Statistical Analysis Summary for ISRCTN

ISRCTN15749621 | SAP Version 1.0 | Finalised 4 November 2026

Study title: Online group self-care seminar using thought field therapy for support workers affected by the 2026 Kumamoto earthquake

Analysis objectives

The primary objectives are feasibility, acceptability, safety, and practical utility. State outcomes are exploratory. No confirmatory hypothesis test of intervention efficacy is planned.

Feasibility and acceptability

Recruitment, consent, attendance, retention, response rates, follow-up completion, fidelity, operational issues, adverse events, acceptability, self-care use, barriers, and perceived usefulness will be summarised using counts, proportions, descriptive statistics, and 95% confidence intervals with clearly stated denominators.

K10

K10 is collected at T0, T1, and T4. A segmented linear mixed-effects model with a participant-level random intercept will use actual elapsed days relative to T1. The prespecified contrast is the difference between the post-seminar slope (T1–T4) and the waiting-period slope (T0–T1). The estimate and 95% confidence interval will be reported; an exploratory p value may be provided as supplementary information.

ProQOL and SUD

ProQOL is collected at T0 and T4. Changes in compassion satisfaction, burnout, and secondary traumatic stress will be reported separately; no total score will be created. SUD changes from T2 to T3 and the T4 distribution will be described. ‘Difficult to recall’ and ‘unable to recall the theme’ will remain separate non-numeric categories.

Missing data and sensitivity analyses

Primary descriptions will use observed data. Mixed models will use available repeated measures under a missing-at-random assumption. Prespecified sensitivity analyses include complete K10 data, exclusion of participants who attended non-study TFT training during the waiting period, and adjustment for seminar session as a fixed effect. Multiple imputation is not planned as a primary analysis.

Reliable change and qualitative data

Reliable Change Indices will describe improvement, deterioration, and no reliable change for K10 and each ProQOL subscale. Free-text responses will undergo human-led content or thematic analysis. Text mining, if used, will be supplementary and conducted only after anonymisation.

Interpretation

All state-outcome analyses are exploratory. Statistical significance alone will not be used to infer benefit, and observed changes will not be interpreted as causal effects of TFT because the study has no randomised control group.

Timing and transparency statement

SAP version 1.0 was finalised on 4 November 2026, after recruitment had commenced but before the first seminar on 9 December 2026 and before review of individual outcome responses. Only aggregate operational recruitment information, form structure, response pathways, and data-field definitions had been reviewed. Any analysis added after outcome review will be labelled post hoc and exploratory.

Suggested registry text (compact version)

> Primary outcomes are feasibility, acceptability, safety and practical utility, summarised using counts, proportions, descriptive statistics and 95% confidence intervals. K10 at T0, T1 and T4 will be analysed exploratorily using a segmented linear mixed-effects model based on actual elapsed days; the prespecified contrast is the difference between the T1–T4 and T0–T1 slopes. ProQOL subscales will be reported separately for T0–T4 change, and SUD will be described for T2–T3 and T4. Non-numeric recall responses will not be converted to SUD scores. No confirmatory test of TFT efficacy is planned. SAP v1.0 was finalised on 4 November 2026, after recruitment began but before the first seminar and before individual outcome data were reviewed.