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Psychometric Evaluation of the Chinese Version of the Informed Consent Process Scale (ICPS-CV)

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Background: Informed consent is essential for the ethical conduct of clinical research and is a culturally sensitive issue. But, a measurable Chinese version of the scale to evaluate the informed consent process has not yet been explored in the existing literature.

Purpose: The current study aimed to develop and psychometrically test the Chinese version of the Informed Consent Process Scale (ICPS-CV).

Methods: Back-translation was conducted to develop the Chinese version of the questionnaire. A cross-sectional survey was administered, after which an exploratory factor analysis was conducted.

Participants: We recruited a total of 375 participants who had experience in signing an informed consent form.The criteria included in the study were the following: (a)the participants had experience of having signed a research ICF within the previous 3 years, (b) their age was over 20, and, (c) they were able to communicate in Chinese. Exclusion criteria were (a) inability to independently consent, and (b) inability to read or sign the study's ICF. In order to keep the heterogeneity high, we tried to reach institutions in three different regions (north, middle, and south) of Taiwan. This study was approved by two Institutional Review Boards, and the autonomy of the participants was respected.

Results: The ICPS-CV is composed of 3 factors with 23 items. Three factors extracted through EFA, including 'Understanding of the research', 'Trust and confidence', and 'Doubt and uncertainty', explained 52.954 % of total variance. Cronbach's αcoefficients of the ICPS-CV total scale was .917, and of three subscales were .925, .865, and .713, respectively.

Conclusion: The ICPS-CV is composed of 3 factors with 23 items. Three factors extracted through EFA, including 'Understanding of the research', 'Trust and confidence', and 'Doubt and uncertainty', explained 52.954 % of total variance. Cronbach's αcoefficients of the ICPS-CV total scale was .917, and of three subscales were .925, .865, and .713, respectively. These findings corroborate previous studies showing participants had too little understanding on the Informed Consent Forms they signs. Our study indicated good internal consistency for this Chinese version instrument. The results were found worthy of further testing and application.

Title:
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Keywords:
factor analysis, informed consent and instrument psychometric evaluation

References:

1. Falagas ME, Korbila IP, Giannopoulou KP, et al. Informed consent: how much and what do patients understand? *Am J Surg* 2009; 198: 420-435.
2. Tam NT, Huy NT, Thoa LTB, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. *Bull World Health Organ* 2015; 93: 186-198H.
3. Sanchini V, Reni M, Calori G, et al. Informed consent as an ethical requirement in clinical trials: an old, but still unresolved issue. An observational study to evaluate patient's informed consent comprehension. *J Med Ethics*2014; 40: 269-275.
4. HalkoahoA, PietilÃ¤ AM, Ebbesen M, et al. Cultural aspects related to informed consent in health research: a systematic review. *Nurs Ethics* 2016; 23(6):698-712.
5. Sauro J. 4 steps to translating a questionnaire. measuringu.com/blog/translation.php(2014, accessed 4 February 2015).
6. Ferketich S. Focus on psychometrics: Aspects of item analysis. *Res Nurs Health* 1991; 14(2): 165-168.
7. Hayton JC, Allen DG and Scarpello V. Factor retention decisions in exploratory factor analysis: a tutorial on parallel analysis. *Organ Res Methods* 2004; 7(2): 191-205.
8. Field A. *Discovering statistics using SPSS for Windows.* London: Sage, 2000.
9. Schenker Y, Fernandez A, Sudore R, et al. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. *Med Decis Making* 2011; *31*(1): 151-173.
10. Wade J, Donovan J, Paramasivan S, et al. Evaluating best practice in informed consent discussions: a new method of evaluating information provision and patient understanding during trial recruitment consultations. *Trials*2013; *14*(Suppl 1): O70.
11. Farrell EH, Whistance RN, Phillips K, et al. Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. *Patient Educ Couns* 2014; 94; 20-32.
12. Susilo AP, Van Dalen J, Scherpbier A, et al., Nurses' roles in informed consent in a hierarchical and communal context. *Nurs Ethics*2013; 20(4): 413-425.
13. Susilo AP, Van Dalen J, Chenault MN, et al. Informed consent and nurses' roles: a survey of Indonesian practitioners. *Nurs Ethics*2014; 21(6): 684-694.
14. Sherlock A and Brownie S. Patients' recollection and understanding of informed consent: a literature review. *ANZ J Surg* 2014; 84(4): 207-210.
15. Krumholz HM. Informed consent to promote patient-centered care. *JAMA* 2010; 303(12): 1190-1191.
16. Kerssens, JJ, Bensing, JM, Andela, MG. Patient preference for genders of health professionals. *Social Science and Medicine* 1997: 44(10): 1531-1540.
17. Caldow, J Bond C, Ryan M et al. Treatment of minor illness in primary care: a national survey of patient satisfaction, attitudes and preferences regarding a wider nursing role. *Health Expectations* 2007: 10(1): 30-45.
18. Alpers, L-M. Distrust and patients in intercultural healthcare: A qualitative interview study. *Nursing Ethnics* 2018: 25(3): 313-323.
19. Beach, MC, Eboni, GP, Gary, TL, et al. Cultural competency: A systematic review of health care provider educational interventions. *Med Care* 2005 43(4): 356-373.
20. Somnath, S. The relevance of cultural distance between patients and physicians to racial disparities in health care. *Journal of General Internal Medicine* 2006: 21(2): 203-205.

Abstract Summary:
Informed consent is essential for the ethical conduct of clinical research and is a culturally sensitive issue. However, a measurable Chinese version of the scale to evaluate the informed consent process has not yet been explored. The study aimed to develop and psychometrically test the Chinese Informed Consent Process Scale.

Content Outline:
I. Introduction

A. Informed consent is essential for the ethical conduct of clinical research and is a culturally sensitive issue.

B. A measurable Chinese version of the scale to evaluate the informed consent process has not yet been explored.

II. Body

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Supporting point#1 Gaps in the existing literature

Supporting point#2 Purpose of the study

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b) Testing of the Chinese version of Informed Consent Process Scale

MainPoint#2 Method of the Study

Supporting point#1

a) Data Collection

b) Data Analyses

Supporting point#2

a) Statistic Findings

b) Major Themes

Main Point#3_Discussion

Supporting points #3

a) Chinese version instrument

b) Understanding of the research

c) Trust and confidence

d) Doubt and uncertainty

III. Conclusion

A. The psychometric results indicated good reliability and validity for this newly constructed instrument

B. The new instrument can be employed to measure the informed consent process before patients signed the consent forms.

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