SAMPLE SIZE AND STATISTICAL METHODS

1. Determination of Sample Size

Details on sample size calculation and the means by which data will be analysed and interpreted. In particular, specify all of the following:

- *Null and alternate hypothesis*
- *Type I error rate*
- *Type II error rate*

The sample size was estimated for a two-arm design with statistical power of 0.80, while the Type 1 error rate was controlled at 0.05. To achieve a moderate effect size of 0.50 on primary outcome for intervention group, and assuming 0.15 response for control group based on rate of spontaneous remission of symptoms, we will need at least 47 patients per arm to reject the null hypothesis. Assuming an attrition rate of 30% based on pilot data, 62 patients will be recruited per arm, ie, 24 patients will be recruited in total.

2. Statistical and Analytical Plans

a. *General Considerations*

The independent variable is control or treatment group. Our covariates include clinical stage, age, sex, race, employment, marital status, educational level, history of psychiatric/psychological treatment. The main dependent variable is psychological distress measured by total Kessler-10 (K-10) score at post-intervention (T3) and 3-month follow up (T4). Secondary outcome variables include their depression symptoms score (PHQ-9), anxiety symptoms score (GAD-7), functional impairment score (WHODAS), and self-efficacy (GSE) at T3 and T4. Number of participants in each group will be analysed according to intention-to-treat.

'2 (therapy type: SFBT, TAU-CM) by 3 (assessment time: T1, T2/3, T4)' factorial analysis of variance (ANOVA) for repeated measures will be conducted to examine the statistical significance for main effect of therapy type and assessment periods; and as well interaction between assessment time and therapy type. Significant main effects will be probed with multiple two-way comparison tests (i.e., T1 vs. T2/3, T1 vs. T4, and T2/3 vs. T4). Effect sizes (Cohen's *d;* Cohen, 1990) for each outcome will be calculated to indicate the magnitude of change in treatment outcomes for each treatment group from T1 to T2/3, T1 to T4, and T2/3 to T4. We will apply the established thresholds for interpreting the effect sizes, with a Cohen's *d* of 0·2 denoting a small effect, 0·5 a medium effect, 0·8 and above a large effect. All statistical analyses will be performed in SPSS version 29 (IBM Corp, 2022).

A blinded statistician will analyse the results between SFBT vs. TAU-CM. Only the study team members and the research assistant are aware of the grouping and this blinding will only be removed at the stage of manuscript preparation.

b. *Safety Analyses*

The PI and/or Co-Is will be informed if there is a worsening of symptoms in a participant during the course of the study. The participant will be reviewed by PI, Co-I or an IMH psychiatrist.

c. *Interim Analyses*

As the sample size of the study is modest and risk of participating in the treatment arm is low, analysis will only be completed at the end of the intervention trial (T3). Analyses of long-term outcomes will occur after follow-up assessment has been collected (T4).

d. *Describe the types of statistical interim analyses and stopping guidelines (if any) that are proposed, including their timing.*

As the sample size of the study is modest and risk of participating in the treatment arm is low, analysis will only be completed at the end of the intervention trial (T3). Analyses of long-term outcomes will occur after follow-up assessment has been collected (T4).

The study may be prematurely terminated in either of the following circumstances:

- Recruitment failure, that is, being unable to reach the target of 124 patients
- Single or multiple AE(s) or AR(s) that are moderate-to-severe and confidently demonstrate an adverse safety profile (i.e., causality is likely); such incidents may include and are not limited to e.g., suicide, homicide

In the case of significant clinical deterioration or improvement, the interim results of the study would be presented to the Programme Director of CHAT, following which their opinion will be sought to determine the ethicality and appropriateness of premature termination.

In the case of AE(s) or AR(s), premature termination should take place based on best ethical judgement, severity of the incidents, and the strength of causality.

Following termination, the participants would return to TAU, however the data collected prior to termination would still be used for further analysis bearing in mind the reason for termination.