Pre-Analysis Plan

Effects of Body Treatment on the Physical and Mental Well-Being of Long-Term Care Workers

Principal Investigator	**Shinsuke Asakawa, Associate Professor (Faculty of Economics, Kagawa University)**
Co-Investigator	**Yuriko Matsunaga, Professor (Department of Nursing, Faculty of Medicine, Saga University)**
Study Practitioner	**Yumi Eto (Representative, Earth Inclusion)**
IRB	**Kagawa University Faculty of Economics Research Ethics Committee (Approval No.: 2026_02_01)**

1. Target Estimand

Estimand	**ATT (Average Treatment Effect on the Treated)**
Definition	The average effect of treatment among participants who received body treatment (the early-intervention group), relative to the counterfactual of not receiving treatment. Because assignment is randomized, ATT is estimated as equal to ATE.
Unit of Analysis	Participant i × survey round t (questionnaire); participant i × treatment session s (HRV)

2. Definition of Outcomes and Measurement Timing

This study follows a rolling implementation design in which facilities begin the intervention at staggered dates. Accordingly, the survey rounds (SR1–SR7) used throughout this section are not defined by calendar month, but as relative survey rounds anchored to each facility's and each participant's own intervention start. SR1 denotes each participant's baseline (pre-intervention) assessment, and SR2 onward denote rounds indexed relative to that participant's own intervention start. All analyses below are conducted in this relative time metric (SR1–SR7) rather than in calendar time.

2-1. Primary Outcomes: Questionnaire Panel

The following five indicators constitute the primary outcomes. All scales are signed so that higher values indicate worse mental health (i.e., stronger symptoms or stress reactions).

Indicator	Definition / Calculation	Instrument / Method	Timing
(1) Mental Health Index	MHI = [z(GAD-7) + z(PHQ-9) + z(JBS) + z(BJSQ Psychological Stress Reaction)] / 4. All four scales are signed so that higher values indicate worse mental health before averaging. Z-scores are standardized using the waitlist group's baseline (T0) mean and SD.	Questionnaire (collected each round)	SR1, SR2, SR3, SR4, SR5, SR6, SR7
(2) GAD-7	Anxiety score (0–21; sum of Question 1, items 1–7). A score of 10 or higher indicates moderate or greater severity. Higher scores indicate greater anxiety.	Questionnaire	SR1, SR2, SR3, SR4, SR5, SR6, SR7
(3) PHQ-9	Depression score (0–27; sum of Question 3, items 1–9). A score of 10 or higher indicates moderate or greater severity. Higher scores indicate greater depression.	Questionnaire	SR1, SR2, SR3, SR4, SR5, SR6, SR7
(4) JBS (Japanese Burnout Scale)	A 17-item scale (Question 5, items 1–17) comprising three subscales: emotional exhaustion, depersonalization, and reduced personal accomplishment. Personal-accomplishment items are reverse-coded so that higher total scores indicate stronger burnout tendencies.	Questionnaire	SR1, SR2, SR3, SR4, SR5, SR6, SR7
(5) BJSQ Psychological	The psychological stress reaction subscale of the Brief Job Stress Questionnaire (BJSQ; Question 7, items 1–	Questionnaire	SR1, SR2, SR3, SR4, SR5, SR6,

Indicator	Definition / Calculation	Instrument / Method	Timing
Stress Reaction	18), comprising five subscales (vigor, irritability, fatigue, anxiety, and depression; 18 items total). Vigor items are reverse-coded so that higher total scores indicate stronger psychological stress reactions. The BJSQ physical stress reaction subscale (Question 7, items 19–29) is not included among this study's outcomes.		SR7

2-2. Secondary Outcome / Mechanism Analysis: HRV Physiological Indices

HRV is treated as both a secondary outcome and a mechanism analysis. Its purpose is (i) to assess whether treatment induces a physiological relaxation response, and (ii) to identify which of the three treatment sessions produces the largest physiological effect. HRV is not used to estimate the policy-relevant treatment effect.

Indicator	Definition / Calculation	Timing
(1) ΔRMSSD	RMSSD_during (20-minute average during treatment) − RMSSD_pre (5-minute resting average before treatment). Measured with the Mybeat-FMCC WHS-1 device; computed from R-R interval (RRI) data using 1-minute windows. Artifact rejection: RRI fluctuations exceeding ±20% are automatically excluded. Only sessions with at least 15 minutes of valid recording are analyzed.	S1, S2, S3 (each treatment session)
(2) ΔLF/HF ratio	LF/HF_during − LF/HF_pre, computed via maximum entropy method (MEM) frequency-domain analysis.	S1, S2, S3

2-3. Secondary Outcomes: Work-Related Attitudes

The following four secondary outcomes are defined based on the relevant items of the worker questionnaire (administered at every round). For each outcome, a single representative item serves as the primary analysis, with related sub-items analyzed exploratorily as needed.

Indicator	Definition / Content	Timing
Job satisfaction	From Question 21 (“Satisfaction with your current job,” items 1–15), the primary analysis uses item 15, overall satisfaction with working life, on a 5-point scale (satisfied / somewhat satisfied / neutral / somewhat dissatisfied / dissatisfied). Other sub-items (e.g., job content, career-advancement opportunities, wage level) are analyzed exploratorily as needed.	All rounds
Occupational continuation intention	From Question 22 (“Your future preference regarding your current job/occupation”), with six response options: (1) wish to continue in the current job; (2) wish to move to a different care-related occupation; (3) wish to move to a different welfare/healthcare-related occupation; (4) wish to move to an occupation outside care, welfare, or healthcare; (5) undecided; (6) do not wish to work. The primary analysis codes this as a binary variable: option 1 = “continuation,” options 2–6 = “other.”	All rounds
Workplace retention intention	From Question 23 (“Do you wish to continue working at your current facility?”; asked of respondents who selected options 1–5 on Question 22), with four response options: (1) wish to continue at the current facility; (2) wish to transfer to a different facility within the same organization; (3) wish to change to a different organization/employer; (4) undecided. The primary analysis codes this as a binary variable: option 1 = “retention,” options 2–4 = “other.”	All rounds
Career orientation	From Question 24 (“Do you intend to pursue a higher position in the future?”), a binary item: (1) intend to pursue a higher position; (2) content with current position. Coded as a binary variable: option 1 = “career-oriented,” option 2 = “not career-oriented.”	All rounds

2-4. Measurement Timing Overview

The table below shows what is measured at each survey round, SR1–SR7. The calendar month corresponding to each round differs across facilities and participants.

Survey Round (SR)	Content	Early-Intervention Group	Waitlist Group
SR1	Baseline questionnaire (BL) + HRV Session 1 (early-intervention group)	Baseline questionnaire (BL)	Baseline questionnaire (BL)
SR2	Pre-treatment questionnaire (before 2nd session) + HRV Session 2 (early-intervention group)	Pre-2nd-session questionnaire	Control questionnaire 1
SR3	Pre-treatment questionnaire (before 3rd session) + HRV Session 3 (early-intervention group)	Pre-3rd-session questionnaire	Control questionnaire 2
SR4	Follow-up questionnaire (early group) / pre-treatment questionnaire (waitlist group) + HRV Session 1 (waitlist group)	Follow-up questionnaire 1	Pre-1st-session questionnaire
SR5	Follow-up questionnaire (early group) / pre-treatment questionnaire (waitlist group) + HRV Session 2 (waitlist group)	Follow-up questionnaire 2	Pre-2nd-session questionnaire
SR6	Follow-up questionnaire (early group) / pre-treatment questionnaire (waitlist group) + HRV Session 3 (waitlist group)	Follow-up questionnaire 3	Pre-3rd-session questionnaire
SR7	Final questionnaire (both groups)	—	—

3. Randomization Balance Checks

Because only a single pre-period round (SR1) precedes the start of Period 1, we do not empirically test pre-treatment parallel trends for the early-intervention group. Balance from randomization is instead assessed via the following between-group comparisons.

Variable	Test	Reporting
Age, sex, occupation, and job position	t-test / χ^2-test	A table of p-values is reported; significant differences are interpreted as chance imbalance.
Years of care-work experience and tenure at current facility	t-test	As above.
Baseline GAD-7 and PHQ-9	t-test	As above.
Baseline Mental Health Index	t-test	As above.
Baseline RMSSD and LF/HF ratio	t-test	As above.

4. Identification Strategy

Event-Study Difference-in-Differences (Primary Analysis)

The questionnaire panel comprises seven survey rounds (SR1–SR7). We use an event-study DiD design as the primary estimation strategy to trace the dynamic evolution of the treatment effect across survey rounds.

Model (1): Event-Study DiD

$$Y_{it} = \alpha_i + \gamma_t + \Sigma_{k\neq -1} \beta_k \cdot (Treat_i \times 1[EventTime_i = k]) + \varepsilon_{it}$$

Variable definitions:

Y_{it} : outcome for participant i at round t (Mental Health Index, GAD-7, PHQ-9, JBS, BJSQ psychological stress reaction, job satisfaction, occupational continuation intention, workplace retention intention, career orientation, etc.)

α_i : individual fixed effects (controlling for time-invariant unobserved heterogeneity)

γ_t : round fixed effects (controlling for common time trends)

$Treat_i$: early-intervention group dummy (1 = early-intervention group, 0 = waitlist group)

Event time k is defined as:

k = -1 : SR1, baseline (reference period, omitted)

k = 0 : SR2 (early group: pre-2nd-session; waitlist group: control questionnaire 1)

k = 1 : SR3 (early group: pre-3rd-session; waitlist group: control questionnaire 2)
k = 2 : SR4 (early group: follow-up 1; waitlist group: pre-1st-session)
k = 3 : SR5 (early group: follow-up 2; waitlist group: pre-2nd-session)
k = 4 : SR6 (early group: follow-up 3; waitlist group: pre-3rd-session)
k = 5 : SR7, final survey (both groups)
β_k : the treatment effect (ATT) at event time k; the primary parameter of interest
ε_{it} : error term (facility-clustered standard errors)

Interpretation:

βk is defined as the additional change in the gap between the early-intervention and waitlist groups at event time k, giving the ATT at each survey round. We plot the path of βk in an event-study figure to characterize the dynamic evolution of the treatment effect. βk for k = 0, 1 constitutes the primary estimates, corresponding to Period 1 (when the early group is treated and the waitlist group serves as the control). βk for k = 2, 3, 4 captures the evolution of the gap while the waitlist group is receiving treatment; because the waitlist group's status as an untreated control is no longer guaranteed during this period, these estimates are treated as exploratory.

5. Mechanism Analysis: HRV

5-1. Model (2): HRV Comparison across Treatment Sessions

Model (2): HRV Comparison across Treatment Sessions (Secondary / Mechanism Analysis)

$$\Delta RMSSD_{is} = \alpha + \Sigma_{s=2}^{3} \beta_s \cdot Session_s + \gamma_i + \theta \cdot RMSSD_{i,pre} + \varepsilon_{is}$$

Variable definitions:

$\Delta RMSSD_{is}$: ΔRMSSD (during − pre) for participant i at treatment session s
$Session_s$: treatment-session dummy (s = 1 is the reference; s = 2, 3 denote the second and third sessions)
β_s : magnitude of the physiological effect at session s (the parameter of interest in this mechanism analysis)
γ_i : individual fixed effects
$RMSSD_{i,pre}$: the pre-treatment-phase mean RMSSD for the same session (a time-varying covariate)
ε_{is} : error term (facility-clustered standard errors)

The same model is applied to the LF/HF ratio (Model 2′). β2, β3 > β1 would suggest a “habituation” effect (the physiological response strengthens with repeated exposure), while smaller values would suggest a “novelty effect” (the response is strongest at first exposure).

5-2. Model (3): Within-Session HRV Time-Series Profile

Model (3): Within-Session HRV Time-Series Profile (Exploratory, Visualization)

$$RMSSD_{it} = \alpha + \Sigma_j \beta_j \cdot Phase_j + \gamma_i + \theta \cdot RMSSD_{i,pre} + \varepsilon_{it}$$

$Phase_j$: phase dummies (pre = reference; during, minutes 1–20; post, minutes 21–25)
β_j : deviation from the pre-treatment phase at each time point. We plot the path of βj to describe the onset, peak, and decay of the effect (exploratory).

6. Multiple Testing Adjustment

Outcome Group	Adjustment Method	Notes
Primary outcome: Mental Health Index (MHI)	No adjustment	The Mental Health Index is a composite of four standardized scales; because there is only a single primary test at the index level, no multiple-testing problem arises.
Primary outcomes (four individual scales): GAD-7, PHQ-9, JBS, BJSQ psychological stress reaction	Benjamini-Hochberg procedure (FDR = 0.05)	Both unadjusted and adjusted p-values are reported.
Secondary outcomes (job satisfaction, occupational continuation intention,	Benjamini-Hochberg procedure (FDR = 0.05)	Treated as secondary outcomes; reported exploratorily only if the primary outcome results

Outcome Group	Adjustment Method	Notes
workplace retention intention, career orientation)		are significant.
HRV (RMSSD, LF/HF ratio)	No adjustment (only two indices)	Mechanism analysis; a Bonferroni-adjusted version is reported as a sensitivity analysis.

7. Treatment Effect Heterogeneity

The following three variables define pre-registered subgroups. The δk estimates are explicitly designated as exploratory.

#	Subgroup Variable	Split Criterion	Hypothesis
1	Baseline GAD-7 score	At or above median (high anxiety) vs. below median (low anxiety)	The improvement in the Mental Health Index is larger among the high-anxiety subgroup.
2	Years of care-work experience	Less than 5 years vs. 5 years or more	The stress-reduction effect is larger among less experienced staff.
3	Age group	Under 40s vs. 40s and above	Autonomic nervous system responsiveness differs by age.

Treatment Effect Heterogeneity Model (Event-Study DiD with Interaction Terms)

$$Y_{it} = \alpha_i + \gamma_t + \Sigma_{k\neq -1}\, \beta_k \cdot (Treat_i \times 1[k]) + \Sigma_{k\neq -1}\, \delta_k \cdot (Treat_i \times 1[k] \times Z_i) + \lambda \cdot Z_i + \varepsilon_{it}$$

Z_i : subgroup variable (e.g., high-anxiety dummy)
δ_k : heterogeneity in the treatment effect at each event time (exploratory; pre-registered)

8. Control Variables

Category	Variable	Measurement	Timing
Individual characteristics	Age, sex, occupation, job position	Initial worker questionnaire	T0 (baseline)
Individual characteristics	Years of care-work experience, tenure at current facility	Initial worker questionnaire	T0
Treatment-related	Treatment type (oil-based / dry-touch)	Treatment log	Each treatment session
Treatment-related	Treatment session number (1st–3rd)	Treatment log	Each treatment session
Treatment-related	Self-rated physical condition on the day	Questionnaire (every round)	Each measurement occasion
Facility characteristics	Facility type, facility size, type of operating organization	Organization questionnaire	T0
Temporal factors	Day of week, time of day of measurement	Study log	Each measurement occasion
Temporal factors	Prior night's sleep duration and quality	Questionnaire (every round)	Each measurement occasion
Environment	Self-reported workplace busyness on the day	Questionnaire (every round)	Each measurement occasion

9. Planned Sample Size

Item	Planned Value	Notes
Total planned participants	Up to 50	25 in the early-intervention group, 25 in the waitlist group
Planned number of clusters	Up to 5 facilities	Approximately 10 participants per facility
Number of treatment sessions	Up to 150	Up to 50 participants × 3 sessions
Number of questionnaire waves	7 survey rounds (SR1–SR7)	Panel observations for the event-study DiD (50 participants × 7 rounds = 350 observations); HRV sessions: 50 participants × 3 sessions = 150 observations