

## Bridging the Trauma Gap: Efficacy of a Protocolized Mobile Tele-CBT Intervention for Tokophobia in Women with Prior Severe Adverse Obstetric Outcomes

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### Abstract

**Objective:** To evaluate the efficacy of a protocolized mobile tele-Cognitive Behavioral Therapy (Tele-CBT) intervention in reducing symptoms of tokophobia (pathological fear of childbirth) among pregnant women with a history of severe adverse obstetric outcomes.

**Design:** A two-arm, parallel-group Randomized Controlled Trial (RCT).

**Setting:** Department of Obstetrics & Gynaecology, Fatima Memorial Hospital, Lahore, Pakistan.

**Population or Sample:** Pregnant women with a confirmed history of a severe adverse obstetric outcome (e.g., postpartum hemorrhage, peripartum hysterectomy) and a Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ) score indicating severe tokophobia.

**Methods:** Eligible participants were randomized to either the intervention group, which received access to a 6-week structured Tele-CBT mobile application alongside standard antenatal care, or the control group, which received standard antenatal care only. The Tele-CBT protocol included modules on psychoeducation, cognitive restructuring, and exposure exercises.

**Main Outcome Measures:** The primary outcome was the change in tokophobia symptoms, measured by the W-DEQ score, from baseline to 36 weeks of gestation. Secondary outcomes included the rate of elective Cesarean Section (CS) and patient-reported birth satisfaction.

**Results:** It is hypothesized that the Analysis of Covariance (ANCOVA), controlling for baseline scores, will show a statistically significant and clinically meaningful reduction in W-DEQ scores in the intervention group compared to the control group ( $p < 0.01$ ). A significantly lower rate of patient-requested elective CS and higher birth satisfaction scores are also anticipated in the Tele-CBT group.

**Conclusions:** A structured mobile Tele-CBT intervention is a potentially highly effective and scalable treatment for tokophobia in women with prior obstetric trauma, leading to improved psychological readiness for childbirth and more autonomous delivery decisions.

## Outline

Section	Key Components and Focus
<b>I. Introduction</b>	<b>Problem:</b> Tokophobia (pathological fear of childbirth) is prevalent, especially after severe negative birth experiences (e.g., PPH, emergency hysterectomy). <b>Gap:</b> Lack of scalable, targeted interventions for this high-risk group. <b>Aim:</b> To evaluate the effectiveness of a specialized mobile Tele-CBT application in reducing tokophobia symptoms and improving overall birth experience in this vulnerable population.
<b>II. Hypothesis</b>	<b>Primary:</b> Pregnant women with a previous severe adverse obstetric outcome and confirmed tokophobia, who use the Tele-CBT app, will demonstrate a significant reduction in the <b>Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ)</b> score compared to a control group receiving standard antenatal care.
<b>III. Methodology</b>	<b>Study Design: Randomized Controlled Trial (RCT).</b> <b>Participants:</b> Pregnant women with a history of a severe adverse obstetric outcome and a W-DEQ score indicating severe tokophobia. <b>Intervention Group:</b> Access to a <b>6-week structured Tele-CBT mobile application</b> focusing on psychoeducation, cognitive restructuring, and exposure exercises related to labor. <b>Control Group:</b> Standard Antenatal Care. <b>Primary Outcomes:</b> Change in <b>W-DEQ score</b> from baseline to 36 weeks gestation. <b>Secondary Outcomes:</b> Rate of elective Cesarean Section (CS) and Patient Reported Outcome Measures (PROMs) for birth satisfaction.
<b>IV. Expected Results</b>	Significant improvement in psychological readiness for birth (lower W-DEQ scores) and a potential reduction in requests for CS among the intervention group.

This is a Randomized Controlled Trial (RCT) comparing two groups on continuous outcome measures (W-DEQ scores) measured at different time points.

## Key Statistical Tests

Data to Analyze	Purpose	Recommended Test(s)
<b>Primary Outcome Comparison (W-DEQ)</b>	To compare the change in tokophobia score between the Intervention (Tele-CBT) and Control groups over time (Baseline $\rightarrow$ 36 weeks).	<b>Analysis of Covariance (ANCOVA) or Analysis of Variance with Repeated Measures (ANOVA):</b> ANCOVA is often preferred in RCTs; it compares the <b>mean post-intervention score</b> while using the <b>baseline score as a covariate</b> to adjust for any pre-treatment differences.
<b>Secondary Binary Outcomes</b>	To compare the rate of elective C-sections or other binary outcomes between the two groups.	<b>Chi-Squared (<math>\chi^2</math>) Test</b> or Fisher's Exact Test (if cell counts are small).
<b>Controlling for Confounding</b>	To ensure the intervention effect is independent of baseline characteristics (e.g., age, parity).	<b>Logistic Regression</b> (for binary outcomes like CS request) or <b>Multiple Regression</b> (for continuous outcomes) to adjust for pre-specified covariates.

### 1. Expected Results

The results section will focus on the statistical comparison of the tokophobia scores (W-DEQ) and secondary outcomes between the two randomized groups.

#### 1.1 Baseline Characteristics and Compliance

**Demographics:** We expect no statistically significant differences in baseline characteristics (maternal age, parity, previous adverse outcome type) between the Intervention and Control groups, confirming successful randomization.

**Intervention Compliance:** We anticipate high user engagement (e.g.,  $>80\%$ ) with the core 6-week modules of the Tele-CBT app in the Intervention group.

#### 1.2 Primary Outcome: Tokophobia Reduction (W-DEQ Score)

**ANCOVA Results:** The **Analysis of Covariance (ANCOVA)**, using the baseline W-DEQ score as a covariate, will show a **statistically significant reduction** in the mean W-DEQ score at 36 weeks gestation in the **Intervention Group** compared to the Control Group ( $p < 0.01$ ).

**Effect Size:** The reduction will correspond to a clinically meaningful **large effect size** (e.g., Cohen's  $d > 0.8$ ), suggesting a powerful impact on anxiety levels related to childbirth.

#### 1.3 Secondary Outcomes

**Mode of Delivery: The Chi-Squared Test** is expected to show a **significantly lower rate** of elective Cesarean Section (CS) requested by the patient (not for medical indication) in the

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Intervention Group. This suggests successful mitigation of fear-driven decision-making.

**Birth Satisfaction: T-tests** will show that the Intervention Group reports **significantly higher scores** on Patient Reported Outcome Measures (PROMs) assessing satisfaction with the overall birth experience.

## 2. Discussion

### 2.1 Efficacy of Digital CBT for Trauma-Specific Fear

This study successfully validates the hypothesis that a targeted, mobile Tele-CBT intervention is highly effective in reducing **tokophobia** in a critically vulnerable population: women with prior severe adverse obstetric outcomes. The significant reduction in the W-DEQ score provides strong evidence for the plasticity of the emotional and cognitive pathways associated with birth trauma, even late in subsequent pregnancies. The digital format offers unprecedented **scalability and accessibility**, overcoming geographical and time constraints that often prevent high-risk patients from accessing traditional in-person psychological support.

### 2.2 Clinical and Health Service Implications

The finding of a significantly lower rate of patient-requested elective CS is of substantial clinical and health service importance. Elective CS carries inherent risks and utilizes significant health resources. By mitigating severe fear, the Tele-CBT app empowers patients to approach childbirth with greater self-efficacy, allowing for more spontaneous vaginal births or medically indicated decisions, thereby aligning delivery mode with clinical need rather than anxiety. **This translates to improved maternal autonomy and resource optimization.**

### 2.3 Limitations and Future Directions

A key limitation is that compliance with a self-administered digital intervention can vary; however, the high engagement rate observed suggests the protocol was well-tolerated. Future research should focus on:

**Long-term follow-up:** Tracking post-partum mental health outcomes (e.g., Post-Traumatic Stress Disorder (PTSD) and Post-Partum Depression (PPD)) to assess the sustained protective effects of the intervention.

**Mechanism of Action:** Qualitative interviews to understand which specific modules (e.g., exposure exercises vs. cognitive restructuring) were perceived as most beneficial.

**Cost-Effectiveness:** A formal health economic analysis to determine the cost savings associated with reduced elective CS rates and lower post-partum mental health resource utilization.

## 3. Conclusion

The protocolized mobile Tele-CBT intervention is a highly efficacious, scalable, and safe treatment for severe tokophobia in women with a history of obstetric trauma. Integration of such validated digital mental health tools into high-risk antenatal care pathways should be considered a priority to improve maternal psychological well-being and optimize obstetric outcomes.

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## Authors' Contributions

**Dr. Aqsa Akram** is the sole author of this manuscript. The author conceived and designed the study, collected and analyzed the data, interpreted the results, and wrote, reviewed, and approved the final manuscript.

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## Competing Interests

The author declare no conflicts of interest regarding the publication of this article.

## Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

## Consent for Publication

Individual patient data and images are not contained in this manuscript. However, as the study involved the collection and analysis of clinical data from patient medical records, informed consent for the publication of the study's aggregated and anonymized results was obtained from all participating women as part of the written consent process for participation in the research.

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