English Translation and Validation of the Ikigai-9 in a UK Sample [Protocol]

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Abstract

The psychological construct of 'ikigai' reflects the sense of having a 'reason for living' and has been associated with various positive health-related outcomes. This proposal presents an English translation of the Ikigai-9, empirically explores the manifestation of ikigai in the United Kingdom, and outlines its associations with facets of well-being.

Keywords: Ikigai-9, positive health-related outcomes.

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Methodology	Cross sectional, correlational design with factor analysis		
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Study Duration	Estimated duration for the main protocol (i.e., first to last participant sampled) was one		
	month		
Study Centre	University of Derby, Derby, UK		
Objectives	Primary Objective:		
Ū	Translate and validate the Ikigai-9 for use in English-speaking populations		
	Secondary Objective:		
	Delineate associations between ikigai and state measures of mental wellbeing, depression,		
	anxiety, and stress		
Number of	368 participants (as dictated by a priori power analysis)		
Participants			
Main Inclusion	Inclusion Criteria:		
Criteria	- Male and female participants aged 18 years and above		
	- UK nationality		
	- Fluent in English		
	Exclusion Criteria:		
	- No current (within six-months) diagnosis of psychiatric, affective, or neurological		
	disorder		
Statistical	Hierarchical multiple regression using ikigai to predict state measures of mental		
Methodology	wellbeing, depression, anxiety, and stress after controlling for age and sex		

Purpose:

The primary objective is to translate the Ikigai-9 (Imai, Osada, & Nishi, 2012) into English and to validate it within a cohort derived from the United Kingdom (UK).

Background:

The formal definition of ikigai refers to a "joy and a sense of well-being from being alive" and "realizing the value of being alive" (Toshirō, Skrzypczak, & Snoewden, 2003, p. 459). In Japanese culture, having a sense of 'life worth living' (i.e., ikigai) is considered an indicator of well-being, which amalgamates psychological well-being and consciousness about motivations for living (Mori et al., 2017). Previously, ikigai has been associated with lower risk of functional disability (Mori et al., 2017), longevity (Tanno et al., 2009), and reduced impact on caregiver burden (Okamoto & Harasawa, 2009) in Japanese populations. However, to date, no published research has explored the role of ikigai in Western populations. In modern Western literature, the concept of ikigai has grown in significance within the fields of positive psychology and well-being (Buettner, 2017; García & Miralles, 2017), however no study has quantitatively examined this concept in English-speaking populations, partly because of the absence of an appropriate measurement tool in English. Previously, use of the Japanese Ikigai-9 scale has only been empirically used in a single study (within an elderly sample). As such, in order to achieve our aims, we seek to translate (including backtranslation) the Ikigai-9 into English and investigate its validity in a more general population (e.g., male and

female adults) within the UK. Moreover, as the Ikigai-9 has never-before been investigated alongside other more general well-being measures, this study will seek to delineate baseline associations between ikigai and mental well-being, depression, anxiety, and stress.

Objectives:

- 1. Translate the Ikigai-9 into English (including back-translation)
- 2. Validate the Ikigai-9 (Eng) in an Englishspeaking sample
- 3. Delineate associations between ikigai and state measures of mental wellbeing, depression, anxiety, and stress

Duration of the Study:

Through use of the participant crowdsourcing website Prolific (see '*Recruitment Methods*'), enrolment and data collection for this study is estimated to take no longer than one month to complete. However, enrolment will remain open until the minimum sample size (n = 368) is met. The duration of this study for each participant is expected to be no longer than 15 minutes.

Methods:

Study Design

This cross-sectional study will involve ~368 participants completing a battery of questionnaires at a single timepoint. Demographics (i.e., age, sex, nationality) and state-measures of ikigai, mental well-

being, depression, anxiety, and stress will be measured online using survey software Qualtrics.

Study Population, Selection Criteria, and Sample Size Justification

All participants will provide full informed consent, as indicated by a button press on the first and final pages of the survey. Participants will be males and females aged 18 years and over, of UK nationality, and fluent in English. Participants will be excluded if they have a current (i.e., within six-months) diagnosis of psychiatric, affective, or neurological disorder, so as not to bias data pertaining to mental well-being.

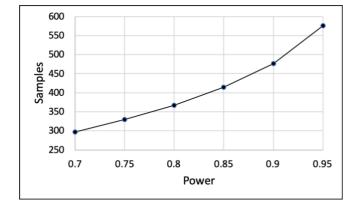
As visualised in Table 1 and Figure 1, an a priori power analysis ($f^2 = .03$, $\alpha = .05$) determined that around 368 participants were required to have 80% power in the planned analyses (G*Power, v3.1). Here, power is defined as the likelihood of correctly detecting an effect in the event that said effect exists, so a higher power level indicates a reduced likelihood of concluding an absence of an effect when that effect exists (i.e., Type II error). As a function of data being captured at a single timepoint, no calculation adjustments have been made for participant attrition.

Table 1

Power analysis across power levels

	Power $(1 - \beta)$					
	0.70	0.75	0.80	0.85	0.90	0.95
Sample	297	329	368	414	476	576
Size						

Figure 1



Visualisation of power analysis across power levels

Recruitment Methods

Participants will be identified through the crowdsourcing website Prolific (*prolific.co*), and the study survey) will be made available to all members

who meet the required inclusion criteria. This is an automated process determined through member responses to a series of questions first answered when signing up to the platform. Prolific is thought to generate data quality comparable to that obtained via face- to-face means (Peer et al., 2017), and members who go on to participate in the study will be paid an average of £5 per hour; roughly £0.85 for this study (10 minutes). At the time of writing, there are 80,714 potential participants to take part in this study, so data collection for this purpose is entirely feasible.

Data Collection and Study Schedule

Individual data will be collected at a single time point, with all data expected to be collected within a period of one month. On the first two pages of the survey, participants will be presented with all study information and will be asked to affirm their consent. On subsequent pages (not accessible unless consent has been given), participants will be asked to answer brief demographic questions (i.e., age, sex, nationality) prior to completing three short psychometric measures, namely the nineitem English version of Imai et al.'s (2012) Ikigai-9, the seven-item Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS; Stewart-Brown et al., 2009), and the 21-item Depression Anxiety Stress Scales (DASS-21; Lovibond & Lovibond, 1995) – all of which the research team have expertise and qualification in distribution and interpretation. Each scale will be presented, along with completion instructions, on a separate page, and the study will close with a debrief page where participants will be asked to re-affirm their consent. Data will be maintained for as long as necessary (with identifiable data destroyed after two weeks) for the purpose of transparent and open science, with the exception of data obtained from participants who withdraw from the study either during or following participation (up to a period of two weeks). In such cases, any associated data will be permanently deleted.

Expected Outcomes

The research team expects the English translation of the Ikigai-9 to hold a similar factor structure in UK responders to that observed in a Japanese cohort elsewhere (Imai et al., 2012). Moreover, as existing literature suggests, it is expected that scores on the Ikigai-9 will be positively associated with self-reported mental wellbeing and negatively associated with state depression, stress, and anxiety.

Adverse Events

There is no expectation of any adverse outcomes or effects on participants as a direct result of this study. Nevertheless, the research team acknowledges that questions asked within this study relate to mental wellbeing, which has the potential to lead participants to ruminate on their own mental wellbeing. As such, participants will be signposted to UK-based mental health charities (e.g., Mind) and their healthcare providers (e.g., general practitioners) at both the point of consent and debrief. Participants are neither asked nor expected to disclose any subsequent correspondence with such services to the research team.

Withdrawals:

Reasons for Withdrawal

Potential participants identified via Prolific are under no obligation to take part in the study. Participants who do consent to take part can withdraw their consent either during the study (by closing their web browser or by not affirming consent at the point of debrief) or after taking part in the study up to two weeks prior (by e-mailing the Principal Investigator (PI) using the provided e-mail address with their Prolific ID, an ID associated with their specific data entry). No reason for this withdrawal will be asked or expected to be given. Participation in the study may be automatically terminated (via Qualtrics settings) should the participant decline to give consent. No adverse events will be measurable during the study due to the data being collected remotely and not in person. As such, no considerations are made for adverse events that lead to participant termination up to two weeks following participation.

Handling of Participant Withdrawal

As mentioned above, participants may withdraw at any time during the study and up to two weeks afterwards, and participants will not be asked to give a reason for their withdrawal. Participants who withdraw from the study will not be replaced, so long as the study sample does not fall under 0.75 power (n = 329); in such instances, further participants will be sampled.

Premature Termination or Suspension of Study

Although not expected, the study may be temporarily suspended or prematurely terminated if there is sufficient and reasonable cause to do so. In such instances, the PI will directly notify the research ethics committee that approved the study in writing, providing reason(s) for the suspension and/or termination of the study. Potential circumstances which might result in temporary suspension or premature termination include [1] unexpected, significant, or unacceptable risk to participants, [2] determination of futility, and [3] unexpected detriment to the secure maintenance and quality of data. The study may resume once any concerns have been addressed and satisfy the needs of both the research team and research ethics committee. **Statistical Analysis Plan:**

All analyses for this study have been determined a priori. To determine construct validity of the Ikigai-9 (the English version), confirmatory factor analysis will be run on the composite dataset, and the root mean square error of approximation (RMSEA), comparative fit index (CFI), and Tucker-Lewis index (TLI) will be reported according to cut-off values provided by Hu and Bentler (1999). If the two-factor structure delineated in

Imai et al. (2012) is not confirmed, principal axis factor analysis will be conducted to determine a better fit.

To determine concurrent validity, four hierarchical multiple regression analyses will be conducted (whereby the dependant variables will be scores on well-being, depression, anxiety, and stress). In each analysis, age and sex (0 = male, 1 = female) will be entered at step 1 and ikigai will be entered at step 2. Alongside these analyses, assumption testing will be carried out with bi-variate correlations. If post-hoc analyses are conducted, these will be reported as such in any resulting manuscript.

Assessment of Safety:

Although not expected, this study will follow standard definitions of adverse events (AEs) and report any AEs to the research ethics committee for up to two weeks after the final participant has taken part in the study.

Adverse Events are defined as any unanticipated physical or mental well-being occurrence, regardless of its relationship to the study, such as self-reported stress or anxiety following participation in the study that may or may not require further intervention.

Serious Adverse Events are defined as AEs that are considered serious, such as those requiring hospitalisation, are life-threatening, or result in death.

In the event of any AE being acknowledged by the research team, the PI will assign a level of severity to the event (Mild, Moderate, Severe) and assess the likelihood that said AE is related to the study protocols (Definitely, Probably, Possibly, Unrelated). These categories are further delineated in Table 2.

Table 2

Severity and relationship of adverse event to the study protocol

Label	Description		
Mild	Requires no or minimal intervention;		
	not impacting the participant		
Moderate	Moderate inconvenience to the		
	participant; potentially interfering with		
	day-to-day activities of the participant		
Severe	Severe inconvenience to the participant		
	that may require intervention; severely		
	interfering with day-to-day activities of		
	the participant and may be life-		
	threatening		
Definitely	The relationship between the AE and		
	the study protocol can be clearly		
	established		

Probably	The relationship between the AE and
	the study protocol cannot be clearly
	established, however there is no other
	reason or event which could clearly
	explain the occurrence of the AE
Possibly	The relationship between the AE and
	the study protocol cannot be clearly
	established, but the definite lack of a
	relationship cannot be concluded
Unrelated	There is no relationship between the AE
	and the study protocol.

Prior to gaining ethical consent to conduct the study from the research ethics committee, only a single possible risk has been identified by the research team: that of 'consciousness of poor mental wellbeing' after being presented with questions asking them to reflect on their own mental wellbeing (including questions asking about stress, anxiety, and depression). This risk was identified as being mild (as opposed to moderate or severe) and will be protected against within the study by two methods. First, it will be made clear to the potential participants within the study information that questions about mental wellbeing will be asked, so as to allow opportunity to refuse consent. Second, participants will be signposted to charity and wellbeing services at both the point of consent and debrief, allowing an opportunity for participants to access support even without taking part in the research.

Data Monitoring:

The PI will be responsible to ensure the study is conducted in accordance with the protocol, standards of Good Clinical Practice (GCP), and applicable regulatory requirements as defined by the British Psychological Society (BPS), and that the data recorded is valid and appropriately stored and maintained. To this end, data collection (via Prolific) will be collected in three stages to ensure quality: Stage 1 being a short pilot of five participants to check data quality and difficulties arising from the usability of the questionnaire, and Stages 2 and 3 being the collection of male and female responses separately to ensure a good distribution of data across sexes. Due to the nature of data collection (i.e., anonymous participants over a single time point), it will not be possible to follow-up on any incomplete data, nor will it be possible to verify the accuracy of submitted data. However, the questionnaire pack is devised in a manner to minimise errors (e.g., clear instructions) and uses a 'request response' function in order to remind participants to complete all sections of the survey should any question be missed. To comply with ethical standards, although this function is enabled, participants will be able to subsequently skip said item should they not wish to complete it.

No external data monitor will be appointed to ensure the study complies with GCP or BPS standards; however,

data and analysis scripts will be made freely and openly available to those wishing to replicate our findings (via the Open Science Framework or ResearchGate).

Data Handling and Record Keeping:

The collection of personal data from the participants will be limited to the number and type required to perform the planned analyses and in order to achieve the aims of the research. Data will be maintained on Qualtrics (survey software and secure database) until the required sample size has been collected, at which point the data will be exported into an Excel or SPSS file format (password protected), backed-up, and subsequently deleted from Qualtrics. Any unique identifiers collected within the dataset will be permanently deleted two weeks after the final participant completes the study, and there will be no hard copies of the data generated or maintained. Fully anonymised data will be used for data analysis, which will be led by the PI (DF).

As part of the publication process, a permanent openaccess version of the subscale-level data (i.e., no individual participant responses per item) will be made available on the Open Science Framework. Where possible, a link to such files will be included within the manuscript publication for the purpose of transparency and scrutiny. At no point will participants be identifiable from this dataset.

Research Ethics Committee:

The protocol, participant-facing documents, and questionnaire pack will be submitted to a local research ethics committee for review, feedback, and approval. Approval of all documents is required before any participant enters into the study. Any amendment to the protocol will undergo further review and approval by the research ethics committee before the changes are implemented to the study; however, as participation is anonymous and participants are not requested to provide contact details, re-consent to take part in the study will not be possible, and as such any data obtained prior to amendments will only be treated in accordance with the elements and procedures for which consent was given.

Consent Process:

After clicking on the study link and being presented with the study information sheet (including all information about the study, methods of withdrawal, information about data management, and contact details of the study team and signposted services), participants will then be presented with the consent form on the subsequent page of the online survey. To take part in the study, participants must affirm their consent and understanding of the aforementioned information via a button press; refusal to do this will lead the Qualtrics software to terminate their participation with a 'thank you' message. Participants will not have to sign, date, or present any additional identifiable information. Following a debrief of the study, and in accordance with guidelines for internet mediated research (BPS, 2017), participants will be asked to re-affirm their consent as a means of mitigating against the usage of data from participants who prematurely exited the study and/or those who no longer wish for their data to be used after completing the study.

Protocol Deviation:

Protocol deviations are defined as any deviation from the ethically-approved study protocol and can be attributed to either the research team or study participants. However, as the nature of the study makes it improbable that participants could generate protocol deviations, a research team-related example of a protocol deviation for this study might include the use and storage of data in an unapproved manner. Any protocol deviation will be made aware to the research team at the earliest availability and corrective measures will be actioned if appropriate. Causes, actions, and results of any protocol deviations will be signalled to the research ethics committee in writing at the first available opportunity.

Publication and Data Sharing Policy:

It is the intention of the research team to publish any and all findings of this study in written (e.g., posters, journal publications, blog posts) and verbal (e.g., conference paper) form. The research team might also use findings of this study as a base for future research submissions and/or grant applications. At all stages, individual participant responses and associating identifiable information will be kept confidential, and only group-level analyses will be presented/published. In accordance with emerging trends in open science, anonymised raw data and pre-print manuscripts will be made openly available.

Study Personnel and Roles:

Table 3 documents the members of the research team and their associated responsibilities throughout the duration of the project.

Table 3

Outline of research team personnel and associated project roles

Personnel	Role	Responsibilities		
Dean Fido	Principal	Responsible for all		
	Investigator	study-related issues		
Yasuhiro	Co-	Study design; Data collection;		
Kotera	Investigator	Manuscript drafting and final		
	_	review		
Kenichi	Co-	Manuscript drafting and final		
Asano	Investigator	review		

Conflict of Interest:

No conflicts of interest have been reported.

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