



VALIDATION OF THE MODIFIED WHO TEMPLATE FOR INFORMED ASSENT, AND THE SELF-EFFICACY, DECISION-MAKING, AND KNOWLEDGE SCALES FOR UNDERSTANDING THE ASSENT PROCESS IN CHILDREN

Elizabeth Grace Perez, MD
Primary Investigator

Ma. Lucila Perez, MSc, FPPS MD
Supervising Investigator

BACKGROUND

Children belong to a vulnerable population in research. Despite this, there has yet to be a uniform informed assent and validated measures evaluating Filipino children and the factors associated with their decision to involve themselves in research.

OBJECTIVES

This study aimed to provide a validated informed assent as well as reliable and valid scales for evaluating self-efficacy, decision-making involvement, and knowledge in the assent process in the Philippine setting.

METHODS

A cross-sectional study (i.e. interview with cross sectional study) involving N= 57 children divided into 3 age groups: 1) 7-11 years old, 2) 12-14 years old, 3) 15-17 years old was conducted. A World Health Organization based informed assent was adapted and checked for readability. Linguistic validation was done for the Filipino informed assent, self-efficacy, decision-making involvement, and knowledge questionnaires. Face, content, and construct validity, as well as reliability of the three questionnaires were then assessed.

RESULTS

The Informed assent had an FRE score of 75.1 and F-K grade level of 6.2. Upon Filipino translation, key terms in assent process were noted to be difficult and alternative terms were obtained from the children. The self-efficacy scale and RDMIS-R/C tool had acceptable Cronbach alpha (0.77 and 0.808, respectively). All items in the self-efficacy scale were essential as per face validity. Only items 4 and 10 did not meet the CV critical (i.e. 0.571) for content validity; while, only items 2 and 4 were not significant as per Spearman Rho (0.05 two-tailed). Majority of items in the RDMIS-R/C were valid except for four items on face validity (i.e. 8, 12, 14n, 15), six items on CV critical (i.e. 2, 6, 8, 11, 12, 14n), and one item (i.e. 2) on Spearman Rho (0.05 two-tailed). The knowledge scale, although valid did not meet the criteria for reliability.

CONCLUSION

A linguistically validated assent form was made. Validation of the questionnaires, resulted in a 10-item self-efficacy and 14-item Decision-making involvement questionnaire which are both reliable. The 6 concepts in the knowledge scale was retained with a recommendation for item-per-item description per correct answer.