STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Study Title: Vaginal Breech Birth Management: serious mobile game design and evaluation for midwifery students

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1. Background and Rationale

Vaginal breech birth (VBB) is now an infrequent clinical event; consequently, midwifery students have limited real-life learning opportunities. Serious games offer cost-effective, repeatable simulation experiences that can enhance knowledge acquisition. This study evaluates a bespoke mobile serious game designed to teach VBB management and compares it with traditional lecture-based instruction.

2. Aims

- To determine whether the serious mobile game improves short-term knowledge of VBB management compared with a traditional lecture.
- To compare knowledge retention at 14 days and 7 months post-intervention between groups.

3. Study Design

Prospective, parallel-group, randomised controlled quasi-experimental trial with pre-test/post-test assessments.

- **Setting**: Midwifery departments of two Turkish universities (Kocaeli University & Eskişehir Osmangazi University).
- **Duration**: February 2022 – December 2022 (follow-up to July 2023).

4. Study Population and Eligibility Criteria

Third-year midwifery students.

Inclusion:

- Completed "Normal Childbirth & Postpartum" course.
- Provide written informed consent.

Exclusion: Previous theoretical or practical training on breech presentation.

5. Interventions

5.1. Experimental Arm – "Game Group"

Students play the **Vaginal Breech Birth Management Serious Mobile Game** once (≈ 30–45 min) under supervised classroom conditions. Headphones supplied; individual play; no time limit.

5.2. Control Arm – "Lecture Group"

Traditional 45-min lecture covering identical VBB content, delivered by the same investigator with slides & discussion.

6. Outcome Measures

Type	Name	Description	Scale (range)	Direction
Primary	Vaginal Breech Birth Management Knowledge Test	47-item multiple-choice test assessing knowledge of trauma & management in VBB. Each correct answer = 1 point; **Total score 0–47**. No subscales; **higher scores = better knowledge/outcome**.	0–47 scores on a scale	Higher = better

Assessments at baseline (pre-test), Day 0 (immediately after intervention), Day 14, and Month 7.

7. Sample Size & Power Calculation

Using Day 0 pilot means (Game=40.5±4.2; Control=37.8±5.1), α=0.05, two-sided Mann–Whitney U, power=0.80 required **n=35 per group**. Allowing 10 % attrition, recruitment target set at 40 per group (total 80). Final analysed: Game=39; Control=40.

8. Randomisation and Allocation

Simple randomisation (1:1) using computer-generated list by independent statistician. Group assignment placed in sealed opaque envelopes; opened by researcher immediately before session.

9. Data Collection Procedures

Knowledge test administered on paper. Unique codes used instead of names. Data entered twice into SPSS 20.0; discrepancies resolved by audit.

10. Statistical Analysis Plan (SAP)

10.1. Primary Outcome Analysis

- **Between-group comparison (Day 0)**: Mann–Whitney U test.
- Report Median (IQR) & Mean ± SD.

10.2. Secondary/Exploratory Analyses

- **Within-group change over time**: Friedman two-way repeated measures ANOVA (pre, Day 0, Day 14, Month 7). Post-hoc Dunn-Bonferroni pairwise tests.
- **Between-group at Day 14 & Month 7**: Mann–Whitney U.

10.3. Assumptions & Checking

- Normality checked via Shapiro–Wilk; non-normal distribution anticipated ⇒ non-parametric tests chosen.

10.4. Handling Missing Data

Complete-case analysis. Participants with missing follow-up tests excluded from that specific time-point analysis; no imputation performed (anticipated < 5 % missing).

10.5. Software

IBM SPSS Statistics v20.0 (Armonk, NY, USA).

10.6. Interim Analysis

None planned; single-session educational intervention with minimal risk.

11. Ethical Considerations

Ethics approval: Kocaeli University Non-Interventional Clinical Research Ethics Committee (28 Jan 2022; GOKAEK-2022/02.11). Study conducted by Declaration of Helsinki. Written informed consent obtained. Data anonymised.

12. Data Monitoring & Safety

Minimal-risk educational study; no independent DSMB. Adverse events unlikely; any unanticipated problems to be reported to ethics committee within 7 days.

13. Administrative Information & Protocol Amendments

All substantial amendments approved by ethics committee and recorded in ClinicalTrials.gov history.