Study Protocol

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- Official Title: Mobile Self-Management Program Integrating Positive Psychology and Behavioral Activation for Stress Reduction in Young Adults: A Community-Based Randomized Controlled Trial
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- Brief Title: Mobile Self-Management Program for Stress Reduction in Young Adults
- Study Type: Interventional

1. Background and Rationale

In South Korea, young adults experience heightened stress stemming from academic and economic pressures, yet rates of treatment-seeking and service utilization remain low. Although mobile and online mental health programs have become increasingly available, few have been rigorously tested, particularly among non-clinical populations. This underscores the need to develop and validate evidence-based digital interventions. Stress during young adulthood is a critical mental health concern, closely linked with depression, anxiety, and diminished resilience. Mobile interventions offer accessible and scalable methods to support stress management and overall well-being. Both Positive Psychology (PP) and Behavioral Activation (BA) are empirically supported approaches that enhance psychological functioning and alleviate distress. The present study investigates the effectiveness of a mobile self-management program that combines PP and BA strategies to reduce stress and improve associated outcomes among young adults reporting elevated stress.

2. Objectives

This study sought to evaluate a mobile self-management program integrating Positive Psychology (PP) and Behavioral Activation (BA) as a mental health intervention for young adults in South Korea. The program was grounded in established theoretical frameworks and designed to (1) enhance positive emotional experiences, (2) help participants identify their personal strengths, (3) encourage engagement in strengths-based activities, and (4) support planning for a meaningful and fulfilling future. These goals drew on PP principles while incorporating BA techniques to promote and sustain positive affect and adaptive behaviors in young adults. Using a randomized controlled trial design, the study examined the program's effectiveness in improving psychological outcomes—including stress, depression, anxiety, and resilience—among young adults with elevated stress, as well as its usability and perceived quality.

Primary Objective:

- To evaluate whether a mobile self-management program integrating PP and BA reduces perceived stress in young adults with elevated stress.
- To assess whether the program improves depression, anxiety, and resilience.

Secondary Objectives:

- To evaluate usability and perceived quality of the mobile interventions.

3. Study Design

This study employed a randomized controlled trial with a wait-list control design to evaluate the effects of a mobile-based self-management program for young adults experiencing elevated stress in community settings in South Korea.

4. Study Setting

Participants were recruited nationwide in South Korea through both offline and online platforms. Recruitment sites included youth centers, mental health welfare centers, and a suicide prevention center. The intervention was delivered entirely via a mobile application, and outcome assessments were conducted online.

5. Eligibility Criteria

Inclusion Criteria:

- Age 19–34 years at the time of participation
- Proficiency in using digital devices
- Use of an Android-based smartphone or tablet
- Score ≥14 on the Perceived Stress Scale–10 (PSS-10)
- Provision of informed consent for random assignment

Exclusion Criteria:

- Score <14 on the PSS-10
- Declines random assignment

6. Interventions

Experimental: Intervention Group

Participants assigned to the intervention group received a text message with a link to install the *DodaMe* mobile self-management program, which integrates Positive Psychology (PP) and Behavioral Activation (BA). The intervention lasted eight weeks, consisting of:

- **Guided Phase (Weeks 1–4):** Weekly objectives included (1) enhancing positive affect, (2) identifying personal strengths, (3) applying strengths in daily life, and (4) planning for a positive future. Program activities involved emotional check-ins, gratitude journaling, mindfulness practice, positive behavioral tasks, and goal setting.
- **Self-Directed Phase (Weeks 5–8):** Participants voluntarily selected from 10 recommended activities tailored to their strengths to encourage continued engagement and self-management.

Assessments were completed in-app at baseline and at Weeks 2, 4, and 8.

No Intervention: Wait-list Control

Participants in the wait-list control group did not receive the intervention during the initial 8 weeks. Instead, they were asked to complete the same assessments at baseline, Weeks 2, 4, and 8 via survey links delivered by text message. After Week 9, participants were granted access to the *DodaMe* app.

7. Outcome Measures

Primary Outcome:

- Stress: Perceived Stress Scale–10 items (PSS-10, Korean version)
  Range: 0–40 (higher = greater stress)
  Time Frame: Baseline, Weeks 2, 4, and 8

Secondary Outcomes:

- Depression: Patient Health Questionnaire–9 items (PHQ-9, Korean version)
  Range: 0–27 (higher = more severe depression)
  Time Frame: Baseline, Weeks 2, 4, and 8

- Anxiety: Generalized Anxiety Disorder–7 items (GAD-7, Korean version)
  Range: 0–21 (higher = more severe anxiety)
  Time Frame: Baseline, Weeks 2, 4, and 8

- Resilience: Brief Resilience Scale (BRS, Korean version)
  Range: 1.0–5.0 (higher = greater resilience)
  Time Frame: Baseline, Weeks 2, 4, and 8

8. Sample Size and Randomization

A total of 261 individuals were screened. Of these, 50 were excluded (46 scored below 14 on the PSS-10, 4 declined randomization). The final sample included participants who provided informed consent and were assigned de-identified IDs.

Participants were randomized to either the intervention group or the wait-list control group using simple randomization (https://www.randomizer.org/). Randomization was conducted by a research assistant not involved in data collection or outcome assessment. The principal investigator remained blinded to the allocation process to minimize bias.

An a priori power analysis (G*Power 3.1, repeated-measures ANOVA) indicated a minimum of 128 participants (64 per group) was required to detect a medium effect ($f = 0.25$) with 80% power at $\alpha = 0.05$.

9. Data Collection and Management

Data were collected via the mobile application and online surveys. All data were de-identified at export, and participants were assigned unique IDs. Only the principal investigator and a designated data manager had access to the de-identified dataset.

All study records will be securely stored for three years after study completion in compliance with institutional and national guidelines. After this retention period, electronic files will be permanently deleted, and physical records securely destroyed.

10. Statistical Analysis Plan

All analyses will follow the intention-to-treat (ITT) principle, including all randomized participants with available data. Descriptive statistics will summarize baseline demographic and clinical characteristics.

Primary Analysis

- The primary outcome is perceived stress (PSS-10).
- Changes in stress scores across time points (Baseline, Weeks 2, 4, and 8) between the intervention and wait-list control groups will be examined using generalized estimating equations (GEE) with an appropriate correlation structure to account for repeated measures.

Secondary Analyses

- Depression (PHQ-9), anxiety (GAD-7), and resilience (BRS) will be analyzed in the same manner as the primary outcome.
- Effect sizes and 95% confidence intervals will be reported for all outcomes.

Handling of Missing Data

- Missing data will be addressed using multiple imputation methods, assuming data are missing at random (MAR). Sensitivity analyses will be conducted to assess the robustness of findings.

11. Adverse Events / Safety Monitoring

Although classified as minimal risk, safety procedures were implemented. All research staff were licensed mental health professionals. Participants were provided with direct contact information for the research team to report discomfort or adverse experiences.

Participants also received information about local mental health welfare centers and suicide prevention centers, with emergency contacts provided at enrollment. If severe depression, anxiety, or stress symptoms were reported, participants were promptly referred to appropriate mental health services.

12. Ethical Considerations

The study was reviewed and approved by the Institutional Review Board of The Catholic University of Korea, Medical center(No. MC23FNSI0059). Written informed consent was obtained from all participants prior to study entry. All participants provided written informed consent. Confidentiality and the right to withdraw without consequence were guaranteed. Participants in the wait-list control arm were granted access to the intervention after the study period.