the project director. When enrolling, research staff select the next sequential envelope, to be opened after the baseline evaluation assessment is complete. The allocation sequence will be

released upon completion of data analysis. Due to the nature of the intervention, blinding is only possible at the level of the statistical analyst. An unlabeled code denotes study group membership in the dataset, which will be revealed following final analysis of the dataset.

Research ethics approval.—All study procedures have been approved by the institutional review board (IRB) at the study host institution.

Safety monitoring.—Potential harms from study treatments experienced by participants are monitored throughout the study. Adverse events and serious adverse events are recorded and reported regardless of whether it is likely that they are the result of study procedures, and are reported to the NIH and the local IRB in accordance with a prespecified and NIH-approved data and safety monitoring plan.

Confidentiality.—All research activities are conducted in as private a setting as possible. The project director maintains a master list of study participants that includes the participant's name, enrollment date, clinical medical record number, and a four-digit study identification code. This list is kept in a password-protected electronic file accessible only to study staff. A hardcopy backup of the master list is filed in a locked cabinet separate from study source data. Data are further protected by a Certificate of Confidentiality issued by the NIH.

Data management.—All project staff and investigators maintain certification in good clinical practice, human subjects protections, and health insurance portability and accountability act compliance training. All study investigators also complete *Conflict of Interest* (COI) and research misconduct training and report COIs annually and as part of IRB annual progress reports. Only the principal investigator and project director have access to a master list connecting identifying information to study ID numbers. The master list of study participants will be destroyed within 18 months of completion of study funding. Other study records will be retained for a minimum of 3 years from the date of completion of study funding. All study data will be de-identified prior to data sharing. De-identified data will be retained for analysis until the materials are no longer valuable for research purposes.

Data analytic strategy.—The primary study objective is to assess feasibility of the APPEAL intervention and evaluation methods in preparation for a confirmatory trial. Feasibility will be assessed through description of the following: (a) study eligibility rates among screened contacts, (b) study recruitment rates among eligible screened contacts, (c) consent rates among those who are eligible, (d) percent consented who are randomized, (e) number of intervention sessions completed among those randomly assigned to APPEAL, (f) proportion of randomized participants in each group who complete baseline, 3-month, and 6-month assessments, and (g) completeness of data collection efforts for ACASI, chart review data, and Wisepill adherence tracking. Feasibility of the Wisepill will also be assessed by monitoring gaps in data over the observation period. Intervention acceptability will include monitoring of the percentage of those assigned to the APPEAL intervention group who complete one, two, or all three sessions or who do not present for any intervention sessions. Continuous variables will be summarized using the descriptive statistics *N*, *N* missing, mean, *SD*, median, minimum and maximum, and categorical

variables will be summarized using frequency, percent, and missing values. Measurement properties for self-report scales will be assessed (range, mean, standard deviation, Cronbach's alpha). Unit and item nonresponse will be tracked to identify approaches to prevent nonresponse error, and to develop methods for handling missing data to analytically account for nonresponse. Information gained from these assessments will be utilized to identify issues that may arise in a larger, fully powered trial. We will assess whether the methods used to recruit, engage, and retain participants should be translated to a subsequent powered trial, or whether refinements are required prior to implementation.

To gain further insights regarding the suitability of our program in the priority population, we will observe whether exposure to the intervention is associated with expected directional shifts in positive affect utilizing mixed effect models with the experimental group as the between-subjects factor and time as the within-subject factor, with group by time interactions as the effect of interest; this will provide estimates of the intervention effect and the variance of the effect. A sample size of 40 per group was selected as an adequate number by which to gain key insights into program feasibility in preparation for a fully powered experimental trial, and to detect changes in the mechanistic target of positive affect months. In order to power for the difference in baseline and follow-up positive affect, we utilized effect sizes reported in a previous positive affect intervention (Taylor, Lyubomirsky, & Stein, 2017). We employed a two-sided, two-sample *t* test assuming unequal variance to detect the differences between pre- and posttest mDES scores utilizing mean (standard deviation) data on control difference reported in that study: −2.67 (3.20) and intervention differences: −8.75 (8.04) at 0.05 level of significance. Utilizing $n = 32$ per group (assuming 80% loss to follow up), we anticipate greater than 95% power to detect this difference.

If we do not have evidence for statistically significant increases in positive affect, then it may be the case that the APPEAL intervention is not powerful enough in its current form to impact our proposed mechanism of change, and would need further refinement and testing. Therefore, our ability to detect a difference in positive affect will inform whether we will move forward to test the intervention in its current form in the context of a fully randomized trial.

Open science plans.—In order to enhance transparency and reproducibility of study procedures and findings, an open science approach will be utilized. First, in compliance with the NIH final rule and as a mechanism to reduce publication bias, the project was preregistered at ClinicalTrials.gov prior to study recruitment (Identifier: NCT04035759). Any protocol modifications will be reported to the IRB, updated on the informed consent form, and posted to ClinicalTrials.gov (Protocol V7.0, 2.21.20). In addition, data will be de-identified, including removal of personal health information, and the resulting raw data and accompanying codebook will be deposited to the Open Science Framework (OSF link: http://osf.io/s7ve9) following publication of the results. This data can then be used by other scientists for replication purposes and for inclusion in meta-analyses and other research syntheses. Findings from the study will also be shared through traditional outlets such as open access articles and conference presentations, and will serve as pilot data if the findings support testing of APPEAL in the context of a confirmatory trial.

Discussion

Adherence to HIV medication is an ongoing problem, for which there is a need for continued innovation into effective and acceptable interventions. New developments for ensuring adequate ART exposure, such as injectable, long-acting formulations, are promising, but there will remain a need for adherence support programs for those who are not eligible or who refuse these modes of delivery.

Promotion of positive affect may be a useful approach for enhancing medication adherence, in that it has been shown to be associated with HIV RNA viral control and survival. The APPEAL intervention seeks to integrate and adapt several evidence-informed approaches to emotional regulation. The regulation of positive affect may, in turn, function to reduce overall perceived stress, promote adaptive coping, reduce the impact of stressful events on maladaptive behavior, and thereby increase ART adherence.

The APPEAL intervention does not address the many barriers to adherence that exist in the social environment, including but not limited to transportation barriers, “stockouts” of medication, HIV-related stigma, quality of the patient-provider relationship, and food and housing insecurity (Aidala et al., 2016; Engler, Toupin, Vicente, Ahmed, & Lebouché, 2019; Shubber et al., 2016; Singer, Weiser, & McCoy, 2015). However, if APPEAL is successful, it may serve as a useful addition to multicomponent interventions to improve and sustain adherence. Should the proposed study demonstrate feasibility, acceptability, and short-term changes in positive affect, next steps would involve testing in the context of a fully powered, randomized controlled trial.

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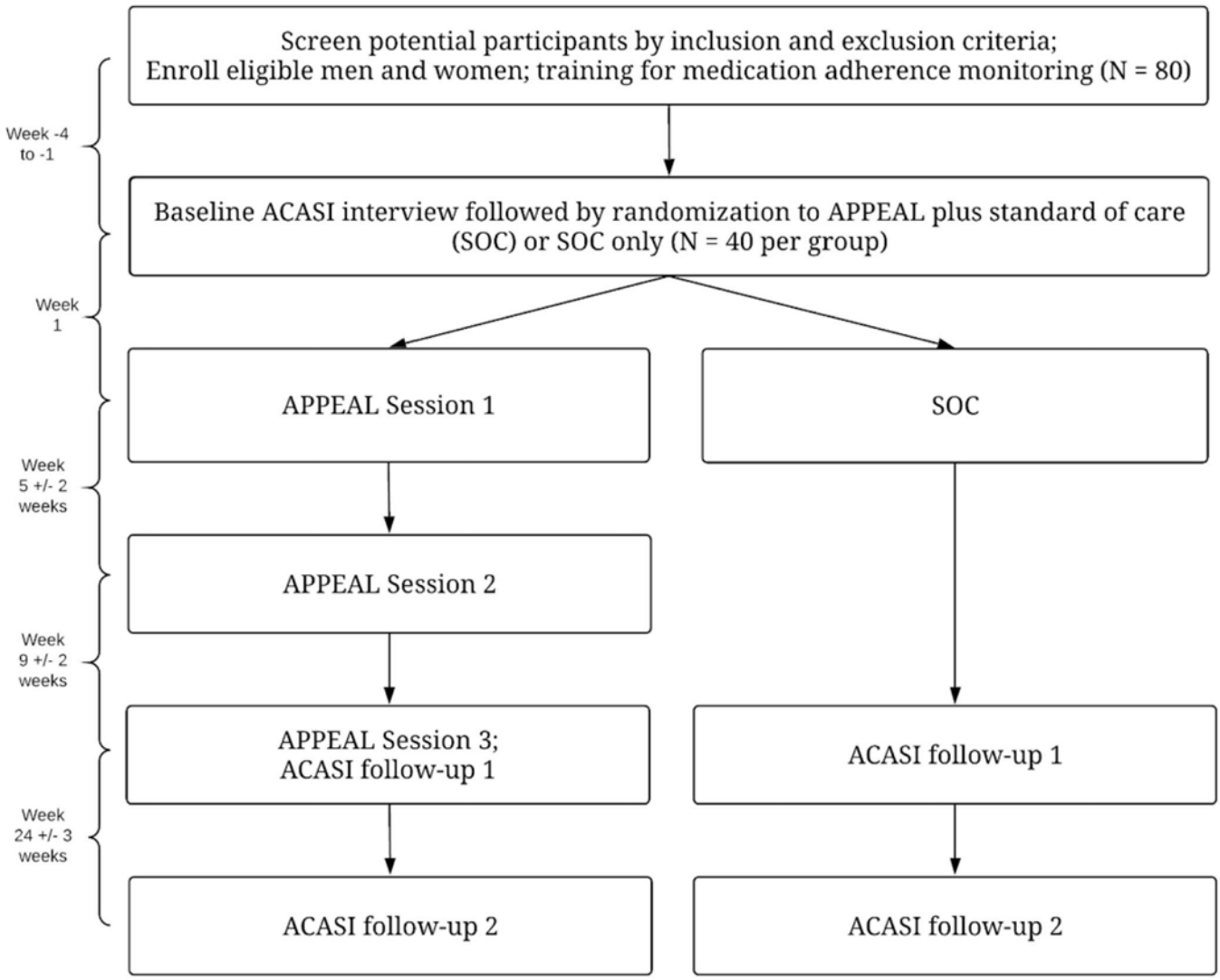

Figure 1.

Participant flow diagram: Positive Affect, Promoting Positive Engagement, and Adherence for Life (APPEAL) randomized feasibility trial. ACASI = audio computer-assisted structured interview.

Table 1

Project APPEAL Intervention Session Summary and Objectives

Session	Session objectives	Education materials
1	Participant will: Name 2–3 personal character strengths Describe a personal example of character strength utilization for each identified strength Identify 1–2 short-term, achievable behavioral goals for an activity that engages strength of character	Participants receive a written summary of middle character strengths, along with a goal sheet describing behavioral goals. Participants receive a small gift with project logo.
2	Participant will: Reflect on progress toward character strength goals, review thoughts and emotions regarding progress Refine goals based on feedback Identify 1–2 longer-term life goals Discuss emotional, social, or behavioral steps needed to achieve goal Describe 2–3 ways that character strengths can support longer-term goals Identify a daily activity into which medication taking can be integrated Identify a daily activity into which medication taking can be integrated	Participants receive a written summary of longer term goals, and receive a personalized character strengths summary.
3	Participant will: Reflect on progress toward character strength goals, review thoughts and emotions regarding progress Refine goals based on feedback Describe changes in habits of medication taking Identify 1–2 strategies for continuing practice of behaviors that engage strengths of character Gain skills in attentional deployment of positive events and emotions	Participants receive a written summary of attentional deployment goals, and a tip sheet of “savor strategies.” Participants receive a small gift with project logo.

Note. APPEAL = Positive Affect, Promoting Positive Engagement, and Adherence for Life.

Table 2

Project APPEAL Self-Report Measures

Construct measured	Measurement	Measurement description
Positive affect	Positive and Negative affect scale: PANAS[a]	This 20-item measure utilizes five response options for each question, assessed over the past week, and ranging in value from 1 to 5 and includes two 10-item subscales: Positive Affect and Negative Affect. Positive Affect and Negative Affect items are summed separately, with each subscale ranging from 10 to 50. Higher scores for the Positive Affect subscale indicate higher levels of positive affect and lower scores for Negative Affect items indicate lower levels of negative affect.
Positive affect	Modified differential emotions scale: mDES[b]	This 20-item measure utilizes five response options for each question, ranging in value from 0 to 4 and includes two 10-item subscales: Positive Affect and Negative Affect. Positive Affect and Negative Affect items are summed separately, and each is divided by 10, with each subscale ranging from 0 to 4. Higher scores for each subscale indicate greater frequency of experiencing positive or negative emotions.
Perceived stress	Perceived stress scale: PSS4[c]	This four-item measure utilizes five response options for each question, ranging from 0 to 4. The resulting summed scale can range from 0 to 16, with higher scores indicating greater stress.
Coping	Coping strategies inventory, Short form: CSISF[d]	This 16-item measure utilizes five response options for each question, ranging from 1 to 5, and items are grouped into four 4-item subscales (Problem-Focused Engagement, Problem-Focused Disengagement, Emotion-Focused Engagement, Emotion-Focused Disengagement). Subscale items are summed, resulting in a range from 4 to 20 each. Higher subscale scores indicate greater frequency of use of that particular coping strategy.
Life events	Crisis in family systems: CRYSIS[e]	An adapted version of the CRISYS checklist is being utilized, based on formative feedback on the scale. The adapted measure lists 34 events, with a 0 indicating no experience and a 1 indicating an experience. The checklist can range from 0 to 34 possible events.
Optimism	Revised life orientation test: LOT-R[f]	This six-item measure utilizes five response options per question, ranging from 0 to 4. Items are summed on a scale of 0 to 24. Higher scores indicate greater optimism.
Depression symptoms	Patient health questionnaire-8 item: PHQ8[g]	This eight-item measure utilizes four response options ranging from 0 to 3. Items are summed with a resulting scale range of 0 to 24. Higher scores suggest greater risk for depression.
Drug abuse	Drug abuse screening test: DAST 10[h]	The DAST 10 includes 10 items, each response with a 0 or 1. Items are summed, with a range of responses from 0 to 10. Higher scores indicate greater negative consequences of drug abuse.
Alcohol use disorder	Alcohol use disorders identification test—Concise: AUDIT-C	The AUDIT-C is a three-item measure. Each item has four response options ranging from 0 to 4, and items are summed with a resulting range from 0 to 12. In men, a score of 4 or more is considered positive for an alcohol use disorder; in women, a score of 3 or more is considered positive.

Note. APPEAL = Positive Affect, Promoting Positive Engagement, and Adherence for Life.

[a]Crawford and Henry (2004); Krijthe et al. (2011); Watson et al. (1988).

[b]Fredrickson et al. (2003); Moskowitz et al. (2012).

[c]Cohen and Williamson (1988).

[d]Carver (1997).

[e]Shalowitz, Berry, Rasinski, and Dannhausen-Brun (1998).

[f]Glaesmer et al. (2012).

[g] Bengtson et al. (2016); Manea, Gilbody, and McMillan (2012).

[h] Maisto, Carey, Carey, Gordon, and Gleason (2000).

[i] Bradley et al. (2007).