

# **STUDY PROTOCOL**

## **Empowering Preschool Children with Personal Safety Skills: A Randomized Controlled Trial of a Multiple Intelligences-Based Education Program**

**Brief Title:** Empowering Preschool Children with Personal Safety Skills

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## **1. Background and Rationale**

Preschool children are vulnerable to preventable injuries due to limited hazard awareness and developing cognitive and motor skills. Unintentional injuries remain a substantial cause of morbidity and mortality in childhood. Early, structured personal safety education can promote protective behaviors and reduce risk in school and community environments.

Howard Gardner's Multiple Intelligences Theory (MIT) proposes that children learn through multiple intelligence domains (e.g., linguistic, visual-spatial, bodily-kinesthetic, musical, interpersonal). Designing safety education activities that address diverse learning styles may increase engagement and support durable learning. This study evaluates an MIT-based Personal Safety Education Program (PSEP) for preschool children.

## **2. Objectives and Hypotheses**

Primary objective: To evaluate the effectiveness of an MIT-based Personal Safety Education Program (PSEP) on preschool children's personal safety knowledge and skills.

### **Hypotheses:**

- H0: The MIT-based PSEP does not affect preschool children's knowledge and skill levels in personal safety.
- H1: The MIT-based PSEP increases preschool children's knowledge and skill levels in personal safety.

## **3. Trial Design**

Randomized controlled trial with two parallel arms (intervention vs control). Allocation was conducted at the classroom level (cluster by class) to reduce contamination among children who interact closely within the same class.

#### 4. Setting and Study Period

The study was conducted in a state-affiliated preschool in a district of a province in northern Turkey. The preschool provides half-day education (09:30–12:30 and 13:30–16:30). Classes typically include 18–20 children.

Study period: March 18, 2024 to May 14, 2024.

#### 5. Participants

##### **Inclusion criteria:**

- Children aged 4–5 years.
- Enrolled in the participating preschool.
- Able to understand and speak Turkish.
- Parental consent provided.

##### **Exclusion criteria:**

- Not within the target age range.
- No parental consent.
- Incomplete outcome data for primary analysis.

#### 6. Sample Size

A priori power analysis using G\*Power 3.1 indicated a minimum sample size of 54 participants to detect a medium effect size ( $f = 0.25$ ) for the group  $\times$  time interaction in a two-way mixed-design ANOVA ( $\alpha = 0.05$ ; power = 0.95). Allowing for potential attrition (~20%), the planned sample size was increased. The final analyzed sample comprised 60 children (30 intervention; 30 control).

#### 7. Recruitment and Participant Flow

A total of 150 children were initially assessed at the school. Forty children aged 3 years (two classes) were excluded, leaving six classes of 4–5-year-old children ( $n = 110$ ) as the eligible pool. Each class included approximately 18–20 children. To prevent interaction between groups, classes attending at different times were assigned to the intervention and control conditions. Through classroom-level randomization, four classes (two intervention, two control;  $n = 80$ ) were allocated. Due to post-test nonresponse and incomplete data, the final analysis included 60 children (30 per group).

#### 8. Randomization and Blinding

Randomization unit: classroom (cluster randomization).

Sequence generation and allocation: The preschool principal conducted a random draw to assign classes to intervention or control conditions.

Blinding: Parents were not informed of group allocation. Pseudonyms were assigned to children at pre-test and post-test. The dataset provided for statistical analysis did not label groups as intervention or control; groups were coded (e.g., Group 1/Group 2) during analysis.

## 9. Interventions

### **Intervention arm (Experimental): MIT-based Personal Safety Education Program (PSEP)**

The intervention consisted of eight interactive sessions (15–20 minutes each) delivered over five weeks (including a familiarization week). The program was developed by a child development specialist trained in MIT and a researcher specializing in child health and diseases, and was revised through expert review (one child development specialist and three pediatric nursing researchers).

Program topics included safe bicycle use, safe play practices, sun protection, hazard recognition, prevention of home accidents, stranger safety, what to do if lost, and school safety awareness. Materials included games, creative drama, music and movement, coloring/design activities, interactive questions, and age-appropriate videos/cartoons approved by a pedagogue.

### **Control arm: Routine preschool education**

Children in the control group continued routine preschool education without the PSEP during the study period.

## 10. Outcome Measure

Primary outcome: Personal safety knowledge and skills, measured using the Personal Safety and First Aid Subscale (PSFAS) of the Health Education Scale (Aydos & Tugrul, 2015). The PSFAS includes 25 items rated on a five-point Likert scale; higher scores indicate higher personal safety and first aid knowledge/skills.

Reliability: In this study, Cronbach's alpha was 0.930 (pre-test) and 0.960 (post-test).

## **11. Data Collection Schedule**

### **Pre-test:**

Baseline data collection prior to the intervention.

### **Post-test:**

Outcome assessment four weeks after completion of the education program.

Parents completed the demographic form and PSFAS on behalf of the child; forms were distributed and collected through teachers.

## **12. Statistical Analysis Plan**

Analyses were performed using IBM SPSS Statistics 27.0. Descriptive statistics summarized participant characteristics. Baseline group comparability was evaluated using chi-square tests for categorical variables.

Primary analysis: A two-way mixed-design ANOVA was conducted with time (pre-test, post-test) as the within-subject factor and group (intervention, control) as the between-subject factor. Bonferroni-adjusted pairwise comparisons were performed when appropriate. Assumptions were examined using Levene's test and Box's M test. Effect sizes were reported using partial eta squared ( $\eta^2p$ ) and interpreted as small (0.01), medium (0.06), and large (0.14). Statistical significance was set at  $p < 0.05$ .

## **13. Ethical Considerations**

Prior to the research, permission to use the scale in the study was obtained from the scale owner via email. Ethical approval was obtained from Bulent Ecevit University Human Research Ethics Committee (Date: 28.09.2023; No: 24). Institutional permission was obtained from the Karabuk Provincial Directorate of National Education (No: E-36771699-302.08.01-380832; Date: 22.11.2023). Parents who consented to their children participating in the research signed an informed consent form. All stages were conducted in accordance with the principles of the Helsinki Declaration.

## **14. Reporting**

The study procedures and participant flow were reported in accordance with the CONSORT 2010 statement for randomized trials.