RESEARCH PROTOCOL

REFRESH-study

REfreshment of dialectical behaviour therapy for veterans to Further reduce symptoms and prevent Relapse of post-traumatic stress disorder and Emotion regulation symptoms by guided Self-Help

Version number: 3.0, date 30-3-2026

STATISTICAL ANALYSIS

Analyses will include mixed regression analyses and survival analyses. No imputation of data is necessary due to the fact that mixed regression uses the same terms and conditions. When pairwise comparisons are made, post-hoc holm correction will be applied. If explorative analyses are performed, FDR correction will be applied.

Primary study parameter(s)

Linear mixed model is used for the primary (PCL-5 and DERS) parameters. These parameters are measured at four different timepoints: baseline (T0), pre-intervention (T1), post-intervention (T2) and follow-up (T3). The effect of the intervention will be estimated by comparing the situation after the intervention (T2 + T3) with the situation before the intervention (T0 + T1). The analysis of intervention effect will be performed using the fixed effects of a linear mixed model for repeated measures, based on the time indicators in the model. The random effects are random intercepts and (if the model fit and convergence allow it) random slopes for the time indicators.
For the secondary (REFRESH) parameter, assuming the assumptions for mixed models are met (normality of residuals), we will investigate if the parameters change during the different phases (i.e., baseline + waiting phase, intervention phase and follow-up phase) and how time within each phase contributes to change. For each different time phase, a dummy variable will be made and put into the model. On individual level, centred times will be added (to investigate the time effect within each phase and to decrease multicollinearity). If the mixed model converges, there is a random intercept to account for the fact that each participant will have their own starting point at baseline and a random slope because each participant will have their own change in time due to variances in improvement speed. The covariance between random intercept and random slope will be determined randomly with AR1 or ARMA (best fitted structure is chosen). This allows participants to a relatively high value of the parameter at baseline to have different improvement speeds. All of the different time variable will be put into the fixed part of the model. In addition, the effect of time will be tested to determine if time overall is more important than time per phase. If the linear time effect does not become significant, it will be eliminated from the model. Stepwise simplification is used for every time variable, meaning that each not significant time variable will step by step be eliminated (Arntz et al., 2013; Videler et al., 2018; Khasho et al., 2018, Valente et al., 2026).

Secondary study parameter(s)

General psychiatric symptoms (OQ-30.2), emotion regulation problems (AVL, NSSI-AT, LPFS, self-direction (i-ROC, DSES) and substance use (DUDIT, AUDIT) will be measured at the four different timepoints. These tertiary parameters are analysed in the same way as the primary parameters (i.e., using a linear mixed model).

Kaplan-Meier survival analyses are performed to investigate relapse of PTSD and emotion regulation symptoms (i.e., score below or above clinical cut-off point). In addition, cox regression is performed to determine if social network (ISB) and socioeconomic factors (e.g., daily activity patterns, housing and financial problems measured with background questionnaire) are moderators in relapse outcome.

Other study parameters

The clinical interviews will be used to describe the researched population. Moreover, unpaired t-test will be performed to investigate the difference between the completer's vs drop-out groups.