Adapting the Unified Protocol to Facilitate Activity in Older Adults

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Study Protocol

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Older adults experiencing emotional distress also report reduced engagement in daily activities. Up to 25% of older adults (age 65+) report symptoms of emotional (e.g., anxiety, depressive) disorders which negatively impact their ability to engage in daily activities**,** and overall physical and mental health. Cognitive-behavioral therapies (CBT) are well-established treatments for these problems. They can increase engagement in daily activities by teaching patients skills to manage the emotional distress that interferes with daily activities. However, the demand for mental health services among older adults is rising and existing treatments are insufficient. Existing therapies are typically 12-16 sessions, yet data suggest patients attend an average of five sessions. Brief treatments are more feasible for older adults to complete. Thus, it is crucial to develop brief, evidence-based interventions that can be implemented in community settings for older adults experiencing emotional distress to increase their activity. Because it can take decades to develop a novel treatment, a strategic approach is to adapt an existing evidence-based treatment for this population.

Table 1. UP-5 Session-by-Session Content

Session	Skill Targets	Relevance to older adults
1	Motivation and Psychoeducation about Emotions	Build motivation to increase activity, reduce perception that emotions should be avoided.
2	Breaking Down Emotions and Mindfulness	Observe and describe emotional experiences, mindfulness of activities
3	Cognitive Flexibility	Generate flexible interpretations of situations (e.g., ability to be active)
4	Countering Emotion-Driven Behaviors	Reduce avoidance of activities
5	Exposure and Relapse Prevention	Plan for continued skill use

The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP) is an optimal intervention to adapt for older adults to increase their engagement in daily activities. The UP is an evidence-based CBT. As a transdiagnostic treatment, it can be applied across diagnostic categories to address a wide range of presenting problems. The UP contains five core skills for increasing activity engagement (Table 1).

Transdiagnostic treatments, like the UP, are advantageous for dissemination and implementation because they are adaptable and reduce clinician training burden. The UP has demonstrated adaptability for underserved patient populations and has been successfully abbreviated to meet the needs of unique patient populations. Further, it has been successfully delivered by clinicians without previous CBT experience, increasing its potential for dissemination. A five-session version of this treatment (UP-5) was developed that includes the core skills (Table 1) and showed acceptability in adults with acute suicide risk. The **primary aim** of this study was to adapt the UP-

5 for use with older adults reporting emotional distress to increase their daily activity. Because research indicates the proportion of older adults who access and receive evidence-based treatments is low, we propose developing therapist-delivered and self-guided versions of the treatment. Self-guided interventions may be ideal for older adults because they do not compete with other healthcare demands, and they have potential for significant public health impact for older adults with low access to services. The **secondary aim** of this study was to compare the self-guided and therapist-delivered versions to identify the minimum level of intervention needed to increase activity in older adults.

Recruitment. Patients were recruited from Duke MyChart, ResearchMatch.org, and referrals from Duke clinics.

Screening. Eligibility was determined before consent. Patients interested in completing the study were directed to an online screen in REDCap, which provided more information about the research and asked potential participants to complete self-report questionnaires. Those meeting initial eligibility were contacted for a phone screen (also done as an interview in REDCap). After online/phone screen, patients were eligible if they (1) were age 65+, (2) reported moderate or higher emotional distress (T-score ≥ 60) on the Patient-Reported Outcomes Measurement Information System (PROMIS) emotional distress anxiety OR depression forms, which had been used with older adults, (3) reported reduced engagement in instrumental daily activities indicated by an average score below “8” on the Patient Specific Functional Scale (PSFS), and (4) were willing to engage in telehealth. Patients meeting these criteria by phone screen completion were scheduled for a first study visit.

Consent. Patients completed an electronic consent form in REDCap and pre-treatment questionnaires during the first study visit. Participants were deemed eligible based on the screening questions they completed on the REDCap online screen & phone screen. Patients also completed pre-treatment measures at this consent visit: Demographic Data Survey, PSFS, PROMIS-anxiety, PROMIS-depression, PROMIS-Physical Function (PF) and the Credibility and Expectancy Questionnaire (CEQ: Devilly & Borkovec, 2000). We also included the Cognitive Flexibility Scale (Martin & Rubin, 1995, CFS), Brief Experiential Avoidance Questionnaire (Gamez, et.al, 2013, BEAQ), and Southampton Mindfulness Questionnaire (Chadwick, et al., 2008, SMQ) at intake and the 1-week post-treatment to explore changes from pre- to post-intervention. Participants who attended this first remote visit were then mailed an Accusplit Pedometer to begin using 1 week before their first therapy session, to track the number of daily steps. They were emailed an electronic Word document of a weekly table for tracking steps. For those in Phase 2, they were mailed the pedometer as well as a measuring tape and electrical tape.

Phase 1. The purpose of Phase 1 was to adapt self-guided and therapist-delivered versions of the UP from the existing UP-5 using stakeholder feedback. We also examined physical function and physical activity as independent variables that may serve as moderators and as outcomes. We used a successive cohort design and delivered the UP-5 to two cohorts of two patients. Treatment was provided via telehealth by the Roybal Center interventionist, who has expertise delivering evidence-based psychological therapies to older adults. All sessions were audio or video recorded to be rated for therapist adherence. Patients were asked for consent to record.

Those who did not consent to recording were still allowed to participate in the study. During each treatment session, participants reported the number of steps they took daily over the past week to the study interventionist. Starting at session 2, the interventionist completed a Clinical Global Impressions-Improvement (CGI-I) rating and documented how much homework the participant completed since the last session (0-100%). After the fifth session, participants were reminded to track their number of steps over the next week. One week later, patients provided feedback about the treatment in exit interviews. Interviews inquired about modifications needed to develop the self-guided UP-5 (e.g., automatic prompts) and whether/how to include a support person (e.g., caregiver) in treatment as well as treatment preferences and length of treatment. Patients also completed post-treatment measures at this 1-week f/u visit: PSFS, PROMIS-anxiety, PROMIS-depression, PROMIS-PF, CFS, BEAQ, SMQ, and the Credibility and Expectancy of Improvement Scale (CEIS). They also provided an electronic form for the interventionist to enter the number of steps they had taken over the past week. After each cohort, the UP-5 was adapted to reflect the stakeholder feedback, and the revised treatment was delivered to the subsequent cohort. At the end of Phase 1 we developed a self-guided version of the UP-5.

Phase 2. Phase 2 was a pilot randomized controlled trial comparing the adapted self-guided and therapist-delivered versions of the UP-5. As in Phase 1, participants completed the PROMIS_PF at both intake and post-treatment follow-up to assess physical function. Patients were randomized to complete one of these two treatments using the randomization module in REDCap. Each arm had eight patients. Therapist-delivered treatment was provided via telehealth. All sessions were audio or video recorded to be rated for therapist adherence. Patients were asked for consent to record. Those who did not consent to recording were still allowed to participate in the study.

Whether randomized to online or therapist-delivered treatment, all participants in Phase 2 underwent the Virtual Short Physical Performance Battery (SPPB) before the first online or therapist treatment session and again at 1 week follow-up after the last session. The Short Physical Performance Battery (SPPB) is a performance-based test assessing older adults' mobility by measuring balance, strength, and speed. In this study, we only used the gait speed portion. Performance in this category was scored on a scale of 0 to 4. The trained study team member performed the gait speed test virtually at intake or the front end of the 1st therapy/online session. Participants also reported the number of steps they took daily over the past week before their first session. After consenting and before the virtual SPPB, all participants were mailed a pedometer and materials to use for the virtual SPPB (measuring tape and black tape) and for those participants in the self-guided therapy arm, they received a copy of the self-guided manual (uploaded in protocol documents). During each therapist-delivered treatment session, starting at session 2, the interventionist completed a Clinical Global Impressions-Improvement (CGI-I) rating. It documented how much homework they thought the participant completed since the last session (0-100%). Outcomes were evaluated pre/post treatment and included measures of daily activity (PSFS), depression (PROMIS-depression), and anxiety (PROMIS-anxiety), CFS, BEAQ, and SMQ, and PROMIS-SF. Treatment satisfaction (Client-Satisfaction Questionnaire-8) was evaluated post-treatment, the Credibility and Expectancy of Improvement Scale (CEIS) was assessed, and a semi-structured exit interview as in Phase 1. The PI provided weekly supervision on the therapy sessions and an independent coder rated 10% of completed sessions for adherence. Post-Treatment occurred one week after the final therapy or self-guided online

session, and participants were reminded to track their number of steps in the 1 week after the final session. They reported this information to the interventionist/trained study team member at the 1-week f/u where they completed the gait speed test virtually one more time & the semi-structured exit Interview. The rest of the self-report, including the noted outcomes, were also completed.

Participants were allowed to start treatment up to 1 month after the time of consent. For the five sessions of UP-5 treatment, there was a minimum of 3 days between therapy sessions and all participants completed the five sessions within 2 months (~8 weeks). There was an expected short delay from the consent visit to the first therapist-delivered or online platform session to allow for the pedometer to arrive at the participant and be able to track steps for the 1 week leading up to their first therapy visit. Participants in Phase 1 were in the study approximately 7-12 weeks. In phase 2, participants were in the study for approximately 12-17 weeks.

One month F/u (post the 1 week post-treatment visit- *approximately 5 weeks after the final online/therapy delivered session*): For Phase 2 participants only, to measure effects over a more extended period, participants again received the following outcome measures to complete via REDCap CFS, CSQ-8, CEIS, BEAQ, and SMQ, (PSFS), depression (PROMIS-depression), and anxiety (PROMIS-anxiety and PROMIS-SF. They were sent an email reminder via REDCap to begin tracking their steps for 1 week leading up to the 1-month f/u final visit. Participants were paid $20 for completing this 1-month f/u.

Of note, i*f participants used assisted mobility devices and were enrolled in Phase 1 or 2, they could still participate in the study. They were not required to do the gait speed and/or pedometer assessment. This was not considered a deviation in the study if not completed.*

Also, if the participant started the virtual SPPB mobility assessment and felt uneasy, uncomfortable, unsteady, they were allowed to stop the SPPB at any time and still be allowed to continue in the study. If the participant refused to try the SPPB or complete it at the 1-week follow-up, they were still allowed to be in the study, and again, this was not considered a deviation, but it was noted in their REDCap record.

Remote Self-Guided Therapy Only: An orientation video with instructions and videos for UP sessions 1-5 (corresponding to the sessions in the self-guided manual) was posted on the PI's Lab YouTube Channel, Duke CHANT, and embedded into REDCap. Comments were disabled on YouTube videos, and participants could not "like" the videos or identify themselves or others. Only the participants assigned to the self-guided arm were directed to these video links, which were not public.

Study Intervention: The study intervention is a 5-session version of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2018). Below is a brief description of the sessions.

Session 1: Motivation and psychoeducation about the adaptive nature of emotions - focuses on setting goals and increasing motivation for treatment, provides psychoeducation about the adaptive nature of emotional experiences. In this session the patient and therapist will collaborate to set specific, measurable goals for treatment (e.g., go on one walk per day). Next, the patient

and therapist will discuss the pros/cons of engaging in therapy versus not pursuing treatment. This activity facilitates motivation for treatment. Finally, the therapist and patient will discuss the reason humans have emotions as well as the purpose of specific emotions such as anxiety and sadness.

Session 2: Learning to observe and describe emotional experiences - teaches mindfulness skills and promotes non-judgmental, present-focused awareness of experiences and how to break down experiences into three components (thoughts, physical feelings, behaviors). In this session, the patient and therapist will discuss the rationale for taking a non-judgmental, present-focused approach to experiencing emotions. As part of this discussion, the therapist will teach the patient to break down their experiences into thoughts, physical sensations, and behaviors to understand their experience in more detail.

Session 3: Cognitive flexibility - helps develop balanced thoughts through cognitive restructuring techniques. The patient and therapist will discuss the reciprocal relationship between thoughts and emotions in this session. The therapist will introduce the idea of automatic thoughts and thinking traps (i.e., habitual thought patterns that tend to be overly negative) and help the patient identify relevant thinking traps. Next, the therapist will introduce the idea of cognitive flexibility and work with the patient to develop multiple interpretations of a given situation. This skill is analogous to cognitive restructuring in cognitive-behavioral therapy.

Session 4: Countering emotion-driven behaviors helps patients engage in effective behaviors when experiencing strong emotions. In this session, the therapist and patient discuss how behavior can influence the experience of emotions. The therapist helps the patient identify ineffective behaviors and then presents the idea of alternative actions. Alternative actions are behaviors that can help the patient manage their emotions in a way that is consistent with their long-term goals.

Session 5: Exposure and relapse prevention - reduces avoidance of emotion provoking stimuli by teaching patients to approach situations they would usually avoid and implement the skills learned in treatment in these situations to help them cope, promotes continued practice of skills learned in treatment. This session focuses on encouraging patients to approach situations they would usually avoid and use their coping skills. The therapist will help the patient brainstorm situations to approach and discuss how to use skills. Finally, the therapist and patient will review the skills learned in treatment and plan how the patient will continue to practice those skills once the treatment is over.