Abstract

Background: According to general ethical and legal principles, valid consent must be obtained before starting any procedure.

Objectives: Due to the lack of a standard tool for assessing patients' capacity to consent to medical treatment in Iran, the present study was carried out aiming to devise a Persian version of a cross-cultural adaptation of the MacArthur competence assessment tool.

Patients and Methods: By reviewing different methods of cultural translation and adaptation for assessment tools, and due to the lack of consensus on its processes, we selected Wild's model as one of the most comprehensive methods in this regard. Wild's (2005) 10-stage model includes preparation, forward translation, reconciliation of the forward translation, back translation of reconciliation, back translation review, cognitive debriefing and cognitive review, and finalization, proofreading and final reporting. Using this model, we translated the MacArthur assessment tool and made it adaptable to Iranian patients.

Results: The MacArthur assessment tool is not dependent on any specific culture and language. As a result, if translation and its scientific adaptation are done based on an integrated and detailed model, the tool can be used for every culture and language. In other words, this tool is not culture-specific; so, it is applicable in cases where a translation is needed, and it can be culturally adapted to suit different societies.

Conclusions: In the present study, we are able to focus on and prove the efficacy and benefits of this measurement tool.

Keywords: Decision-Making Capacity, Competency, Assessment Tools for Treatment, Translation and Cross-Cultural Adaptation, Macarthur Assessment Tool

1. Background

Patient consent is required for all medical procedures; prevention, diagnostic, and therapeutic interventions; and clinical research (1). According to general ethical and legal principles, valid consent must be obtained before starting any procedure, in recognition of the patient's right to autonomy. To validate this consent, it must be obtained voluntarily by an appropriately informed patient who has the capacity to agree to the specific intervention. To be appropriately informed, the patient should be prepared with all necessary information in a way that he or she can understand. If any of these elements are not met, the consent is deemed invalid (2). With the above in mind, it can be inferred that consent has three components: disclosure, which refers to the provision of relevant information by the clinician and its comprehension by the patient (3); capacity, meaning that the patient has the ability to understand the relevant information and to appreciate the reasonably foreseeable consequences of his or her decision; and voluntariness, which refers to the patient's right to come to a decision freely, without force, coercion, or manipulation (4).

Our study covers patients' decision-making capacity as one of the components of informed consent. Although decisional capacity of subjects in different studies shares something in common with our study, in terms of dimension and components (5), however, this issue is beyond the scope of our study because there are other specific tools in this respect (6). Whenever we speak of "decision-making capacity" throughout the study, we are referring to a patient's capacity to consent to treatment. Patient decisional capacity is a complicated, multidimensional, and controversial matter (7). As far as ethics are concerned, judgment about decision-making capacity involves considerations and interactions between two
issues: 1, respecting the autonomy of the patients who are capable of making their own decision; 2, protecting beneficially incapable persons in the process of making decisions. Consequently, we seek to balance these different moral concerns (8).

Capacity assessment is one of the significant priorities for nurses, physicians, and other care providers in all wards, because the establishment of incapacity can deprive an individual of many of his or her fundamental rights (9). According to legal and bioethics experts, decisional capacity is generally composed of at least four components: 1, understanding information relevant to the decision, 2, appreciating the information (applying the information to one’s own situation), 3, using the information in reasoning, and 4, expressing a consistent choice (10). Despite the availability of various guidelines and tools, there is no single clinically accepted standard for decision-making capacity. Current medical textbooks have discussed this issue only very briefly and do not help physicians with determining its presence or absence (11). So far there is no consensus on how informed consent to treatment should be measured, what we currently have is a hodgepodge of practices. There is no gold standard and integrated experimental data in this regard (10).

Some believe that, although clinical judgment is not reliable, it can be treated as a gold standard for determining decision-making capacity. The application of different measurements in this regard, not as a measuring tool, but as a subsidiary tool, can be beneficial in assessing capacity (12). On the contrary, there are others who insist on the availability of standardized instruments and believe that many informal measurements performed by clinicians are subjective and unreliable (13). It seems that physicians can reach optimized outcomes in clinical judgment by means of tools, resorting to a patient’s history, and conducting clinical interviews (14). Cognition is one of the main components of capacity, so any disease or treatment that threatens cognition may therefore impair decision-making capacity. In other words, any disease or therapy that weakens cognition may also weaken capacity, and the chance of reduced capacity is related to the severity of cognitive impairment.

Four high-risk groups for impairment at decision-making capacity include the following: 1, patients with traumatic brain injuries; 2, patients with psychiatric illnesses (e.g., schizophrenia, bipolar disorder, and unipolar major depression); 3, patients with neurodegenerative diseases (e.g., dementia, Alzheimer’s disease, and Parkinson’s disease); 4, hospitalized patients and older adults are also at risk due to cognitive impairment from chronic diseases, cognitive aging, and delirium.

Patients with traumatic brain injury (TBI) across a range of severities are at risk for impairment in capacity that may improve over time. The severity of these injuries generally correlates with the severity of impairment in decision-making capacity.

In a cross-sectional study including 28 patients with mild TBI, impairments in decision-making abilities were present in less than 30%. By contrast, impairments were present in half of those with complicated mild TBI and more than 50 percent of those with moderate to severe TBI. At a six-month follow-up, all three groups showed recovery in performance, although some patients with moderate to severe TBI appeared to have impairments. Recovery of capacity was proven to be associated with baseline measures of executive function and working (short-term) memory (15). Traumatic brain injury is one of the causes that results in a loss of consciousness. These injuries lead to changes in cognition, social and behavioral status, and often have an immediate and devastating impact on medical and financial decisions that may last long after hospitalization. Medical staff must deliver the sustaining life support care without the participation of patients and their families. After the patient is stabilized, his or her family is then involved in medical decisions. These decisions involve life support, resuscitation, removing ventilators, changes in medications and surgeries (16). Therefore, continuous patient monitoring, in terms of patient capacity in making decisions, is essential during the entire processes of treatment (17). At least a six-month period of monitoring is required in this respect (18).

Studies have shown that one-third of all patients with mild traumatic brain injuries (MTBI) had compromised capacity ratings. This suggests that medical decision capacity in TBI must be judiciously considered in all patients, including MTBI patients with normal findings on routine neuroimaging (17).

2. Objectives

As previously mentioned, the selection and availability of a tool that can help physicians measure patient decisional capacity is both necessary and essential. Of course, this instrument would be useful for all patients, but it is even more practical and useful for high-risk groups such as those with neurodegenerative diseases, psychiatric conditions, and TBI.

3. Patients and Methods

In recent years, a variety of assessment tools have been introduced to address decision-making capacity (13). These tools are applied for screening competent and incompetent patients. For instance, the mini mental state examination (MMSE) is one of the tools used to distinguish those patients that deserve more detailed examination. A score of less than 19 identifies incompetent patients, while a score more than 26 confirms patient competency. This tool seems to be useful for patients at the two ends of the range of competence or incompetence. Since today we are faced with more formal tools for promoting the validity and reliability of assessments, we should follow them. The assessment tool known as
the MacArthur competence treatment is the most common tool that provides information specific to a patient’s decision-making situation. The clinician can ultimately reach a judgment about competence or incompetence by integrating the results with other data (19).

In the last two decades, various tools have been developed for assessing capacity to consent to treatment. The MacArthur competence assessment tool for treatment (MacCAT-T) has received the highest rating and been considered the best choice for measuring capacity to consent to treatment (20). Although the MacCAT-T tool has appeared as the most comprehensive assessment tool for decision-making capacity, it reveals no significant correlation between its results on decision making capacity and the results of neuropsychological testing instruments in patients with dementia (21).

In 2010, some Chinese researchers compared neuropsychological tests like the MMSE with the MacArthur tool and concluded that these tests were not capable enough to assess some dimensions of decision-making capacity, such as reasoning (22). According to MacCAT-T, the four aspects of decision-making capacity are scored as follows: 1, understanding of disclosed information (0 to 6); 2, deep understanding (appreciation) of the importance of that information (0 to 4); 3, reasoning ability for different choices (0 to 8); and 4, the ability to communicate a choice (0 to 2). The MacCAT-T does not provide a total score; due to this fact, deficits in one dimension might be translated as incompetence. Further, there is no specific cutoff score conveying competence or incompetence (23).

The MacCAT-T was first developed in 1998, after eight years of study and research. This tool was introduced in a 35-page paper (accompanied with an eight-page form to be completed for each patient). Implementation of MacCAT-T involves four stages: 1, preparation: The physician sorts and records in the MacArthur consent form the essential information about the patient’s diagnosis, probable duration of disease with or without treatment, disease characteristics, nature of proposed treatments, advantages and risks of proposed treatments, and so on; 2, interview: After a description and disclosure of the recorded data in the report form, understanding and appreciation, reasoning, and treatment choice expression are evaluated; 3, scoring: Based on both patient responses recorded in the report form and scoring guidelines, a score summary is recorded for each dimension; 4, interpretation: We are not able to make judgments about the absence or presence of consent capacity in patients based on a score summary, so clinical data, including an examination of the patient’s mental status, psychiatric and neurologic conditions, and previously made decisions are all reviewed to interpret a unique result (24).

To find a valid Persian tool for assessing patient capacity to consent to treatment, we thoroughly searched existing Persian databases. We found only one translated tool, along with one particular study that was performed on patients admitted to surgical wards of the Tehran Imam Khomeini Hospital, by means of the Persian version of Aids to Capacity Evaluation (ACE). This semi-structural tool allows physicians to classify patients into one of four categories: definitely incapable, probably incapable, probably capable, and definitely capable. The benefits of this tool include its short-term period of test implementation (nearly 12 minutes) and its adaptability to every patient with any impairment (25). Consequently, if the patient is put in the probably capable or probably incapable groups, we are not finally convinced of his or her competence or incompetence.

Cultural adaptation is considered one of the means for the adaptive use of measuring tools from one language and culture to another. Though the cultural adaptation process is difficult and time-consuming, it is beneficial and valuable. This process should be properly directed to contribute to a detailed, understandable, and culturally suitable and valid product for all users. Translators should be familiar with the outline of the project, including its aims and subjects (26). In order to use a tool or questionnaire in a new culture, language, and/or country, the use of both translation and cultural adaptation is essential, and the process should aim to reach equivalence between the original source and the target questionnaire (27). This present study aims to evaluate the Persian version of cross-cultural adaptation for the MacArthur competence treatment.

3.1. Cross-Cultural Adaptation

Through adaptation, we aim to maximize the cultural appropriateness of an instrument and to minimize its bias. Adaptation is also referred to a procedure of transferring an instrument from one culture to another. Despite the traditional concept of translation, this new concept insists that transferring a test to a new cultural and linguistic context involves more than merely translating an instrument (the linguistic equivalent of a version in another language) (28). One efficient solution for the absence of non-English instruments is to translate and adapt them to other languages and cultures (29). Cultural adaptation is the first and main step in translating foreign instruments, which is done to ensure the proper application of the instruments in other societies. If the cultural adaptation and the translation process are appropriately performed, a common language is developed that makes us able to compare the results of different studies (30). Chart 1 depicts the process of developing new instruments and shows the use of foreign research instruments.

There seems no consensus on the cultural adaptation for instruments in the extant literature (31). Some researchers have followed world health organization guidelines (32), including five stages: forward translation, backward translation by a panel of experts, a practical test of the instrument in the targeted population, a cognitive inter-
view, and preparation of the final copy (33). Some others have offered six stages, including translation into the target language, a synthesis of the versions translated, evaluation of the synthesis by experts, evaluation by the target population, back translation, and a pilot study (34). On translating into the target language, some others propose an expert committee comprised of methodologists, health professionals, and translators (forward and back-translators) to authenticate the new version (31).

3.2. Methodology

By reviewing different methods, we selected Wild’s (35) 10-stage model, as one of the most comprehensive methods for validating the MacArthur assessment tool. This procedure is given in Table 1.

Other researchers, such as Khorami Markani, in his “Developing and measuring psychometrics of oncology nurses’ spiritual wellbeing scale” (36), Hassanvand, in her “Translation, cultural adaptation, and reliability of nursing students’ belongingness scale” (37), and Rosnah et al., in their “A systematic translation and cultural adaptation process for three-factor eating questionnaire” (38) have also used Wild’s model for translation and cultural adaptation. Some examples of changes made in the cultural adaptation process for the MacArthur tool are given as follows: in stage three, the term “appreciation” was first translated as “understanding,” but we have agreed on the term “deep understanding” instead. For the term “logical consistency,” we selected the same equivalent in Persian; instead of “consequential reasoning,” we used “final reasoning,” and the term “generating consequences” was replaced with “achieving consequences.” We should also mention that, in stage seven, two patients were excluded because of their unwillingness to participate in the study.

Figure 1. Processes of Designing and Development of the New Instruments
4. Results

When investigating databases about the non-English versions of the Mac-CAT-T, we found two related studies. The first one was done in 2013 in Greece, by Bilanakis et al. (39). It featured the Mac-CAT-T translated and back translated between English and Greek. They finally concluded that the Greek version was standardized and could be used in clinical settings. The above-mentioned researchers used their instrument without cultural adaptation. In reply to our e-mail, the first author of the article stated that cultural adaptation had not been considered in the Greek study. The second study, done in Spain in 2014, was about the validity of the Spanish version of the Mac-CAT-T (40). Due to the unavailability of its English version, the methods of this work seem somehow vague. However, this study did consider translation and cultural adaptation of the instrument.

Translation and cultural adaptation of different measures are advantageous and essential for other cultures and contribute to the scientific progress and promotion of countries. Nevertheless, application of appropriate scientific methods is of great concern. In this study, we successfully came to a consensus regarding a method of translation and cultural adaptation for different measuring tools. It is obvious that the more detailed and scientific care with which this matter is treated, the more confidently it will be used by researchers. In search of measuring tools for patient decision-making capacity, we encountered a variety of tools, some of which appear to fail to assess the entire dimensions of capacity. Therefore, the competence or incompetence of some groups is not definitely specified. We used the MacArthur competence assessment tool for treatment, the Mac-CAT-T, in this study. Mac-CAT-T can assess all facets of decision-making capacity by means of a clinical patient interview and history review, so that patient decision-making capacity is determined at a certain time for a certain treatment.

Since the Mac-CAT-T process takes at least 90 minutes per patient (or longer, in some cases), and because the physician needs to be trained prior to administering the test, it seems that this tool is one of the best methods for judging patient competence. Although this process is time-consuming and involves a physician’s specific training, the use of this tool is most beneficial, especially on occasions when we are not certain about a patient’s decision-making capacity. In addition, it can be resorted to legally in the courts. For instance, if the patient or attendants complaints about his or her decision-making capacity, we can refer to the case of the interview performance and tool implementation, asserting whether that very patient has decision-making capacity or not in that specific time and for the specific treatment. This tool has been approved by scientific societies in the United States, and is performed practically in many hospitals. The standardized Mac-CAT-T has obtained full validity and reliability.

**Table 1. Cultural Adaptation Processes of the MacArthur Competence Assessment Tool Based on the Wild’s Model**

| Stages    | Title                          | Description                                                                 |
|-----------|-------------------------------|-----------------------------------------------------------------------------|
| First     | Preparation                   | Pre-translation preparation, including e-mail correspondence with one of the main modelers of the Mac-CAT-T (Thomas Grisso), obtaining original version of the tool in 56 pages (comprised of eight pages of report forms), and obtaining a license to translate the tool into Persian from the related publications (Professional Resource Press) |
| Second    | Forward Translation           | Translating from the original language into the target language (Persian) by one of the researchers (A.S.) and two persons separately, both of whom are qualified in English |
| Third     | Reconciliation                | Combination and reconciliation of the three initial translations in one session and merging them into a single translation after modifying differences and conflicts. In some cases, we used opinions of other experts for deciding on equivalent words. |
| Fourth    | Back Translation              | Translation of the finally translated tool into English by a person qualified in English to ensure the accuracy of the Mac-CAT-T translation process in Persian. |
| Fifth     | Back Translation Review       | Matching the translated tool with its original version and detecting inconsistencies in the two tools based on comparison. Back translation is defined as a process for ensuring the match between the translated version and the original one. |
| Sixth     | Harmonization                 | Reviewing and correcting inconsistencies                                      |
| Seventh   | Cognitive Debriefing          | Implementation of the final tool on a 20-person group of patients hospitalized since 18 years longer in the psychological ward of Kargarnejad Hospital (Kashan University of Medical Sciences). The group included individuals with gender, social, and economic diversity tasked with reviewing the obviousness, clarity, and intelligibility of questions, removing ambiguities, detecting cultural differences in Iran, and testing equivalent words and patients’ cultural behaviors towards the tool. |
| Eighth    | Review of Cognitive Debriefing Results and Finalization | A majority of experts do not specifically separate this stage from other stages. Patients’ cognition and interpretation of the translated version is compared with that of the original version by the researcher to detect differences and make corrections and simplifications. |
| Ninth     | Proofreading                  | Final proofreading of the target translation to correct printing, spelling and grammatical mistakes, etc. |
| Tenth     | Final Report                  | Final report of processes along with a description of the methodology. |
5. Discussion

This study focused on the translation and cultural adaptation of the MacArthur assessment tool among Persian-speaking patients. It determined that the interview, scoring, and interpretation components are applicable in those patients. Therefore, it is inferred that this tool is not most likely dependent on the original culture and language, providing that the translation process and cultural adaptation are appropriately implemented. Instances of independent cultural standards are observed in the field of psychology. For example, such standards are found in the Diagnostic and Statistical Manual of Mental Disorders. A diagnostic criterion for major depressive disorder is one of those standards included in the fifth version of that manual, which is adaptable to a majority of cultures. Of course, further studies are needed to approve this matter in the future. We hope this measuring tool for patient consent to treatment can be received warmly by physicians in Iran. Due to the capacity of this tool, it has the potential for use in the courts in the near future. We are not only keen to evaluate the validity and reliability of Mac-CAT-T in patients in Iran, we are also inclined to measure the prevalence of incompetence in both psychological and non-psychological Iranian patients.

5.1. Ethical Considerations

We received permission to use and translate the MAC-CAT-T instrument from one of its main models (Professor Thomas Grisso) via e-mail contact. This research received approval from the 12th committee for research ethics at Kashan University of Medical Sciences (24/02/2014).

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Footnotes

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