

# Comparing Linking Approaches for Patient Reported Outcomes under Non-Normal Distribution: A Monte Carlo Simulation Study with Floor Effects & Latent Correlations

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## Introduction

- In the field of patient-reported outcomes (PROs), **linking** establishes a relationship between scores from different instruments.
- Few studies have systematically compared the performance of linking approaches under key factors such as latent correlation and floor effect.
- The aim of this study is to evaluate the three widely used linking approaches: (1) Unidimensional IRT, (2) Equipercentile, (3) Calibrated Projection, using a Monte Carlo simulation study under a wide range of conditions.

## Methods

A Monte Carlo simulation study was conducted to evaluate and compare the performance of the three linking approaches, in the context of linking PROMIS Anxiety and the Generalized Anxiety Disorder Scale (GAD-7).

### Data Generation

- Two-dimensional  $\theta$  was generated from a bivariate normal distribution  $N(0,1)$ , with a pre-specified latent correlation. To introduce floor effects,  $\theta$  falling below a specific quantile threshold as replaced with a value of -1.5.
- The response dataset for 27 PROMIS Anxiety items and 7 GAD-7 items were simulated under a Graded Response Model (GRM).
- 20 datasets (N = 1,000) were generated for each condition.

### Simulation Conditions & Evaluation Criteria

- Floor Effect (%): Equal / Unequal pairs (5%-50%, increments of 5%)
- Latent Correlations: 0.6 – 1.0 (increments of 0.05)
- Evaluation Criteria: Root mean squared error (RMSE)

## Results

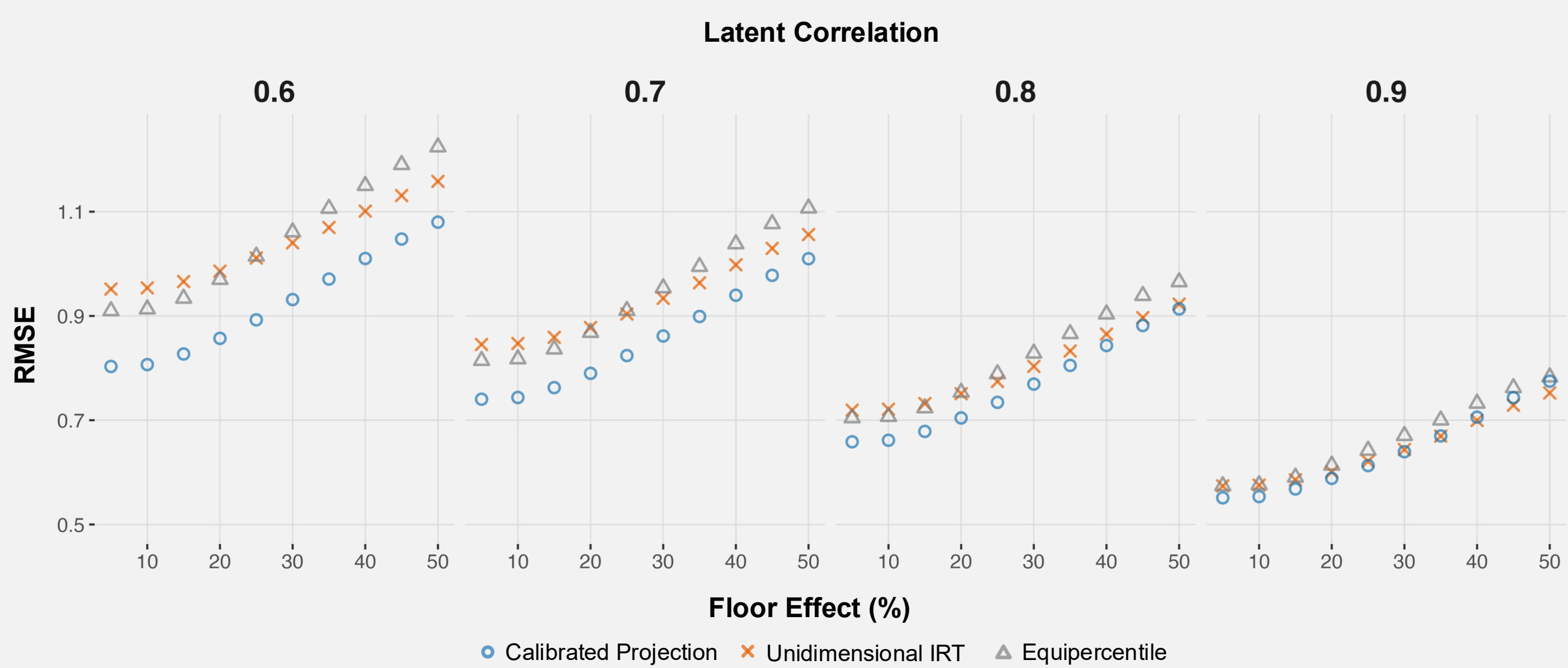


Figure 1. RMSE for Equal Floor Effect Proportion and Latent Correlations

### Equal Floor Effect Proportions

- Overall, RMSE increased with lower correlations and higher floor effect, indicating greater linking error.
- Differences across the three methods became more pronounced when correlations < .90.
- At  $\leq 20\%$  floor effect, error rose gradually;  $\geq 30\%$  floor effect, increase was steep.
- Calibrated Projection consistently outperformed the other methods, especially when latent correlations < .90.
- Equipercentile produced the highest RMSE when floor effects exceeded 30%.

### Unequal Floor Effect Proportions

- Again, RMSE increased with lower correlations and higher floor effect proportions.
- Regardless of floor effect pairs, all methods performed similarly when correlations > .90.
- Equipercentile was the most sensitive to floor effects, with the highest RMSE when both measures had  $\geq 30\%$  floor effects, while Unidimensional IRT demonstrated the highest error in the rest of the floor effect pairs.
- Across all pairs of floor effect, Calibrated Projection consistently outperformed the other methods.

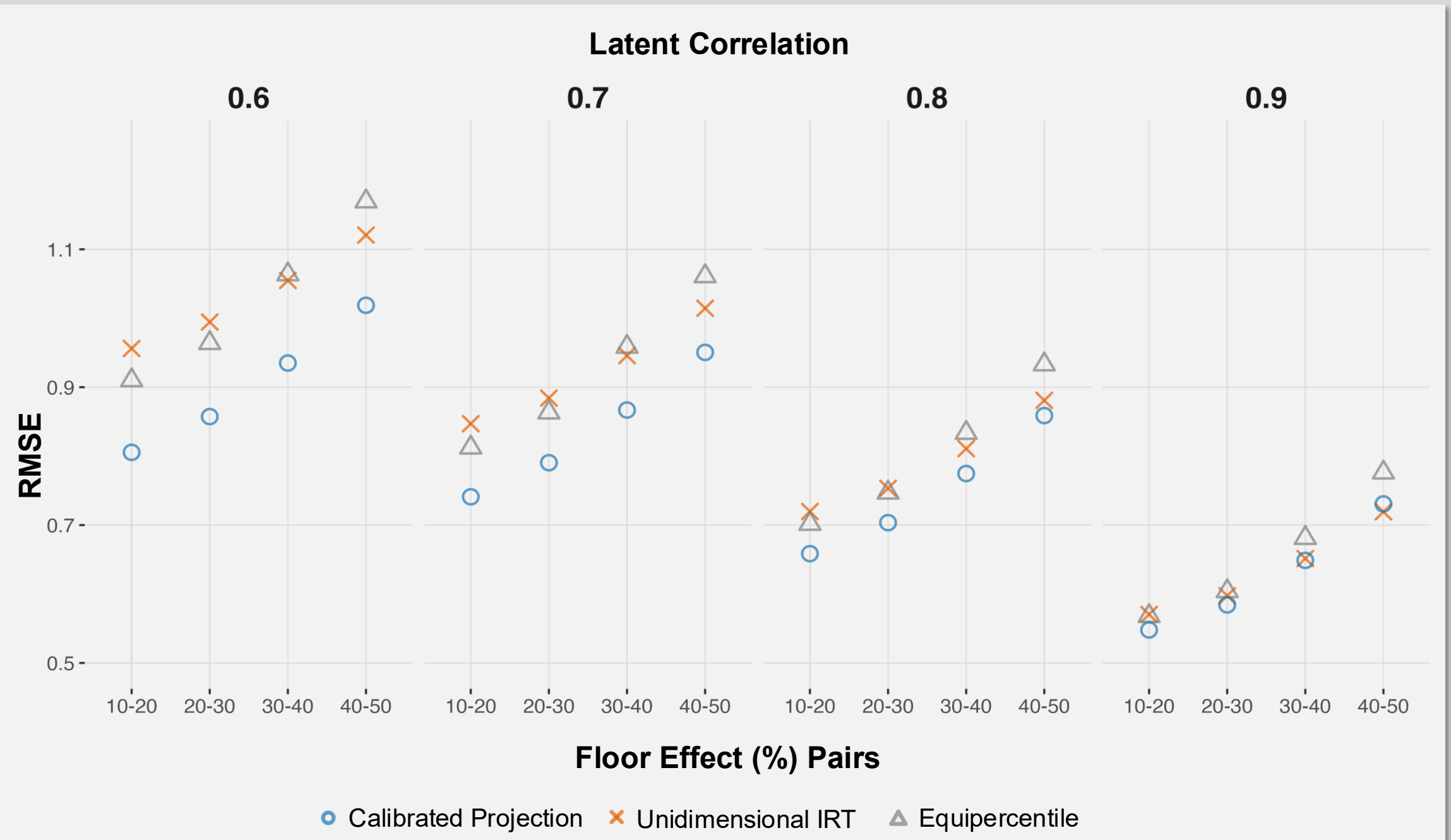


Figure 2. RMSE for Unequal Floor Effect Proportion and Latent Correlations

## Summary / Discussion

- **Calibrated Projection** explicitly models the latent correlations, making it more robust to the non-normal score distributions introduced by floor effects.
- **Equipercentile** was most sensitive to higher floor effects, as percentile mapping amplifies irregularities in heavily skewed distributions.
- **Unidimensional IRT** performed poorly under most unequal floor effect pairs, reflecting its reliance on unidimensionality assumption.

The findings of this study suggest caution is warranted when selecting linking approaches in PRO settings, particularly when floor effects exceeds 30% or under lower latent correlations.