

## **Protocol**

*A Comparison of Cognitive Processing Therapy (CPT) versus Accelerated  
Resolution Therapy (ART) versus Wait List (WL)  
(CPT vs. ART vs. WL)*

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## **I. Study Purpose**

The purpose of this research study is to compare two psychotherapy treatments for the symptoms of Posttraumatic Stress Disorder (PTSD) with a no therapy, wait-list control condition. The two treatments are Cognitive Processing Therapy (CPT) and Accelerated Resolution Therapy (ART). CPT looks at the impact the traumatic event has had on your life and helps you to examine and change unhelpful thoughts and feelings related to the event, yourself, others and the world. CPT is a gold-standard treatment for PTSD. Prior randomized control trials of CPT have demonstrated efficacy of the intervention in reducing PTSD symptom severity with samples of victims of childhood sexual abuse, interpersonal violence, and military-related trauma (e.g., Chard, 2005; Monson et al., 2006; Resick et al., 2008). CPT is widely disseminated within the Veterans Affairs Healthcare System (VA), where CPT is one of two empirically-supported PTSD-focused treatments offered to veterans (Chard, Ricksecker, Healy, Karlin, & Resick, 2012), and across community treatment and academic medical centers.

Accelerated Resolution Therapy (ART) also involves processing thoughts and feelings related to the event, but does this in a different way than CPT by relying more on visualization or imagination rather than talking. There has only been one randomized clinical trial of ART for the treatment of PTSD (Kip et al., 2013), and the effectiveness of ART in comparison to a gold-standard PTSD psychotherapy is unknown. In order to prove efficacy, ART must to be compared to a gold standard treatment for PTSD, such as CPT.

The purpose of this research study is to compare the effectiveness of these two therapies on PTSD symptoms, along with related symptoms such as depression, sleep and physical health to see which treatment is better. The study will also try to determine if there are people who respond better to one treatment or the other.

## **II. Specific Objectives**

This study is designed to provide clinicians, researchers, administrators, and patients with information on the comparative effectiveness of PTSD psychotherapy treatments.

### **A. Primary Objective**

The primary objective is to compare the effectiveness of Cognitive Processing Therapy and Accelerated Resolution Therapy in reducing PTSD symptom severity for Veteran and civilian patients with PTSD.

### **B. Secondary Objective**

The secondary objective is to compare the effectiveness of Cognitive Processing Therapy and Accelerated Resolution Therapy in reducing depression symptom severity.

### **C. Tertiary Objective**

The tertiary objective is to examine whether treatment effectiveness is reduced when patient preference for treatment is incongruent with their random assignment.

### **D. Exploratory Analyses**

Exploratory analyses will be performed to examine whether demographic (e.g., sex, age, Veteran/Non-Veteran status) and other clinically-relevant variables (e.g., sleep quality, anger, pain, health care utilization) predict differential response and/or drop-out across treatment condition.

## **III. Study Design**

This study will examine the effectiveness of Cognitive Processing Therapy (CPT) as compared to Accelerated Resolution Therapy (ART) and a Wait list (WL) control using a Randomized, Cross-Over Design with blinded assessment. 280 participants will be randomly assigned to receive ART, CPT or WL condition. Upon completion of the WL condition after 7 weeks, participants will be re-randomized to ART or CPT.

The primary outcome is improvement in PTSD symptom severity as measured by change on the Clinician-Administered PTSD Scale for DSM-IV or DSM-5 (CAPS-IV/ CAPS-5) after treatment. This primary outcome measure will be administered by post-doctoral fellows in psychology who will remain blinded to treatment condition. The

CAPS-IV and CAPS-5 will be administered at pre- and post-treatment, and 3-month and 1-year follow-up visits.

## **A. Study Population**

Participants will be 280 male and female Veterans and civilians who meet criteria for PTSD, or subthreshold PTSD, due to any Criterion A traumatic event. Subthreshold PTSD occurs when a patient has a Criterion A traumatic event, and endorses symptoms in each of the PTSD Diagnostic Criteria (B-E), but falls below the number and/or severity of total Criterion requirements to meet criteria for a PTSD diagnosis. Inclusion and exclusion criteria and recruitment are described in Section IV.

### **1. Rationale for Inclusion of Non-Veteran participants**

Civilians will be included in this study as they have different Criterion A traumatic events (e.g., non-combat). It is imperative to the primary study objective to assess the comparative effectiveness of CPT and ART across a variety of trauma(s).

## **B. Study Treatment Conditions**

### **1. Treatment Conditions**

Cognitive Processing Therapy (CPT). CPT looks at the impact the traumatic event has had on your life and helps you to examine and change unhelpful thoughts and feelings related to the event, yourself, others and the world. CPT will be conducted in 5-15, 60 minute sessions held once or twice a week. CPT will be implemented using the Cognitive-Only version, excluding the trauma account.

Acceleration Resolution Therapy (ART). ART, like CPT also involves processing thoughts and feelings related to the event, but does this in a different way relying more on visualization or imagination rather than talking. ART will be conducted in 5-15, 60 minute sessions held once or twice a week.

Wait List (WL). WL will include a 7 week minimal attention control period with weekly check-in calls (see Appendix A for telephone script) to ensure that the participant has

not experienced any significant worsening in their symptoms that might require interventions, (e.g. suicidal intent).

## **2. Rationale for Wait List Condition**

The 7 week timeline for the Wait List condition is commensurate with the average length of psychotherapy. Many of the clinics within the Department of Veterans Affairs have a wait time to start psychotherapy. In the national Cooperative Studies Program research study CSP-591, VAMC sites such as Cincinnati, have averaged 38 days from initial participant screening to entry into treatment. Furthermore, patients with PTSD have symptoms of avoidance and may prefer not to start therapy immediately.

## **3. Procedure for Determining the Number of Sessions for CPT and ART**

**Early completers:** After a minimum of five sessions, individuals with two successive sessions (i.e., sessions 4 and 5) with a PCL-5 of 18 or under and with agreement of both therapist and participant, will be considered early completers and will be given their post-test assessment. They will be reassessed at 3-months and 1 year follow ups from their last treatment session.

**Drop Outs:** Participants in any of the three conditions (CPT, ART, or WL) who drop out of treatment will be asked to remain in the study for participation in the assessment portion of the study only. Treatment discontinuation will be based on a discussion between the participant, the study therapist, and the research team to determine the best clinical care plan for ongoing treatment. Participants will be discontinued from treatment if they show substantial worsening of PTSD, other symptoms, or functioning requiring lengthy hospitalization if the worsening is due to treatment. If participants decide to discontinue treatment early, they will be asked by their clinician for a reason and if they consent to be contacted for post-treatment assessments. If they agree to be contacted, study staff will contact the participant to schedule their post-treatment assessment immediately following their last treatment session. Participants will also be contacted to participate in the 3 and 12 month follow up assessments. Participants will be reminded of the voluntary nature of this study and their option to withdraw participation at any time.

### C. Study Sites

The study will be conducted at the Cincinnati VA Medical Center, Trauma Recovery Center, in Fort Thomas, Kentucky, and at the UC Health Stress Center located in Cincinnati, Ohio.

<b>Table 1.0 Participant Flow Through the Randomized Clinical Trial</b>		
<b>Study Phase (timeline)</b>	<b>Site</b>	<b>Event</b>
Enrollment (2-3 weeks)	VA only	Telephone Screening Phase: Inclusion and Exclusion Criteria assessed & Site Determination for participant*
	VA or UC	Informed Consent, Pre-Treatment Assessment, & Randomization Assigned by sealed envelope opened by participant after site visit
	VA or UC	Phone scheduling of initial session with therapist
Waitlist (if assigned)	VA or UC	Waitlist Condition participants will wait 7 weeks, will receive weekly Phone Check-In calls by study staff (see Appendix A), then will be randomized to CPT or ART
Treatment (5-15 weekly or biweekly sessions)	VA or UC	Treatment begins (session 1)
	VA or UC	Mid-Treatment Assessment (session 2 – 7)
	VA or UC	Treatment Ends (session 5 – 15)
Post-Treatment (1 year)	VA or UC	Post-treatment Assessment
	VA or UC	3-month follow-up Assessment
	VA or UC	1-year follow-up Assessment

\* Prior to the phone screen, participants will be asked to identify how they learned about the study and which site (UC or VA) they were referred from. Veteran participants may be seen at the Cincinnati VAMC or the UC Health Stress Center depending on their associated site. All civilian participants will be seen at the UC Health Stress Center.

### D. Outcome Measures



The primary outcome is improvement in PTSD symptom severity as measured by clinically significant change on the Clinician-Administered PTSD Scale for DSM-IV or DSM-5 (CAPS-IV/CAPS-5).

A complete description of all of the outcome measures is in Appendix B.

## **E. Sample Size and Planned Statistical Analyses**

### **1. Planned Statistical Analyses**

The primary objective is to compare the effectiveness of CPT and ART in reducing the primary outcome -- PTSD symptom severity -- for Veteran and civilian patients with PTSD. We predict that CPT will be significantly superior to WL (and potentially superior to ART) in reducing PTSD symptoms post-treatment. To test this hypothesis we will use a 3 (Group: CPT, ART, WL) x 4 (Time: Baseline, Post-treatment) mixed-model ANCOVA covarying for baseline PTSD ratings. A significant omnibus interaction, and lower-order interactions, in the hypothesized direction will confirm this hypothesis.

The secondary objective is to compare the effectiveness of CPT and ART in reducing depression symptom severity. We predict that CPT will be superior to WL (and potentially ART) in reducing depression symptoms post-treatment. We will test this hypothesis with a mixed-model ANCOVA following the same analysis plan as for the primary objective.

The tertiary objective is to examine whether treatment effectiveness is reduced when patient preference for treatment is incongruent with their random assignment as we predict. To test this hypothesis, we will first categorize participants to a dichotomized preference group based on self-report. We will then perform a 2 (Group: Preferred Therapy, Non-preferred Therapy) x 4 (Time: Baseline, Post-Treatment, 3 Month, 1 Year) mixed-model ANCOVA covarying for baseline PTSD for both the primary (PTSD) and secondary (depression) outcome variables. A significant omnibus interaction, and lower-order interactions, in the hypothesized direction will confirm this hypothesis. Additionally, the primary and secondary analyses will be rerun covarying for preference to examine this variable's differential influence on CPT and ART outcomes.

Exploratory analyses will be performed to examine whether demographic and clinical variables differentially predict response and drop-out across treatment condition. Considering the exploratory nature of these analyses we make no predictions. However, we will use hierarchical multiple regression to examine the influence of demographics independent of the influence of clinical factors in predicting response (i.e., 50% symptom reduction) and drop out for each treatment. Based on the sample size estimate below, we will recruit a sample sufficient to include up to 24 predictors within these analyses – a more than sufficient number.

## **2. Sample Size Estimates**

In order to estimate sample size, we used means and SDs from pilot data, prior studies from other groups (Frost et al., 2014; Kip et al., 2012; 2014) and a previously published study from our group (Suris et al., 2013) to determine the expected effect size (ES) for differences in PTSD symptoms across pre- and post-treatment (i.e. time). We also calculated treatment differences at the post-treatment time point only. We employed the ES metric delta ( $\Delta$ ) for mean time differences and Cohen's  $d$  for mean treatment differences. According to Cohen (1990), an ES  $d = 0.2$  is considered small, 0.5 medium, and 0.8 large for behavioral research. Effect sizes within the large range are clinically relevant for behavioral research and even medium effect sizes should be “visible to the naked eye of a careful observer (Cohen, 1990).” Sample size estimates were then made using G\*Power version 3.1 (Franz Faul, University of Keil, Germany). Using G\*Power, we also estimated the a priori sample size required to identify the repeated-measures ANOVA interaction terms to be tested in the primary and secondary analyses.

ESs were large for active treatment differences across pre- and post-treatment times ( $d = 1.04$  for CAPS reduction with CPT;  $d = 2.02$  for PCL reduction in civilians with ART;  $d = 1.28$  for PCL reduction in military with ART). To detect similarly large differences ( $d_s > 0.8$ ) in PTSD severity means over time at  $\alpha = 0.05$ , power = 0.95 (to be conservative since there should be considerable power for these analyses), two-tailed in the proposed study would require at least a total  $N = 32$  ( $n = 16$  for each active treatment). A total sample size of  $N = 152$  ( $n = 76$  per active treatment condition) would be required

to identify PTSD symptom reductions over pre-and post-treatment in the WL condition considering the medium ES.

ES was small for active treatment difference between CPT and PCT symptoms post-treatment ( $d = 0.16$ ). No data directly comparing CPT and ART are available in the extant literature. To detect a similarly small difference ( $d_s < 0.2$ ) in PTSD severity means post-treatment with  $\alpha = 0.05$ , power = 0.80, two-tailed in the proposed study would require at least a total  $N = 706$  ( $n = 353$  for each active treatment). Therefore, the proposed  $N = 240$  would be insufficient to identify statistically significant differences between CPT and ACT post-treatment if we assume a similarly small effect size. The extant literature does not provide ES estimates between CPT vs. WL and ART vs. WL, but these ESs would be expected to be considerably larger than the CPT vs. PCT estimate.

In the absence of prior WL data with which to estimate ES, and considering that we intend to test interaction effects primarily, we estimate the necessary sample size to detect statistically significant Time x Treatment interactions across the entire power and ES range. Results indicate that for the primary analysis we will have sufficient power to detect even small effects with a total sample size = 246 ( $n = 123$  per active treatment condition). For the secondary analysis we will have sufficient power to detect even small effects with a total sample size = 138 ( $n = 69$  per active treatment condition).

It should be noted that the above calculations are based on simple contrasts between means and hypothetical power functions for the interaction term in repeated measures ANOVA, none of which include covariates. **These estimates are conservative in that inclusion of covariates, as expected in the final analysis, generally increases power and we intend to over-sample minimally to accommodate participant attrition, further assuring adequate power. *The total sample, then, will be  $N = 240$ , split equally between the two active treatments.*** This estimate, based primarily on repeated measure ANOVA, is very conservative as it provides a sufficient sample size to detect even small interaction effects. If needed, we propose oversampling by up to 40 participants to account for drop-outs from assessment or to bolster marginal effects.

## **F. Random Assignment:**

David Fleck, PhD, our statistician, has created a randomization table for all participants using a randomized, cross-over design. For participants who are randomized to the Wait List condition, following the completion of this seven week condition, they will be randomized into one of the two active treatment conditions, CPT or ART, using the randomization table (see Appendix C).

## **IV. Participant Characteristics and Recruitment**

### **A. Inclusion Criteria**

Participants will include 280 males and females ages 18 and older who meet criteria for PTSD (or subthreshold PTSD). Individuals will be included regardless of gender, ethnicity, military/civilian status, or type of trauma(s).

Participants must also agree to participate in either treatment, agree to allow IRB-approved study staff to access their medical record to review the extent to which they use UC or VA services before or during the study, have access to a telephone or agree to come into the Cincinnati VAMC, Trauma Recovery Center for the initial set of questions to determine whether they are eligible to participate, and agree to have their assessment and treatment sessions digitally audio recorded.

### **B. Exclusion Criteria**

Participants who 1) meet criteria for unmedicated bipolar, mania, or unmedicated psychotic disorders; 2) meet criteria for a substance use disorder requiring detoxification treatment; 3) have active suicidal or homicidal intent with (a) plan(s) and (a) means; 4) have a medical condition that will interfere with twice weekly therapy sessions will be excluded from the research study; 5) show severe problems with memory or other problems with thinking and reasoning (defined as 1 SD below age-graded norms on the Montreal Cognitive Assessment [MoCA], Nasreddine et al. 2005).

Individuals with a psychotropic medication change within the last 30 days will be asked to stay consistent with their current dose for a minimum of 30 days before admission to the study.

### **C. Concurrent Treatment**

Participants will be asked to refrain from any concurrent psychotherapy that focuses on treating the symptoms of PTSD or related mental health disorders. Exceptions will be made for those active in substance use treatment programs, including 12 step programs and relapse prevention.

### **D. Recruitment**

Participant recruitment will take place both at the University of Cincinnati, and at the Cincinnati VA Medical Center. The Trauma Recovery Center hosts a weekly orientation group for patients seeking PTSD-specific treatment which enrolls approximately 10 new Veterans per week. Historically, sharing research study information in this orientation group, in addition to soliciting UC and Cincinnati VAMC clinician and physician primary care referrals, have been successful methods of recruitment (*See Recruitment Material: VA Orientation Group Recruitment Slide*). Participants will indicate interest in this study through completion of a confidential questionnaire, given to the orientation group leader (*See Recruitment Material: VA Orientation Group Questionnaire\_ART Question*).

Participants in the group will also sign a permission to contact form during the orientation group, granting permission for the clinician leading the group to discuss the potential participant's eligibility in the research study with study staff (*See Recruitment Material: Contact Permission Form*). Participant recruitment will also take place at the UC Health Stress Center. This clinic currently treats an average of 40 patients per week, and receives approximately 10-15 weekly referrals for PTSD-specific treatment. IRB-approved study fliers will be posted in approved areas to aid in recruitment, in addition to distributing IRB-approved mailings to providers within the Cincinnati VAMC, UC Stress Center, local primary care centers, hospitals, and community mental health treatment centers within the greater Cincinnati area (*See Recruitment Material: Recruitment Flyer*). We will also use Study KIK and radio advertisements as additional

recruitment tools, and the Study KIK and radio advertisements will only use study descriptive information that has been IRB approved from the study flier. The contact number on all study recruitment tools will be 513-233-1620. This telephone number is associated with the VA site, so all interested participants for the study from both UC Stress Center and Cincinnati VAMC will contact study staff at the VA site.

## **E. Screening and Informed Consent**

### **1. Phone Screen and Study Site Determination**

All phone screens will occur at the VA site. Study staff will contact potential participants, and prior to any screening data being collected participants will be asked to identify how they learned about the study and which site (UC or VA) they were referred from. Civilian participants can only be seen at the UC Health Stress Center. Once the participant's associated site is known, study staff will inform the participant that all study appointments will be held at their associated site and changing study sites during their involvement in the study will be prohibited. If the participant agrees with staying with their associated site, the phone screen will continue. If the participant does not agree, study personnel will explain the requirements for the study and refer the participant back to their original provider. All data collected during the phone screen will be stored on the appropriate secure network. Study staff will be equipped with access to both sites network, despite being housed at the VA site (e.g. UC laptop will be provided to store all UC participant's phone screen data). All data collected during the phone screen, including PHI, will be stored electronically on the appropriate site's secure network (e.g. PHI of VA participants will be kept on the secure VA Network; PHI of UC participants will be stored on the secure UC Network).

The phone screen will be used to determine if the participant might be eligible for the study by assessing inclusionary and exclusionary criteria, including patient current mood, behaviors, treatment, and medications (*See Forms: 01-Phone Screen, 02-Concomitant Medications, 03-Demographic Information, 04-Suicidal & Homicidal Screen*). All forms during the phone screen will be completed electronically in a database on the participant's designated site's secure network. If participants do not

have access to a phone they must agree to come to the Trauma Recovery Center in Fort Thomas, KY to complete the screening in person with study staff. If a participant is initially eligible for this study, staff and the participant will schedule all future study appointments at the participants designated site, either the Cincinnati VA Medical Center--Trauma Recovery Center or the University of Cincinnati Health Stress Center. Study staff will remind the participant that all future study appointments will be held at that location (including assessments and treatment sessions), and changing study sites during the duration of their involvement in the study will be prohibited.

## **2. Informed Consent**

Each site has a site-specific Informed Consent Form (ICF, *See VA ICF and UC ICF*). Research study staff will review and discuss the ICF and HIPAA Authorization forms at the Pre-treatment Assessment with the potential participant. The documents must be completed and signed before any study procedures are performed. The person obtaining the consent will review the documents with the potential participant in a location providing privacy to discuss all elements of the document and study procedures. The person obtaining the consent will give the potential participant time to read the ICF and ask questions. A copy of the ICF will be given to interested participants to review and discuss with study personnel. The following elements will be discussed with the potential participants:

- The purpose and objectives of the study
- The length of the study
- Any potential risks, discomfort, inconvenience
- The importance of following study procedures
- The importance of compliance with all assessments and study visits
- Randomization
- Participation is voluntary and the participant may withdraw from the study at any time without loss of benefits to which he/she may otherwise be entitled
- Alternative treatments
- Reimbursement schedule for visits

- The participant's SSN is required
- Consent to be audio recorded during assessments and treatment sessions
- Provisions for keeping study data confidential and exceptions of confidentiality
- AEs are treated at no cost to the participant

The participant must sign the ICF and the HIPAA Authorization (Cincinnati VAMC site only) before any study procedures are performed. A copy of the signed ICF will be given to the participant. The original signed forms will be filed in the Participant Consent Form Master File, which will be retained at each individual study site. For participant's at the UC Health Stress Center site, a copy of the signed ICF will be scanned into their medical records.

## **V. Assessments**

**A. Assessors:** Clinical psychology post-doctoral fellows will perform all pre-, post-, and follow-up assessment interviews, and will be trained and supervised by licensed clinical psychologists. The assessors will remain blind to treatment condition throughout the study. Assessors will administer the: Clinician Administered PTSD Scale for DSM-IV and DSM-5 (CAPS-IV/CAPS-5), the Structured Clinical Interview for DSM-5 (SCID-5), the Montreal Cognitive Assessment (MOCA), and the Creative Imagination Scale.

Participants in the two active treatment conditions will complete a self-report assessment battery at pre-treatment, post-treatment, 3 month, and 1-year follow-up.

**B. Self-Report Assessments:** The self-report assessment forms will be completed by either paper-and-pencil questionnaires or the survey feature in RedCap. For assessments completed in RedCap survey, participants will complete the RedCap survey on a secure laptop computer or tablet at their designated location (connected to VA patient wifi at the Cincinnati VA or UC Health patient wifi at the UC Health Stress Center). Once a self-report survey has been completed by a participant, the RedCap system will not allow a participant access to change their responses. Participants will not have access to any data within RedCap, and will only be able to view their self-



report assessment forms in RedCap Survey mode. Table 2.0 indicates which self-report assessments can be completed by RedCap Survey and which assessments will be conducted by Assessor interview.

All potential participants will complete a pre-treatment assessment. Following their 7 week wait list period, participants in the WL condition undergo their first post-assessment. Their first post-assessment will be entered as their pre-treatment data when they are randomized to the active treatment condition. All participants will be reassessed in-person or by phone following treatment completion (post-treatment) and for their 3-month and 1 year follow-up.

Participants in the two active treatment conditions will complete additional assessments at post-treatment, 3 month, and 1-year follow-up. The measures in those assessments will be counter-balanced, and will include: the Structured Clinical Interview for DSM-5 (SCID5), Clinician Administered PTSD Scale for DSM-IV and DSM-5 (CAPS-IV/CAPS-5), PTSD Checklist for DSM-5 (PCL-5), Patient Health Questionnaire-9 and -15 (PHQ-9, PHQ-15), Brief Pain Inventory (BPI), State-Trait Anger Expression Inventory -2 (STAXI-2), Pittsburgh Sleep Quality Index (PSQI), Posttraumatic Cognitions Inventory (PTCI), Perth Emotional Reactivity Scale (PERS), The Future Scale (HOPE), Suicide/Homicide Screen (SI/HI Screen), and the Health Care Utilization (HCU).

At the pre-assessment only will the following forms be included: a locator information form, a treatment preference questionnaire, the Montreal Cognitive Assessment (MOCA), and the Creative Imagination Scale (CIS).

Participants in the two active treatment conditions will also be assessed by their clinician at each session with the PCL-5 and PHQ-9. Participant will complete the Expectancy of Therapeutic Outcome form at session #1. Participants will complete the Working Alliance Inventory (WAI-SR) at Session #2 and the Post-treatment assessment. Participants will also complete the HOPE and PSQI assessments at sessions #3 and #6.

*Table 2.0 Research Visit Schedule Grid*

	Pre	Session	Post	3 month	1 year	RedCap Survey	Assessor Interview
Locator Information Form	X					X	
Treatment Preference	X					X	
CIS	X						X
MOCA	X						X
Therapy Expectancy		X (#1)				X	
SI/HI Screen	X		X	X	X		X
HOPE	X	X (#3/6)	X	X	X	X	
CAPS-IV	X		X	X	X		X
CAPS-5	X		X	X	X		X
SCID-5	X		X	X	X		X
PCL-5	X	X	X	X	X	X	
PHQ-9	X	X	X	X	X	X	
PHQ-15	X		X	X	X	X	
PERS	X		X	X	X	X	
BPI	X		X	X	X		X
PSQI	X	X (#3/6)	X	X	X	X	
STAXI-2	X		X	X	X		X
PTCI	X		X	X	X	X	
HCU	X		X	X	X	X	
WAI-SR		X (#2)				X	

\*Participants in the two active treatment conditions will also be assessed by their study therapist at each session, or the session number(s) indicated.

## VI. Participant Payment

Participants may find the continued assessment burdensome, thus their reimbursement will increase for the 3-month and 1-year follow-up assessments by modest amounts in relation to the additional burden. The questionnaire assessments during treatment are brief, and are a standard part of clinical care, so participants will not be compensated.

*Table 3.0 Reimbursement Schedule for Study Participants*

Assessment	Participant Payment (\$)
Baseline	70

Posttreatment*	75
3-month follow-up	85
1 year follow-up	100

\*Individuals in the WL condition will receive two post-treatment assessments (one after WL period and one after completion of either CPT or ART following WL period), and will thus receive an additional \$75.00 for completion of the 2<sup>nd</sup> post-treatment assessment.

Participants randomly assigned to CPT or ART will receive up to \$330 in total compensation for their participation in this study. Participants randomly assigned to WL will receive up to \$405 in total compensation for their participation in the study.

Participants will be issued a debit card by the Greenphire ClinCard System. When a visit is completed funds will be approved and loaded onto the participants' card.

Participants will be issued one card for the duration of their participation. If a participant card is lost or stolen, they are instructed to call (866) 952-3795. An instruction sheet will be provided for further information. Greenphire and its Customer Support members will not have access to participant name or contact information; they will have a participant study ID number that will be provided to you by the study coordinator. Participants are able to use this study ID number to check the balance on their Greenphire debit card.

## **VII. Delivery of Therapy**

**A. Therapists:** Two therapists at the UC Stress Center and 8 therapists at the Cincinnati VAMC, Trauma Recovery Center will perform all of the therapy. Therapists will be licensed clinical psychologists or licensed independent clinical social workers. Participants will be randomly assigned to therapist and then condition at both locations. Thus, all therapists will provide both therapies.

**B. Training:** Laney Rosenzweig and three ART trainers will come to the Cincinnati VAMC for a 3-day ART training of the 10 therapists. Dr. Chard will ensure that therapists are appropriately trained in CPT.

**C. Consultation:** Laney Rosenzweig and her team will provide weekly phone consultation in ART. All study therapists have already achieved CPT Provider status.

Dr. Chard will provide CPT consultation. Therapists will be approved as study therapists after Ms. Rosenzweig signs off on their abilities.

**D. Digital Audio Recordings:** All therapy sessions will be digitally audio recorded for later adherence review. See Data and Safety Monitoring section for more information.

**E. Adherence and Competence Ratings:** Dr. Kevin Kip and his team, (who are otherwise unaffiliated with the conduct or outcome of this study), at the University of South Florida will provide Adherence and Competence Ratings for ART on 10% of the total number of treatment cases.

## **VIII. Data and Safety Monitoring**

Every effort will be made to maintain the confidentiality of participant study records. The University of Cincinnati will be allowed to inspect sections of participant medical and research records related to this study. The data from the study may be published; however, individual participants will not be identified by name. Participant identity will remain confidential unless disclosure is required by law.

There are times when we may have to show participant records to people from the Food and Drug Administration, the Office of Human Research Protections, The General Accounting Office, the Office of the Inspector General, and the study monitors may look at or copy portions of records about participants. This information will not be shared unless requested via official channels from the offices with an appropriate rationale for the request.

**A. Data Entry and Storage:** A paid study coordinator and/or post-doctoral fellow will screen all potential participants over the phone. A paid research associate will enter assessment interview data for the study into RedCap. Each individual site for the study will maintain its own site-specific electronic database through REDCap. All data will be identified by code number. The written interview assessment data will be stored in locked file cabinets that will be accessible only to study staff, located in room 3268.02 at UC and in room 204 for data collected at the Cincinnati VAMC, Trauma Recovery Center. At the end of the research study, data from both sites will be de-identified and

combined into one large data set held by the Cincinnati VA Medical Center at the end of the research study. This combined data set will not include any identifying information. The key listing participant names and code numbers will be kept in an electronic file at each respective site on the S drive that is password protected and only accessible by study staff. During the study, records will be released to appropriate professionals only upon written consent by the participant. Destruction of all research records pertaining to this study will be in accordance with the Department of Veterans Affairs and University of Cincinnati record retention schedule. The electronic recordings of the assessments and sessions will be stored on the S drive in the University of Cincinnati system, or Cincinnati VA system depending on participant location assignment, with password protection accessible by study staff only. The electronic recordings will be uploaded to a secure DMZ sharepoint server that will be accessed by Dr. Kevin Kip and his team for adherence review.

**B. Certification of Confidentiality:** To further protect participant privacy, the researchers will apply to obtain a Certificate of Confidentiality from the Department of Health and Human Services (DHHS), immediately following IRB approval. With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify a participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

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**Appendix A.** Script for weekly phone check-in calls by study staff for participants in the wait-list condition.

**CPT vs ART vs WL Study  
Weekly Check-in for WL Participants**

**PARTICIPANT #** \_ \_ \_ \_ \_

**Week Number:** 1 2 3 4 5 6 7

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Caller Initials: \_\_\_\_\_

Date/Time of call: \_\_\_\_\_

Reached: Yes No Rescheduled \_\_\_\_\_ Notes:

\_\_\_\_\_

Caller Initials: \_\_\_\_\_

Date/Time of call: \_\_\_\_\_

Reached: Yes No Rescheduled \_\_\_\_\_ Notes:

\_\_\_\_\_

Caller Initials: \_\_\_\_\_

Date/Time of call: \_\_\_\_\_

Reached: Yes No Rescheduled \_\_\_\_\_ Notes:

\_\_\_\_\_

Caller Initials: \_\_\_\_\_

Date/Time of call: \_\_\_\_\_

Reached: Yes No Rescheduled \_\_\_\_\_ Notes: \_\_\_\_\_

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*[If machine]*

Good morning/afternoon. I am calling from the [Cincinnati VA Medical Center/University of Cincinnati] for Mr./Mrs. \_\_\_\_\_. Please give us a call back at your earliest convenience at (859) 572-6226 and leave us a message as to the best time and phone number to reach you. Thank you.

*[If a person]*

Hello. My name is \_\_\_\_\_ with the [Cincinnati VA Medical Center/University of Cincinnati]. May I please speak with Mr/Mrs/\_\_\_\_\_?

*[If No]*

May I leave a message for them? Please have him/her call back at this number

(859) 572-6226 and leave a message as to the best time and phone number to reach them. Thank you.

*[If Yes]*

Hello Mr/Ms. \_\_\_\_\_. I am calling from the CPT vs. ART vs. WL research study. We are scheduled to do our [first, second, etc.] of our 7 weekly check-ins. As a reminder, the call usually takes about 15 minutes. Would you like to check-in now?

[If no]

What day/time later today or tomorrow would work well for you?  
[Schedule new call].

*[If Yes]*

Ok, great. There are no right or wrong answers and we appreciate your taking the time to let us know how you are doing *[complete check-in below]*

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*[General Check In]:*

**Overall, have there been any changes in your PTSD symptoms compared to [your initial assessment/your last weekly check-in call]?**

- ☐ No, I feel about the same
- ☐ Yes, my symptoms have improved
- ☐ No, my symptoms have gotten worse

*[If worse]. Tell me more about that. What's been different? [Obtain enough detail to inform research team whether an event might need to be reported as an AE and SAE, including dates/times of any incidents].*

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*[Medication Check]:*

**Have there been any changes in your medications since [your initial assessment/your last weekly check-in call], including new medications, discontinued medications, and any dosing changes.**

- ☐ No
- ☐ Yes *[If yes, note changed medication(s), dosing, and date changed below, and inform research team]*

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*[SI/HI Screen]:*

**We'd like to ask you a few questions to check-in about your safety. Keep in mind that if we are concerned for your immediate safety or that of someone else, we may take steps to make sure you or that other person are safe.**

**1. *[Ideation]* Do you have any thoughts of harming yourself right now?**

- ☐ No [*Skip next two questions*]
- ☐ Yes [**What kind of thoughts have you had?**]

**[Provide the following examples only if needed]. For example, some people have thoughts that they wish they were dead, and other people have thoughts of doing things to hurt themselves or end their lives. What thoughts like that have you had?**

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**2. [*Plan*] Have you been thinking about how you might do this?**

- ☐ No
- ☐ Yes [*Describe. Have you worked out any plan or details of how to kill yourself?*]

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**3. [*Intent*] Do you intend to kill yourself?**

- ☐ No
- ☐ Yes [*Describe*]

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**4. Since the last assessment, have you made a suicide attempt or done anything to harm yourself?**

- ☐ No
- ☐ Yes [*Describe*]

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**\*\*\*\*\*IF PARTICIPANT REPORTS YES TO QUESTIONS 2, 3, or 4 Conduct full Suicide Risk Assessment (SRA; included below). Document full SRA in participant electronic medical record.**

**Is there anything else that you think it would be important for us to know?**

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**What additional questions do you have?** *[Document any questions and answers provided]*

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**Is the best way to reach you still [confirm Phone number, Best Time to Reach, Address].** *[Note any changes below and update participant contact]*

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**[Weeks 1-6].**

**Thank you so much. We really appreciate your taking the time to complete the weekly check-ins. If at any time, your symptoms get worse, you may contact our clinic staff at 859-572-6226. What day/time works for you to complete our next weekly check-in?**

**[schedule next call]. Thank you and have a wonderful day/afternoon.**

**[Week 7 only].**

**We really appreciate your taking the time to complete the weekly check-ins. Since this is your last week, we'd like to schedule a time for you to come back to [The Cincinnati VA/The University of Cincinnati] to schedule your second pre-treatment assessment. As a reminder, you will be compensated \$75.00 for this assessment and, if you still qualify, you will be assigned to one of the two study treatments for PTSD. What day/time works for you to come in for the visit?**  
[schedule assessment].

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## **SUICIDE RISK ASSESSMENT (SRA) [V7.0]**

The following questions are a guide to engaging a patient in an empathetic conversation about a difficult subject. Although there are items to check, suicide risk is best evaluated through a trusting relationship rather than simply relying on a checklist.

### **1) Socio-demographic risk factors (check those that apply)**

- Elderly ☐ -Unmarried ☐
- White ☐ -Male ☐
- Living alone ☐
- Other:

### **2) Stressors (check areas of stress)**

- Poor Health (including chronic pain) ☐
- Financial ☐
- Family ☐ -Legal ☐
- Occupational ☐ -Marital/sig. other ☐
- Other:

### **3) Other risk factors (check those that apply)**

- Depression ☐ -ETOH or drug use ☐
- Anxiety or agitation ☐ -Serious Mental Illness ☐
- Other:

### **4) List Protective Factors, e.g. pt. has family support, wants to live to see his/her children to grow up, etc.**

- Family/friend support ☐
- Sense of Belonging ☐
- Religious beliefs against suicide ☐
- Future oriented ☐
- Provides reason to continue living ☐
- Other:

### **5) Has the patient had thoughts about death or about killing him/herself? Yes ☐ No ☐** (If yes, ask the following):

-Do you have a plan for how you would do this? Yes [ ] No [ ]

-Are there means available? (e.g. a gun, pills) Yes [ ] No [ ]

-Explain:

-Have you actually rehearsed or practiced how you would like to kill yourself? Yes [ ]  
No [ ]

-Do you tend to be impulsive? Yes [ ] No [ ]

-How strong is your intent to do this?

-Have you heard voices telling you to hurt or kill yourself? Yes [ ] No [ ]

-What kinds of things would increase a desire to end your life?

-What kinds of things would decrease a desire to end your life?

6) Is there a history of previous suicide attempts by:

    Yourself           Yes [ ] No [ ]

    Family members   Yes [ ] No [ ]

#### SUICIDE RISK ASSESSMENT SUMMARY/CONCLUSION:

The answers to the above questions can not be totaled for a score. Rather, they are a guide for formulating a clinical judgment. Based on your clinical judgment, using the information currently available, please check below as applicable)

A) There is no current risk of suicide           [ ]

B) There is less than imminent risk of suicide   [ ]

C) There is imminent risk of suicide           [ ]

Narrative explaining conclusion:

#### SUICIDE PREVENTION PLAN

(A, B, and C are suggestions. Describe actual plan below)

Example A: No current risk, no plan needed.

Example B: If there is less than imminent risk of suicide, develop a treatment plan which may include some or all of these elements:

-Inform and involve someone close to the patient.

-Limit access to means of suicide.

-Arrange for increased contact with the patient.

-Make a commitment to help the patient through the crisis.

-Provide the patient/family with crisis telephone numbers,  
e.g. 911 or the (SAMHSA) Veterans Crisis Line 1-800-273-TALK and "pressing 1".

Document that these numbers were given.

Example C: If there is an imminent risk of suicide, do not leave the patient alone.

Arrange for psychiatric consultation or transfer to a hospital emergency room by escort, ambulance or police.

Note: patients who are hospitalized are given an additional assessment by the admitting physician to determine whether special precautions are indicated and level of observation needed.

DESCRIBE suicide prevention plan (if indicated): \_\_\_\_\_

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## **Appendix B. Study Measures.**

**Adult Hope Scale (HOPE; Snyder et al., 1991).** This 12-item self-report measure when administered is labeled the “Future Scale”. Each item is assessed on an 8-point Likert scale. It is designed to measure cognitive strategies to meet a goal and motivation to achieve the goal.

**Brief Pain Inventory (BPI).** This is a 14-item self-report measure of physical pain. Current, average, and worst pain is captured on a 10-point Likert scale. This measure also assess pain management and pain-related functional impairment.

**Clinician Administered PTSD Scale for DSM-IV and DSM-5 (CAPS-IV/CAPS-5;** Weathers et al., 2013). PTSD diagnosis will be determined pre- and post- intervention by a trained clinician using the CAPS-IV/CAPS-5, in which the 20-item DSM-5 PTSD symptoms will be assessed. The CAPS-5 is considered the “gold standard” for PTSD assessment. Preliminary analyses from a Veteran sample at the Cincinnati VAMC Trauma Recovery Center suggest that this measure has demonstrated good internal consistency ( $\alpha = .79$ ).

**Creative Imagination Scale (CIS; Barber & Wilson, 1978).** This is a measure of imaginative suggestibility that will be administered pre-treatment by the post-doctoral fellow in psychology. It is a widely used and accepted valid measure of suggestibility within the field of hypnosis research.

**Health Care Utilization (HCU).** This is a 14-item self-report measure documenting to what extent a patient has utilized care, including participation in treatment including psychotherapy, medication management, and hospitalization.

**Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005).** This is a brief, 10-minute cognitive screening tool to assist clinicians in the detection of mild cognitive impairment. This measure has demonstrated good internal consistency ( $\alpha = .83$ ).

**Patient Health Questionnaire-15 (PHQ-15).** This is a 15-item self-report assessment of somatic symptoms designed for use in clinical practice and research. This measures demonstrated good internal reliability ( $\alpha = .80$ ) in primary care samples.



**Perth Emotional Reactivity Scale (PERS; Becerra et al., 2017).** This is a 30-item self-report questionnaire designed to measure emotional reactivity. Activation, intensity, and duration of a person's emotional responses are measured separately for positive (e.g., happiness) and negative emotions (e.g., sadness). Internal reliability for general negative reactivity scale ( $\alpha = .94$ ) and general positive reactivity scale ( $\alpha = .83$ ) were excellent, with good fit indices for the subscales ( $\alpha = .81-.89$ ).

**Pittsburgh Sleep Quality Index (PSQI).** This is a self-report measure designed to assess the quality and patterns of sleep in seven areas: subjective sleep quality, sleep latency, duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the past month.

**Posttraumatic Cognitions Inventory (PTCI; Foa et al., 1999).** This self-report measure is designed to assess cognitions following trauma(s). There are three factors within the PTCI, Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame. This measure has demonstrated good internal consistency ( $\alpha = .86 - .97$ ) and test-retest reliability ( $P = .74 - .89$ ).

**PTSD Checklist for DSM-5 (PCL-5; Weathers et al., 2013).** Participants will complete the PCL-5, a self-reported PTSD symptom severity measure, pre-, mid-, and post-intervention. The PCL-5 is comprised of 20 items on a four-point Likert scale that assess all DSM-5 PTSD symptoms. Preliminary analyses from a Veteran sample at the Cincinnati VAMC Trauma Recovery Center suggest that this measure has demonstrated good internal consistency ( $\alpha = .88$ ).

**State-Trait Anger Expression Inventory 2nd Edition (STAXI-2; Spielberger, 1999).** The STAXI-2 is a 57-item assessment designed to measure anger from a state-trait personality perspective. The STAXI-2 is comprised of six scales and five subscales and each item is rated on a 4-point scale of anger intensity or frequency. Participants will complete this full measure pre-, mid-, and post-intervention. The STAXI-2 has demonstrated good internal reliability (.81 to .91) and validity ( $\alpha = .73-.84$ ; Spielberger, Krasner, & Solomon, 1988; reviewed in Deffenbacher et al., 1996) and is one of the most commonly used measures of anger.

**Structured Clinical Interview for DSM-5** (SCID-5; First et al., 2015). Diagnoses for any co-occurring mental disorders will be made pre- and post- intervention by a trained post-doctoral fellow in psychology using the SCID-5, a structured clinician interview designed to assess for the presence of DSM-5 disorders and aid in differential diagnoses.

**Expectancy of Therapeutic Outcome (Therapy Expectancy).** This self-report assessment is completed a pre-treatment only, and assesses 4 participant expectancy-related thoughts about the treatment program they have been assigned (e.g., “how logical does this type of treatment seem to you?”). This measure has been used in prior PTSD clinical trials.

**Treatment Preference.** During the pre-treatment assessment, participants are given a brief overview of CPT and ART and are asked to indicate which treatment they prefer and how confident they are in their treatment preference on a 4-point Likert scale. This measure has been used in prior PTSD clinical trials.

**Twenty-Item Toronto Alexithymia Scale** (TAS-20; Bagby, Parker, and Taylor, 1994). This 20-item self-report measure assesses difficulty identifying feelings, difficulty describing feelings, and externally-oriented thinking. This measure has demonstrated good internal reliability ( $\alpha = .81$ ) among a psychiatric sample.

**Working Alliance Inventory-Short Revised** (WAI-SR; Hatcher & Gillaspy, 2006). This 12-item revised and shortened version of the Working Alliance Inventory (WAI) is a measure of working alliance between therapist and patient in three areas: goal, task, and bond. This measure has demonstrated excellent total score internal reliability ( $\alpha = .91 - .92$ ) and subscale internal reliability ( $\alpha = .85 - .90$ ).

## Appendix C. Randomization Tables.

### 1. University of Cincinnati, UC Health Stress Center Site

CPT/ART/WL Randomization Schedule

University of Cincinnati Site

Initial Randomization 1:1:1

block identifier	block size	sequence within block	treatment	provider	code	<u>Participant ID (02-####)</u>
5	48	1	WL		VJ8	
5	48	2	CPT	Honda	QD7	
5	48	3	CPT	Birkley	XY8	
5	48	4	CPT	Honda	VN2	
5	48	5	CPT	Birkley	AA2	
5	48	6	CPT	Honda	HH2	
5	48	7	ART	Honda	BR1	
5	48	8	ART	Birkley	JC1	
5	48	9	ART	Honda	NB1	
5	48	10	ART	Birkley	QT5	
5	48	11	WL		RG0	
5	48	12	CPT	Birkley	MO9	
5	48	13	WL		AM0	
5	48	14	CPT	Honda	KX8	
5	48	15	WL		CC0	
5	48	16	ART	Honda	CU6	
5	48	17	ART	Birkley	XX9	
5	48	18	CPT	Birkley	PW2	
5	48	19	CPT	Honda	EK9	
5	48	20	WL		KQ3	
5	48	21	WL		PH6	
5	48	22	ART	Honda	EM1	
5	48	23	WL		DV2	
5	48	24	WL		EP0	
5	48	25	WL		SN1	
5	48	26	CPT	Birkley	LY3	
5	48	27	CPT	Honda	GA9	
5	48	28	CPT	Birkley	FN5	
5	48	29	WL		DP9	
5	48	30	CPT	Honda	GD7	
5	48	31	ART	Birkley	EN6	
5	48	32	WL		ZF6	
5	48	33	ART	Honda	GF7	

5	48	34	WL		RF9
5	48	35	ART	Birkley	HW4
5	48	36	ART	Honda	KU9
5	48	37	WL		NK4
5	48	38	CPT	Birkley	RD5
5	48	39	WL		JM6
5	48	40	WL		EM0
5	48	41	ART	Birkley	XZ3
5	48	42	CPT	Honda	YN8
5	48	43	ART	Honda	OX8
5	48	44	CPT	Birkley	WU4
5	48	45	ART	Birkley	EE5
5	48	46	WL		KG0
5	48	47	ART	Honda	NN5
5	48	48	ART	Birkley	RJ2

Wait-List Randomization 1:1

block identifier	block size	sequence within block	treatment	provider	code	Participant ID (02-####)
6	16	1	CPT	Honda	VJ8-2	
6	16	2	ART	Honda	RG0-2	
6	16	3	CPT	Birkley	AM0-2	
6	16	4	CPT	Honda	CC0-2	
6	16	5	CPT	Birkley	KQ3-2	
6	16	6	CPT	Honda	PH6-2	
6	16	7	ART	Birkley	DV2-2	
6	16	8	CPT	Birkley	EP0-2	
6	16	9	ART	Honda	SN1-2	
6	16	10	ART	Birkley	DP9-2	
6	16	11	ART	Honda	ZF6-2	
6	16	12	CPT	Honda	RF9-2	
6	16	13	ART	Birkley	NK4-2	
6	16	14	CPT	Birkley	JM6-2	
6	16	15	ART	Honda	EM0-2	
6	16	16	ART	Birkley	KG0-2	

## 1. Cincinnati VA Medical Center, Trauma Recovery Center Site

CPT/ART/WL Randomization

Schedule

Cincinnati VAMC Site

Initial Randomization 1:1:1

block size	sequence within block	treatment	provider	code	Participant ID (01- ####)
192	1	WL		RL7	
192	2	CPT	Bailey	QL9	
192	3	ART	Bailey	YU4	
192	4	WL		YJ1	
192	5	WL		OS5	
192	6	CPT	Dickstein	UB6	
192	7	CPT	Klump	ZR3	
192	8	CPT	McIlvain	SC9	
192	9	ART	Dickstein	AR3	
192	10	CPT	Mesa	CP5	
192	11	ART	Klump	CH6	
192	12	ART	McIlvain	KY7	
192	13	CPT	Monroe	WC7	
192	14	WL		JE6	
192	15	ART	Mesa	AL2	
			Pukay-		
192	16	CPT	Martin	LK7	
192	17	ART	Monroe	SS5	
192	18	CPT	Simpson	YR1	
			Pukay-		
192	19	ART	Martin	OO3	
192	20	CPT	Bailey	PD5	
192	21	WL		YH1	
192	22	ART	Simpson	XA2	
192	23	CPT	Dickstein	AT6	
192	24	ART	Bailey	KA2	
192	25	WL		RW8	
192	26	CPT	Klump	XV3	
192	27	CPT	McIlvain	JA0	
192	28	ART	Dickstein	ZZ0	
192	29	WL		KK2	
192	30	WL		GA9	
192	31	WL		ZE5	
192	32	WL		GA1	
192	33	WL		EY5	
192	34	ART	Klump	FS9	
192	35	CPT	Mesa	GM6	
192	36	ART	McIlvain	SL6	
192	37	ART	Mesa	VN7	
192	38	ART	Monroe	MY6	
192	39	CPT	Monroe	LY1	

192	40	ART	Pukay-	CC7
192	41	ART	Martin	UT0
			Simpson	
			Pukay-	
192	42	CPT	Martin	RE4
192	43	CPT	Simpson	UW4
192	44	ART	Bailey	ZY6
192	45	WL		YU5
192	46	ART	Dickstein	GC6
192	47	CPT	Bailey	OO6
192	48	CPT	Dickstein	AA0
192	49	ART	Klump	IF7
192	50	CPT	Klump	HQ1
192	51	CPT	McIlvain	OT2
192	52	ART	McIlvain	QI3
192	53	CPT	Mesa	AU7
192	54	ART	Mesa	VK8
192	55	ART	Monroe	BC7
192	56	WL		SK9
192	57	WL		ML1
192	58	WL		LL9
192	59	WL		SX5
			Pukay-	
192	60	ART	Martin	VK9
192	61	WL		NG7
192	62	ART	Simpson	WC5
192	63	ART	Bailey	RI0
192	64	CPT	Monroe	DH0
192	65	ART	Dickstein	PF7
			Pukay-	
192	66	CPT	Martin	QI0
192	67	CPT	Simpson	DX3
192	68	WL		NN5
192	69	CPT	Bailey	BJ1
192	70	WL		AL4
192	71	WL		QS8
192	72	WL		KU7
192	73	ART	Klump	OP6
192	74	ART	McIlvain	PK6
192	75	CPT	Dickstein	UU9
192	76	CPT	Klump	ZU1
192	77	CPT	McIlvain	DI3
192	78	CPT	Mesa	ST9
192	79	CPT	Monroe	BD2

192	80	CPT	Pukay-	GF7
192	81	ART	Martin	
192	82	CPT	Mesa	YJ0
192	83	WL	Simpson	QN4
192	84	WL		BR0
192	85	ART		OS7
192	86	WL	Monroe	MY3
192	87	CPT		WY7
192	88	WL	Bailey	SM0
192	89	WL		RI3
192	90	WL		KM5
				MW9
192	91	ART	Pukay-	
192	92	WL	Martin	KQ0
192	93	WL		BJ8
192	94	WL		HA2
192	95	WL		BY7
192	96	ART		CD2
192	97	ART	Simpson	PM4
192	98	ART	Bailey	UO3
192	99	CPT	Dickstein	XC0
192	100	CPT	Dickstein	TQ0
192	101	WL	Klump	EW8
192	102	WL		QI8
192	103	WL		CN8
192	104	WL		CC5
192	105	ART		RT3
192	106	CPT	Klump	KE9
192	107	ART	Mcllvain	OK4
192	108	WL	Mcllvain	FO6
192	109	WL		DQ4
192	110	ART		OP1
192	111	ART	Mesa	OY4
192	112	CPT	Monroe	DK3
192	113	CPT	Mesa	UB5
			Monroe	US0
192	114	CPT	Pukay-	
192	115	WL	Martin	NX6
				VS6
192	116	ART	Pukay-	
192	117	CPT	Martin	NA6
192	118	ART	Simpson	KZ5
192	119	CPT	Simpson	ZE2
			Bailey	WG0

192	120	CPT	Dickstein	XZ8
192	121	WL		IF9
192	122	WL		HO4
192	123	ART	Bailey	RE2
192	124	CPT	Klump	MR3
192	125	WL		JA7
192	126	WL		ZG0
192	127	ART	Dickstein	TI8
192	128	CPT	McIlvain	HN6
192	129	CPT	Mesa	WW2
192	130	CPT	Monroe	WL6
192	131	WL		WL8
192	132	ART	Klump	QQ1
192	133	WL		EW9
			Pukay-	
192	134	CPT	Martin	MC4
192	135	CPT	Simpson	WF0
192	136	WL		HO6
192	137	WL		WT1
192	138	ART	McIlvain	BI4
192	139	CPT	Bailey	KU2
192	140	WL		JE8
192	141	ART	Mesa	CC9
192	142	WL		SM9
192	143	CPT	Dickstein	RX7
192	144	WL		WL0
192	145	WL		BB2
192	146	WL		VE0
192	147	ART	Monroe	LO2
192	148	WL		IK7
192	149	CPT	Klump	PN3
			Pukay-	
192	150	ART	Martin	LD4
192	151	ART	Simpson	OA5
192	152	WL		PN4
192	153	CPT	McIlvain	KY5
192	154	WL		KW6
192	155	WL		WO2
192	156	WL		IP0
192	157	ART	Bailey	CJ0
192	158	CPT	Mesa	BV2
192	159	CPT	Monroe	GH7
192	160	WL		PW4



192	161	WL		SK5
192	162	ART	Dickstein	RT4
192	163	ART	Klump	BT7
			Pukay-	
192	164	CPT	Martin	RQ3
192	165	WL		FX7
192	166	WL		JQ3
192	167	CPT	Simpson	QU5
192	168	CPT	Bailey	DU1
192	169	ART	Mcllvain	LL1
192	170	WL		HT1
192	171	CPT	Dickstein	DM6
192	172	CPT	Klump	VL1
192	173	ART	Mesa	GF4
192	174	ART	Monroe	XG0
192	175	CPT	Mcllvain	BV8
192	176	WL		VE1
			Pukay-	
192	177	ART	Martin	PD2
192	178	ART	Simpson	GH1
192	179	CPT	Mesa	NY2
192	180	WL		NR3
192	181	ART	Bailey	BW2
192	182	ART	Dickstein	XW9
192	183	WL		DS8
192	184	ART	Klump	BY1
192	185	ART	Mcllvain	ZC4
192	186	CPT	Monroe	KE6
			Pukay-	
192	187	CPT	Martin	VS9
192	188	ART	Mesa	J18
192	189	ART	Monroe	YY5
			Pukay-	
192	190	ART	Martin	EB5
192	191	CPT	Simpson	FM0
192	192	ART	Simpson	RG5

Wait-List Randomization 1:1

block identifier	block size	sequence within block	treatment	provider	code	Participant ID (01- ####)
4	64	1	ART	Bailey	RL7-2	
4	64	2	CPT	Bailey	YJ1-2	
4	64	3	ART	Dickstein	OS5-2	
4	64	4	ART	Klump	JE6-2	
4	64	5	ART	Mcllvain	YH1-2	

4	64	6	CPT	Dickstein	RW8-2
4	64	7	CPT	Klump	KK2-2
4	64	8	CPT	McIlvain	GA9-2
4	64	9	CPT	Mesa	ZE5-2
4	64	10	CPT	Monroe	GA1-2
				Pukay-	
4	64	11	CPT	Martin	EY5-2
4	64	12	ART	Mesa	YU5-2
4	64	13	CPT	Simpson	SK9-2
4	64	14	ART	Monroe	ML1-2
				Pukay-	
4	64	15	ART	Martin	LL9-2
4	64	16	CPT	Bailey	SX5-2
4	64	17	ART	Simpson	NG7-2
4	64	18	CPT	Dickstein	NN5-2
4	64	19	CPT	Klump	AL4-2
4	64	20	CPT	McIlvain	QS8-2
4	64	21	ART	Bailey	KU7-2
4	64	22	CPT	Mesa	BR0-2
4	64	23	CPT	Monroe	OS7-2
4	64	24	ART	Dickstein	WY7-2
4	64	25	ART	Klump	RI3-2
				Pukay-	
4	64	26	CPT	Martin	KM5-2
					MW9-
4	64	27	CPT	Simpson	2
4	64	28	CPT	Bailey	BJ8-2
4	64	29	ART	McIlvain	HA2-2
4	64	30	ART	Mesa	BY7-2
4	64	31	ART	Monroe	CD2-2
				Pukay-	
4	64	32	ART	Martin	QI8-2
4	64	33	ART	Simpson	CN8-2
4	64	34	CPT	Dickstein	CC5-2
4	64	35	CPT	Klump	RT3-2
4	64	36	ART	Bailey	DQ4-2
4	64	37	ART	Dickstein	OP1-2
4	64	38	CPT	McIlvain	VS6-2
4	64	39	CPT	Mesa	IF9-2
4	64	40	CPT	Monroe	HO4-2
4	64	41	ART	Klump	JA7-2
				Pukay-	
4	64	42	CPT	Martin	ZG0-2
4	64	43	CPT	Simpson	WL8-2

4	64	44	ART	McIlvain	EW9-2
4	64	45	ART	Mesa	HO6-2
4	64	46	ART	Monroe	WT1-2
4	64	47	CPT	Bailey	JE8-2
4	64	48	CPT	Dickstein	SM9-2
				Pukay-	
4	64	49	ART	Martin	WL0-2
4	64	50	CPT	Klump	BB2-2
4	64	51	CPT	McIlvain	VE0-2
4	64	52	ART	Simpson	IK7-2
4	64	53	CPT	Mesa	PN4-2
4	64	54	ART	Bailey	KW6-2
4	64	55	ART	Dickstein	WO2-2
4	64	56	ART	Klump	IP0-2
4	64	57	ART	McIlvain	PW4-2
4	64	58	ART	Mesa	SK5-2
4	64	59	ART	Monroe	FX7-2
4	64	60	CPT	Monroe	JQ3-2
				Pukay-	
4	64	61	ART	Martin	HT1-2
				Pukay-	
4	64	62	CPT	Martin	VE1-2
4	64	63	ART	Simpson	NR3-2
4	64	64	CPT	Simpson	DS8-2