Additional file 1: Study protocol extract and statistical analysis plan

PART I. STUDY PROTOCOL (ENGLISH EXTRACT)

1. Trial Design

This study was a single-center, randomized, parallel-group clinical trial conducted in France between March 2023 and January 2024. The trial evaluated the effect of PhonixCare, a digital behavioral intervention, on objectively recorded smartphone use among adolescents and young adults.

Participants were randomly assigned in a 1:1 ratio to either:

- The intervention group (PhonixCare behavioral regulation mode), or
- The control group (passive monitoring only).

Because of the nature of the intervention, participant blinding was not feasible. Statistical analyses were conducted blinded to group allocation coding.

2. Participants

Inclusion Criteria

- Age 11–25 years
- Enrollment in middle school, high school, or university
- Ownership of an Android-compatible smartphone
- Ability to understand French

Exclusion Criteria

- Participation in another screen-use intervention within 6 months
- Current psychological or pharmacological treatment targeting screen addiction
- Insufficient French comprehension

Participants (or legal guardians for minors) provided written informed non-opposition prior to enrollment in accordance with French regulations.

3. Intervention

PhonixCare is a digital behavioral self-regulation tool grounded in self-regulation and cognitive-behavioral principles.

Core components included:

1. Passive monitoring of smartphone use
2. Restriction of recreational applications
3. Unlocking of digital time contingent upon completion of non-digital activities
4. Gamified feedback via a virtual companion
5. Progressive autonomy levels

The control group received passive smartphone monitoring without behavioral regulation features.

4. Data Collection Timeline

Passive smartphone use data were continuously recorded throughout the study.

The original protocol specified pre- and post-intervention comparisons. The following observational windows were defined for analysis:

- **T0 (Baseline):** 7 days before randomization
- **T1 (Early post-randomization)**
- **T2 (End of intervention phase)**
- **T3 (Post-intervention follow-up)**

Each time point corresponded to the median smartphone use across 7 consecutive days.

Total follow-up duration was 6 months.

5. Outcome Definition

The behavioral endpoint was objectively recorded total smartphone use.

It was operationalized as:

Median daily smartphone use (minutes per day) calculated across the 7 days preceding each assessment window.

Days without recorded activity were treated as missing and were not imputed.

The outcome definition remained unchanged throughout the study.

6. Sample Size

The initial sample size calculation was based on the questionnaire-based primary endpoint specified in the original protocol (effect size d = 0.30, α = .05, power = 85%, required N = 298).

A total of 143 participants were randomized.

The present manuscript reports results for the prespecified behavioral outcome derived from passive monitoring.

PART II. STATISTICAL ANALYSIS PLAN

1. Overview

All analyses were conducted using R (version 4.4.3).

Descriptive statistics for smartphone use were summarized using medians and interquartile ranges due to non-normal distribution.

Baseline group comparisons used the Mann–Whitney U test.

2. Refinement of the Statistical Analysis Plan

The original protocol specified pre- and post-intervention comparisons for the primary behavioral outcome.

Passive smartphone use data, however, were continuously recorded throughout the study period.

After completion of the intervention phase, and prior to conducting any inferential longitudinal analyses or fitting group-by-time interaction models, the research team refined the statistical analysis plan to leverage the full repeated-measures structure of the passive data.

Instead of aggregating smartphone use into two time points, four observational windows (T0–T3) were defined based on predefined study periods.

This refinement:

- Did not modify the outcome definition
- Did not modify study hypotheses
- Did not introduce new outcomes
- Did not alter the intervention protocol
- Was finalized prior to estimation of longitudinal mixed-effects models

Because this change concerned analytical strategy rather than study design or outcome selection, no update to the trial registry was required.

3. Data Preparation

3.1 Long Format Conversion

Data were reshaped into long format, with one row per participant per time point (maximum 4 observations per participant).

3.2 Time Coding

Time was coded in months since baseline to reflect actual assessment spacing:

- T0 = 0 months
- T1 = 0.25 months
- T2 = 5.75 months
- T3 = 6 months

Time was centered at 3 months (mid-intervention).

A quadratic time term was included to allow non-linear trajectories.

3.3 Covariate Standardization

Continuous covariates (age and baseline depressive symptoms) were standardized (z-scores) prior to modeling.

4. Primary Longitudinal Model

Longitudinal changes in smartphone use were analyzed using linear mixed-effects models (lme4, lmerTest).

Fixed effects included:

- Group (intervention vs control)
- Linear time (centered)
- Quadratic time
- Group × time interactions (linear and quadratic)
- Age (z-score)
- Baseline depressive symptoms (z-score)

Random effects:

- Random intercepts for participants
- Random slopes for linear time

General model form:

SmartphoneTime ~ group × time_c + group × time_c² + age_z + depression_z + (1 + time_c | ID)

5. Model Building Strategy

A hierarchical approach was used:

1. Random intercept model
2. Addition of quadratic time
3. Addition of random slopes
4. Comparison of correlated vs uncorrelated random effects

Model comparisons were conducted using maximum likelihood estimation (REML = FALSE) for nested model comparison.

Model selection was guided by:

- Akaike Information Criterion (AIC)
- Bayesian Information Criterion (BIC)
- Likelihood ratio tests
- Parsimony
- Stability of fixed-effect estimates

Final parameter estimates were obtained under the selected specification.

6. Assumption Checking

Although smartphone use was positively skewed at the raw level, model adequacy was assessed through:

- Standardized residual plots
- Q–Q plots
- Residuals versus fitted values

- Random-effects distribution inspection
- Influence diagnostics

No substantial violations of model assumptions were observed. No transformation of the dependent variable was applied.

7. Sensitivity Analyses

Alternative covariance specifications were evaluated:

- Independent residual structure
- Unstructured covariance (UN)
- Autoregressive residual correlation (AR[1])

Fixed-effect estimates remained stable across specifications.

8. Missing Data

Outcome data were analyzed using maximum likelihood estimation within the mixed-effects framework, allowing inclusion of incomplete repeated measures under the missing-at-random (MAR) assumption.

Predictors of missingness were evaluated. Because missingness was modest and associated primarily with baseline variables, MAR was considered plausible.

Covariate missingness:

- Age (n = 5)
- Baseline depressive symptoms (n = 4)

These were imputed using conditional mean imputation based on regression-derived prediction scores grouped into quartiles.

Sensitivity analyses excluding imputed cases yielded comparable results.