

Development and evaluation of psychometric properties of a common module for the quality of life scale of living organ donors (QLSLOD-CM V1.0) based on liver donors

Yue-Xian Shi¹, Hai-Ming Zhang², Jing Chen³, Hao-Hao Li³, Ming-Ming Yu¹, Yin-Hui Jin^{4,5}, Ya-Qi Huang⁶, Meng Sun¹, Wei Gao³, Shao-Mei Shang¹

¹School of Nursing, Peking University, Beijing 100161, China;

²Liver Transplantation Center; Clinical Center for Pediatric Liver Transplantation; National Clinical Research Center for Digestive Diseases, Beijing Friendship Hospital, Capital Medical University, Beijing 100050, China;

³Department of Liver Transplantation, Tianjin First Center Hospital, Tianjin 300192, China;

⁴Center for Evidence-Based and Translational Medicine, Zhongnan Hospital of Wuhan University, Wuhan, Hubei 430071, China;

⁵Center for Evidence-Based and Translational Medicine, Wuhan University, Wuhan, Hubei 430071, China;

⁶School of Nursing, Tianjin Medical University, Tianjin 300070, China.

A living donor is by definition a healthy person without significant medical problems. However, procedures involved with donation expose living donors to risks from a number of complications and donor safety remains an issue of concern.^[1] Complications can affect the donor's quality of life (QoL) to varying degrees and scales or questionnaires are commonly used to assess their QoL. Based on existing literature, we found three types of instruments for assessing living donors' QoL: (1) generic instruments, (2) disease-specific instruments, and (3) self-developed instruments (scales, questionnaires, survey lists). Generic instruments (eg, 36-item short form health survey),^[2] may not adequately measure some specific problems and/or minor issues associated with the organ transplant surgery. Disease-specific instruments, (eg, chronic liver disease questionnaire), originally developed for use with particular diseases,^[3] may lack precision and comprehensiveness in assessing the QoL of donors from healthy individuals. Self-developed instruments can resolve some of the deficiencies associated with generic and disease-specific instruments.^[4,5] In China, there remains a lack of consensus with regard to an effective scale that is specific for assessing the QoL of living organ donors.

By combining a common module and organ donation type specific module, we developed the Chinese QoL assessment scale system for living organ donors. The common module can be used to evaluate the QoL for all types of organ

donors, which plays a more important role in this evaluation as it serves as the core of the system. Therefore, here we report on the development of the common module and evaluate its psychometric properties. This scale was formulated based on the 6 domains of the World Health Organization QoL assessment.^[6]

A cross-sectional study was conducted in two hospitals, that is, the Tianjin First Center Hospital and Beijing Friendship Hospital, Capital Medical University, China. This study was conducted in accordance with the *Declaration of Helsinki* and approved by the Peking University Institutional Review Board (No. IRB00001052-19005). All participants signed informed consent forms after receiving a detailed explanation. The investigation was divided into two stages, with the first being pre-test and the second, psychometric properties evaluation. Living liver donors older than 18 years and at a minimum of 1-month post-donation were included in the investigation.

Seven steps (identification of the study objective, establishment of the study group, generation of the item pool, initial item selection and revision, item rescreening, psychometric properties analysis and modification and improvement) were used to develop the common module of the QoL scale, with all being used over the period from October 2015 to February 2019 [Figure 1].

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Correspondence to: Dr. Wei Gao, Department of Liver Transplantation, Tianjin First Center Hospital, Tianjin 300192, China
E-Mail: gaowei_tjch@163.com;
Prof. Shao-Mei Shang, School of Nursing, Peking University, Beijing 100191, China
E-Mail: mei916@263.net

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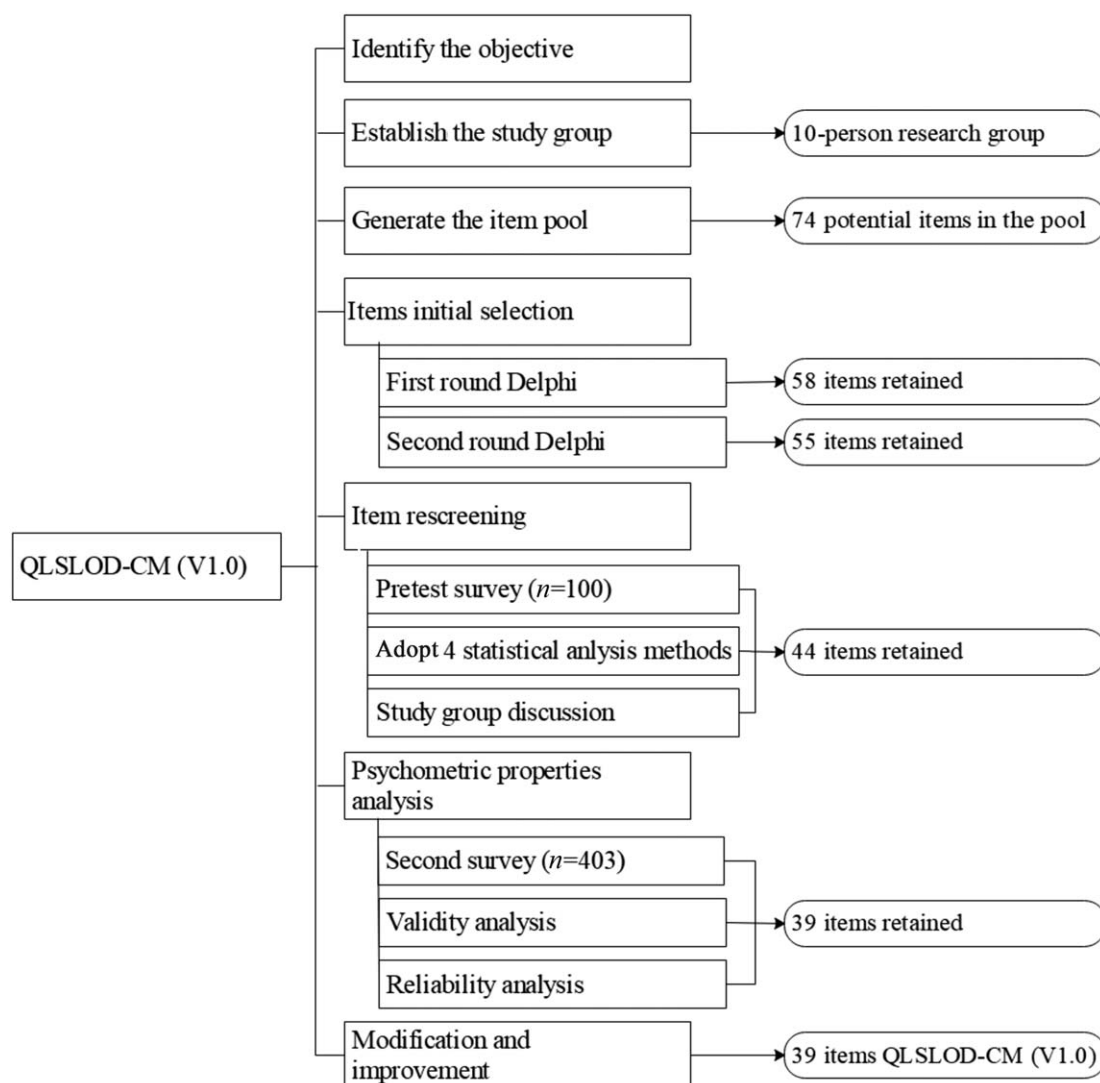


Figure 1: Summary of the development of the QLSLOD-CM (V1.0) for living organ donors. QLSLOD-CM (V1.0): Quality of life scale for living organ donors-common module, version 1.0.

Initially, 74 potential items in the item pool were generated based on previous research, interviews of living liver or kidney donors, suggestions of doctors and nurses, and discussions within the study group. Subsequently, both subjective and objective methods were adopted to select items from the pool. Two rounds of the Delphi method involving consults with 32 experts were performed to assess the correlation, wording, and relevance of each item. Fifty-five items were finally screened from the item pool for further evaluation, and an initial version scale of the common module, dubbed the quality of life scale for living organ donors-common module (QLSLOD-CM) was generated. A hundred participants who met the criteria were invited to complete this initial version of the scale. Four statistical approaches, that is, variation procedure, correlations, factor analysis, and cluster analysis were then used to rescreen the items and a revised 44-item QLSLOD-CM version was produced.

Psychometric properties of the revised QLSLOD-CM version were assessed with another 403 liver donors

completing the survey. An exploratory factor analysis (EFA) and Spearman rank correlation analysis (for scores with non-normal distributions) were performed to assess the structure validity. The Cronbach α coefficients and test-retest correlation coefficients were adopted to evaluate the reliability. Forty-four items were initially assessed by EFA and 12 structure factors were found to account for 61.03% of the total variance. Six items had small factor loadings (<0.4), so one item was modified and five of them were deleted from the scale. Five items loaded in the factors failed to meet our initially proposed potential structure and three items were adjusted according to the results of EFA. Cronbach α of the six domains ranged from 0.65 to 0.83 [Supplementary Table 1, <http://links.lww.com/CM9/A228>]. One hundred out of 403 liver donors repeated the scale test within 2 weeks and the results showed that the test-retest correlation coefficients (r) for the six domains ranged from 0.78 to 0.92 [Supplementary Table 1, <http://links.lww.com/CM9/A228>]. Correlations between the 39 items and the overall score were statistically significant [Supplementary Table 2, <http://links.lww.com/CM9/A228>].

The QLSLOD-CM (V1.0) includes six domains covering 39 assessment items: (1) physical function, (2) psychological state, (3) level of independence, (4) social relationships, (5) relationship with their environment, and (6) personal beliefs. This Chinese version of the scale fulfills our requirements and possesses an acceptable level of validity and reliability. We believe our QLSLOD-CM (V1.0) could be widely used in all types of living organ donors as applied for both pre- and post-donations (34 items suitable for pre-donation). One limitation of our study is that all participants included were living liver donors and may not be representative of other types of organ donors. Moreover, our relatively small sample size limited a full-scale assessment of psychometric properties. Currently, this investigation is under expansion with the inclusion of living kidney donors at multiple centers. The criterion validity, responsiveness of the QLSLOD-CM (V1.0) and confirmatory factor analysis will be determined in our future studies. Although the QLSLOD-CM (V1.0) is a Chinese version, a foreign language version could be readily produced with strict forward/backward translation and cross-cultural adapting procedures based on this scale. An evaluation of the reliability and validity of this scale will be required as applied for use in different cultural contexts.

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Conflicts of interest

None.

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