Combining Treatment Components in Transdiagnostic Therapy for Anxiety and Depression: A Randomized Controlled Trial

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Statistical analysis plan

An overview of measures at each time point is provided in Table 1. Multilevel models will be employed as the primary analytic model, where time (level 1) is nested within individuals (level 2). Models will include a random intercept in addition to random slope if it improves model fit. For the covariance between the intercept and slope, a variance component and unstructured pattern will be tested. We will first evaluate the respective efficacy of each treatment component compared to no treatment (i.e., waiting period) and then compare the efficacy of the two treatment components when delivered first. For our primary analysis, we will compare potential sequencing effects in a time (pre-treatment through post-treatment) x group (mindful emotion awareness first vs. cognitive flexibility first) interaction analysis. Finally, we will explore the potential maintenance of effect at follow-up and at this point compare the two arms. The number of individuals who experience reliable clinical change in each of the groups will also be compared (Jacobson & Truax, 1991). Demographic and clinical baseline characteristics will be explored as moderators.

Table 1. Overview of measures at each time point

	Baseline (T1)	Pre-treatment (T2)	Mid-treatment (T3)	Post-treatment (T4)	Follow-up (T5)	Session (Ts1-6)
Primary outcomes						
PHQ-9	X	X	X	X	X	X
BAI	X	X	X	X	X	X
GAD-7	X	X	X	X	X	
SIAS	X	X	X	X	X	
PDSS-SR	X	X	X	X	X	
Secondary outcomes						
WHO-5	X	X	X	X	X	
RRS brooding subscale	X	X	X	X	X	X
PSWQ	X	X	X	X	X	
AWS						X
EQ decentering subscale	X	X	X	X	X	X[a]
ERQ reappraisal subscale	X	X	X	X	X	X
FFMQ-15	X	X	X	X	X	X
PDQ-D	X	X	X	X	X	
Treatment specific variables						
Experience of therapy				X	X	X
WAI-SR						X[b]
IO						X
Clinical evaluation						
ADIS-5	X					
WAIS-IV Digit span	X					
TMT-A	X					
TMT-B	X					
COWAT	X					
WAIS-IV Coding	X					
STROOP	X					
WAIS-IV Information	X					

Notes. Abbreviations: ADIS-5 = The Anxiety and Related Disorders Interview Schedule for DSM-5 (Brown & Barlow, 2014), AWS = the Ambulatory Worry Scale (Kramer et al., 2021), BAI = Beck's Anxiety Inventory (Beck et al., 1988; Beck & Steer, 1991), COWAT = Controlled Oral Word Association Test (Harrison et al., 2000), EQ = The Experiences Questionnaire (Fresco et al., 2007), ERQ = Emotion Regulation Questionnaire (Gross & John, 2003), FFMQ-15 = Five Facet Mindfulness Questionnaire – 15 (Baer et al., 2006),

GAD-7 = General Anxiety Disorder-7 (Spitzer et al., 2006), IO = Information Overload scale (adapted from Jensen et al., 2014; see Appendix E), PDQ-D = Perceived Deficits Questionnaire – Depression (Fehnel et al., 2016), PDSS-SR = the Panic Disorder Severity Scale – Self-Report Version (Houck et al., 2002), PHQ-9 = Patient Health Questionnaire-9 (Kroenke et al., 2001; Spitzer et al., 1999; Spitzer et al., 2000), PSWQ = The Penn State Worry Questionnaire (Meyer et al., 1990), RRS = The Ruminative Response Scale (Treynor et al., 2003), SIAS = the Social Interaction Anxiety Scale (Mattick & Clarke, 1998), TMT = Trail Making Test (Reitan, 1958), WAI-SR = Working Alliance Inventory – Short Revised (Munder et al., 2010), WAIS-IV = Wechsler Adult Intelligence Scale – Fourth Edition (Wechsler, 2008), STROOP = The Stroop Color and Word Test (Stroop, 1935), WHO-5 = the World Health Organization-5 questionnaire (Bech, 1999; Topp et al., 2015).
a: A brief version reduced to 5 items (cf. O'Toole et al., 2019) is used in the session questionnaires.
b: Only included in Ts2 and Ts5.

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