## Reliability analysis of the Chinese version of the Functional Assessment of Cancer Therapy - Leukemia (FACT-Leu) scale based on multivariate generalizability theory

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#### Abstract.

Background: The Functional Assessment of Cancer Therapy-Leukemia (FACT-Leu) scale, a leukemia-specific instrument for determining the health-related quality of life (HRQQU) in patients with leukemia, had been developed and validated, but there have been no reports on the development of a simplified Chinese version of this scale. This is a new exploration to analyze the reliability of the HRQOL measurement using multivariate generalizability theory (MGT). This study aimed to develop a Chinese version of the FACT-Leu scale and evaluate its reliability using MGT to provide evidence to support the revision and improvement of this scale.

Methods: The Chinese version of the FACT-Leu scale was developed by four steps; forward translation, backward translation, cultural adaptation and pilot-testing. The HRQQL was measured for eligible inpatients with leukemia using this scale to provide data. A single-facet multivariate Generalizability Study (G-study) design was demonstrated to estimate the variance-covariance components and then several Decision Studies (D-studies) with varying numbers of items were analyzed to obtain reliability coefficients and to understand how much the measurement reliability could be vary as the number of items in MGT changes.

Results: One-hundred and one eligible inpatients diagnosed with leukemia were recruited and completed the HRQQL. measurement at the time of admission to the hospital. In the G-study, the variation component of the patient-item interaction was largest while the variation component of the item was the smallest for the four of five domains, except for the leukernia-specific (LEUS) domain. In the D-study, at the level of domain, the generalizability coefficients (G) and the indexes of dependability (0) for four of the five domains were approximately equal to or greater than 0.80 except for the Emotional Well-being (EWB) domain (>0.70 but <0.80). For the overall scale, the composite G and composite Φ coefficients were greater than 0.90. Based on the G coefficient and  $\Phi$  coefficient, two decision options for revising this scale considering the number of items were obtained; one is a 37-item version while the other is a 45-item version.

Conclusion: The Chinese version of the FACT-Leu scale has good reliability as a whole based on the results of MGT and the implementation of MGT could lead to more informed decisions in complex questionnaire design and improvement.

Keywords: Acute leukemia, Chronic leukemia, Quality of life, Evaluation studies, Multivariate generalizability theory, Refiability

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# **Functional Analysis In China**

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#### **Functional Analysis In China:**

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### **Table of Contents Functional Analysis In China**

- 1. Understanding the eBook Functional Analysis In China
  - The Rise of Digital Reading Functional Analysis In China
  - Advantages of eBooks Over Traditional Books
- 2. Identifying Functional Analysis In China
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
- 3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Functional Analysis In China
  - User-Friendly Interface
- 4. Exploring eBook Recommendations from Functional Analysis In China
  - Personalized Recommendations
  - Functional Analysis In China User Reviews and Ratings
  - Functional Analysis In China and Bestseller Lists

- 5. Accessing Functional Analysis In China Free and Paid eBooks
  - Functional Analysis In China Public Domain eBooks
  - Functional Analysis In China eBook Subscription Services
  - Functional Analysis In China Budget-Friendly Options
- 6. Navigating Functional Analysis In China eBook Formats
  - o ePub, PDF, MOBI, and More
  - Functional Analysis In China Compatibility with Devices
  - Functional Analysis In China Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Functional Analysis In China
  - Highlighting and Note-Taking Functional Analysis In China
  - Interactive Elements Functional Analysis In China
- 8. Staying Engaged with Functional Analysis In China
  - o Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Functional Analysis In China
- 9. Balancing eBooks and Physical Books Functional Analysis In China
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Functional Analysis In China
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Functional Analysis In China
  - Setting Reading Goals Functional Analysis In China
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Functional Analysis In China
  - Fact-Checking eBook Content of Functional Analysis In China
  - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks
- 14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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