Woebot for Substance Use Disorders Phase 2 RCT: Digitally Delivered Intervention for Reducing Problematic Substance Use

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Descriptive statistics (means, frequencies) will be run to describe the sample, and the balance achieved by the randomization, and to examine ratings of program feasibility and acceptability. Missing data on individual survey items is anticipated to be minimal. As needed, individual participants' average score values may be imputed when missing individual items on a scale (e.g., PHQ-8). For the outcomes of interest, the target estimand is the intent to treat on the study population with no loss to drop-out of the study (i.e., this estimand incorporates noncompliance with the randomization's assigned level of intervention). We will examine predictors of study retention. Generalized Linear Models (multivariable models) will test for group differences in changes in the primary outcome and secondary outcomes. The dependent variables will be baseline to EOT (and baseline to 1-month follow-up) change scores. The models are used to adjust for baseline group differences and will apply weights to adjust for correlates of study retention. Participant weights will be calculated as the inverse of predicted probability values from a logistic regression model predicting EOT (and 1-month follow-up) retention.

Between-subject differences in baseline variables may be substantial (e.g., baseline number of substance use occasions) so the models will use change from baseline to a given time point (e.g., number of substance use occasions at EOT minus the number of substance use occasions at baseline). This trial, while not an exact replication, extends previous work with a waitlist control where the primary outcome was the change in baseline to EOT in substance use occasions. Thus, we separately analyze changes (a) from baseline to EOT, and (b) from baseline to 1-month.

Correlations also will be examined between W-SUDs engagement metrics and change in primary and secondary outcomes in the treatment group. Additionally, a per-protocol analysis will be limited to treatment participants who use W-SUDs at least 4 of 8 weeks and control participants who view at least half of the online psychoeducational fact sheets.

Bivariate correlations will examine associations between changes in substance use problems and changes in use occasions, confidence, depression, anxiety, and work productivity scores. Participants will be prompted to report craving within W-SUDs daily. If participants provide multiple craving ratings within a day, the scores will be averaged for that day. To examine changes over time in daily craving ratings, generalized estimating equation (GEE) linear models will be run with week entered as a factor, setting week 1 as the reference category.