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TECHNICAL NOTE

Development of the Japanese version of the Ego-Dissolution Inventory (EDI)

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Abstract

Aim: Psychedelics have recently gained attention as potential therapeutic agents for various psychiatric disorders. Previous research has highlighted that a diminished sense of self, commonly termed "ego-dissolution" is a pivotal feature of the psychedelic-induced state. While the Ego-Dissolution Inventory (EDI) is a widely acknowledged instrument for measuring this phenomenon, no Japanese version has been available. This study aimed to develop a Japanese version of the EDI.

Methods: We adhered to the "Guidelines for Best Practices in the Translation and Cultural Modification Process for Patient-Reported Outcomes Instruments: Document from the ISPOR Committee on Translation and Cultural Modification" during our translation approach. Two Japanese psychiatrists independently conducted initial translations, and a consolidated version was achieved via mutual agreement. This version was then back-translated to English and assessed by the original authors for consistency. The repetitive modification process was conducted in continuous dialogues with the original authors until they accepted the concluding back-translated version.

Results: The finalized, approved back-translated version of the EDI is presented in the accompanying figure. In addition, the authorized Japanese version of the EDI is included in the Appendix.

Conclusions: In this study, we successfully developed the Japanese version of the EDI. This instrument will assist in assessing ego-dissolution experiences associated with psychedelic-assisted therapy among Japanese speakers. Additional studies are necessary to evaluate the reliability and validity of this newly translated instrument.

KEYWORDS
depression, EDI, Ego-Dissolution Inventory, human, psychedelics

Keisuke Kusudo and Hideaki Tani contributed equally to this work.

1 | INTRODUCTION

Psychedelics constitute a category of pharmacological agents that induce temporary yet profound alterations in sensory perception, emotional state, and subjective experience.[1] Various studies have indicated the possible therapeutic efficacy of psychedelics in several clinical applications, including alleviating anxiety in end-stage patients[2–4] and the treatment of treatment-resistant depression,[5–7] post-traumatic stress disorder,[8,9] and substance abuse disorders.[10,11] Psychedelics induce altered states of consciousness (ASC), a broad term encompassing various changes in the normal waking state of consciousness. These changes include alterations in thinking, disturbed time sense, feelings of unity with the universe, and ego dissolution. Ego-dissolution has been characterized as a phenomenon typically experienced during ASC and phenomenologically related to both mystical experiences and psychotic states.[12–16] Particularly, alterations in the personal perception of one's "self" or "ego" are fundamental to the psychedelic experience.[12,13,16] Besides, a reduction in the self-referential consciousness characteristic of typical waking states has been observed with several psychedelic drugs.[17–20] Presently, a variety of scales exist to evaluate alterations in self-experience, such as Dittrich's Abnorme Psychische Zustände (APZ) questionnaire,[21] its revised form in German (OAV),[22] and Five Dimensional Altered States of Consciousness Rating Scale (5D-ASC).[23] Yet, previous psychometric analyses of the OAV questionnaire show an intricate 11-factor framework, highlighting its multidimensional nature. This suggests that the scale measures a variety of components, such as cognitive shifts, sensory changes, mood fluctuations, sensations of oneness, and feelings of detachment.[12,22] Moreover, there had been no reliable, validated scale for the unidimensional measurement of ego-dissolution. In light of these issues, the "Ego-Dissolution Inventory" (EDI), an 8-item self-completed questionnaire was developed. Furthermore, internal consistency and construct validity of the EDI has been demonstrated.[12]

The EDI is a psychometric instrument intended to measure the phenomenon of ego-dissolution. It is composed of eight specific items. These items include experiences of dissolution of oneself or ego, a decreased sense of self-importance, and a disintegration of oneself or ego, feelings of a sense of unity with the universe and other people, being much less consumed by the personal issues and concerns, the loss of all sense of ego, and the full dissolution of self and identity. Each item is evaluated using a Visual Analog Scale (VAS), scored between 0 and 100. The ends of the scale are labeled as "No, not more than usually" (representing a score of 0) and "Yes, I experienced this completely/entirely" (representing a score of 100). It is important to note that extreme scores should only be given if the respondent truly identifies with the experience. The total EDI score is calculated as the mean score of all eight items, thus providing a score ranging from 0 (minimum) to 100 (maximum).[12]

To conduct clinical trials of psychedelics globally, self-report questionnaires have to be available in multiple languages. Nevertheless, a Japanese version of the EDI has yet to be developed. In the present report, we therefore aimed to formulate the Japanese version of the EDI.

2 | METHODS

The Japanese version of the EDI was created by translating the original English version. The process followed the "Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation."[24] Initially, we secured official authorization for the translation from the original authors of the EDI. Two Japanese psychiatrists independently carried out the forward translation from English to Japanese. We reviewed the translations and consolidated them into a unified forward-translated version. This was subsequently back-translated to English by a professional translator who is a native English speaker. To evaluate the accuracy of the forward translation, the initial authors of the EDI compared the back-translated version with the original one, assessing them for consistency. When the inconsistencies were present, the translators reevaluated both forward and backward translation procedures. This iterative process, involving ongoing communication with the original authors, was repeated until the revised forward and back-translated versions were considered acceptable. All data are available in the manuscript.

3 | RESULTS

The author-approved, back-translated EDI is shown in Figure 1. Moreover, the authorized Japanese version of the EDI is provided in Appendix S1.

4 | DISCUSSION

In this study, we developed the Japanese version of the EDI, following the "Principles of Good Practice for the Translation and Cultural Adaptation Process for PRO Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation." Considering the growing worldwide interest in psychedelic studies, the development of the Japanese version of the EDI is essential. Evaluation of the reliability and validity of this Japanese version of the EDI warrants future investigations.

Regarding reliability of EDI, Nour et al. reported that the internal consistency of the EDI using the Cronbach's alpha coefficient was 0.93,[12] signifying a strong internal consistency for this measure.[25] They also showed that EDI had robust convergent validity, which was confirmed by a substantial correlation ($\rho = 0.735$) with the unity experience items extracted from the Mystical Experiences Questionnaire (MEQ). The MEQ evaluates mystical experiences within ASC and includes a subset of seven items

Instructions:

Please rate how well each of the following statements fit your experience in question.

Under each sentence, there is a line with "**No**, not more than usual" and "**Yes**, I experienced it completely/totally" on either end. This line is used to assess changes from your normal state. Your normal state corresponds to the leftmost mark on the scale, i.e., "No, not more than usual."

Please put a rating on either end only if it is **truly** applicable.

EDI items (see next page for questions using VAS)

1. I experienced a dissolution of "myself" or ego
2. I felt a sense of unity with the universe
3. I felt a sense of unity with other people
4. I felt a diminished sense of self-importance
5. I experienced a breakdown of "myself" or "ego"
6. I became less* preoccupied *with my own problems and worries
7. I lost all sense of ego
8. All concepts* of *self and identity have dissolved

Scoring Method

Each item was scored on a visual analogue scale (VAS) from 0 to 100, with the following sentences at the lower and upper limits, respectively. "**No**, not more than usual" and "**Yes**, I experienced it completely/totally".

The total EDI score is the average score of all eight items (i.e., 0 = lowest to 100 = highest).

FIGURE 1 The original author-approved, back-translated version of the Ego-Dissolution Inventory (EDI).

aimed specifically at capturing the phenomenology of unity experiences.[26–28] These items are hypothesized to be associated with the concept of ego-dissolution. Additionally, Nour et al. reported that the items related to changes in self-consciousness used to verify the EDI consisted of 16 items. The items are grouped into two distinct subscales, one that reflects the ego-dissolution that constitutes EDI, and the other that captures "ego-inflation," which reflects self-assuredness and confidence. An exploratory factor analysis found that all eight EDI items loaded onto a single factor, suggesting that they measure a consistent concept. This factor was independent of a second factor associated with ego-inflation ($\rho = -0.110$), thereby confirming discriminant validity.[12] Furthermore, the analyses showed that ego-dissolution was specifically linked to psychedelic drug use, not to cocaine or alcohol.[12] Nonetheless, it should be noted that a similar factor structure to that of the original EDI has not been consistently replicated in research conducted within linguistic contexts of other regions.[29,30] These discrepancies could potentially arise from cultural differences, translation intricacies, as well as disparities in the composition of the study samples. These variances underscore the need of additional investigations tailored to each respective country. Currently, there have not been any clinical trials conducted in Japan regarding psychedelic-assisted therapy. Therefore, it is essential to undertake feasibility studies to assess both its effectiveness and safety, as well as to define the experiences of ego-dissolution using the EDI within the Japanese population. Ideally, the Cognitive Debriefing recommended by ISPOR would have been conducted. This process involves testing the translation with a group of individuals similar to the target population of the scale to ensure clarity, accurate interpretation, and cultural relevance. However, in Japan, due to the current regulation of psychedelic substances and the absence of relevant clinical research, there is a lack of suitable patient groups with the necessary specific characteristics. As a result, Cognitive Debriefing could not be conducted in the present study, which underscores a limitation in the translation process of this project. After data collection, investigating the reliability and validity of the Japanese version of the EDI is considered necessary. Future research should also consider cultural difficulties, particularly an adaptation to the daily life of the language in a different culture.

In summary, we created the Japanese version of the EDI to facilitate the measurement of ego-dissolution provoked by psychedelics among Japanese language users. Further investigations are clearly warranted to assess the reliability and validity of this instrument.

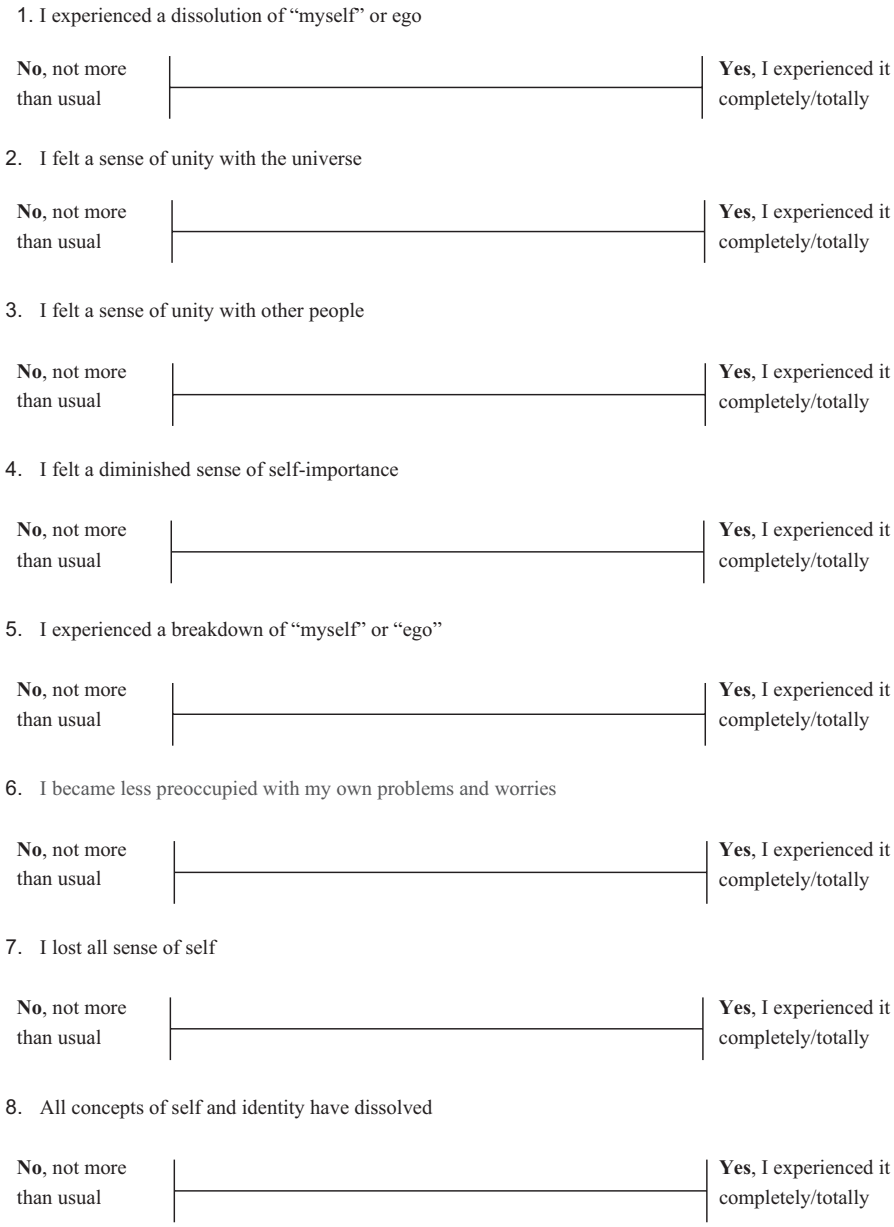

FIGURE 1 (Continued)

AUTHOR CONTRIBUTIONS

Keisuke Kusudo: Conceptualization, translation, writing. **Hideaki Tani**: Conceptualization, translation, writing. **Kengo Yonezawa**: Conceptualization, translation, writing. **Shinichiro Nakajima**: Conceptualization, translation, project administration, supervision. **Matthew M. Nour**: Conceptualization, translation, supervision. **Robin Carhart-Harris**: Conceptualization, translation, supervision. **Hiroyuki Uchida**: Conceptualization, methodology, project administration, supervision, writing. All the authors have approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

Dr. Keisuke Kusudo has received speaker fees from Janssen and Eisai Pharmaceutical within the past 3 years. Dr. Hideaki Tani has received manuscript or speaker fees from Sumitomo Pharma, Janssen Pharmaceutical, Otsuka Pharmaceutical, Takeda, Wiley Japan, and Yoshitomi Yakuhin within the past 3 years. Dr. Kengo Yonezawa declares no conflict of interest. Dr. Shinichiro Nakajima has received grants from Japan Society for the Promotion of Science (18H02755, 22H03002), Japan Agency for Medical Research and Development (AMED), Japan Research Foundation for Clinical Pharmacology, Naito Foundation, Takeda Science Foundation, Uehara Memorial Foundation, Watanabe Foundation, and Osake-no-Kagaku Foundation within the past 3 years. Dr. Shinichiro Nakajima has received an investigator-initiated clinical study grant from Asahi Quality & Innovations, Ltd. Dr. Shinichiro

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DATA AVAILABILITY STATEMENT

All data are available in the manuscript.

ETHICS STATEMENT

Approval of the Research Protocol by an Institutional Reviewer Board: N/A.

Informed Consent: N/A.

Registry and the Registration No. of the study/trial: N/A.

Animal Studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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