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Communicating Through a Brain-Computer Interface: Towards the Assessment of Quality of Life in Minimally Conscious and Covertly Aware Vegetative State Patients

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Abstract

Neuroimaging has been utilized to establish communication, using a brain-computer interface, with select patients with severe brain injuries and profound communication impairments. Due to the severe injuries sustained by these patients, traditional techniques used to develop quality of life instruments cannot be used. The Aware Study used a novel approach to establish the key dimensions for assessing the quality of life of patients who can only communicate using this sophisticated technology. Consensus methodology was employed, with the assistance of a multidisciplinary panel of experts, to collectively decide which dimensions are essential for the inclusion in a quality of life instrument for these unique patients.

Keywords

Severe Brain Injury, Disorders of Consciousness, Delphi Method, Consensus, Surveys, Quality of Life

Co-Authorship Statement

All chapters were written by Jasmine Tung and were intended to partially fulfill the requirements for the degree of Master's of Science in Epidemiology and Biostatistics. The work presented in this thesis is a part of the larger grant, "The Ethics of Neuroimaging After Serious Brain Injury", funded by the Canadian Institutes of Health Research (ROLA # 2014-18). Specifically, this project falls under Subproject 2C of the grant, "Measuring Quality of Life in Behaviourally Nonresponsive Patients", which aims to development a preliminary quality of life instrument for use in behaviourally nonresponsive patients. However, the original idea was to convene an interdisciplinary group of experts in a two-day workshop to address the problem. A team including Dr. Charles Weijer (CW), Dr. Kathy Speechley (KS), and myself redesigned the methodology to include a systematic search and online surveys using consensus methodology. Members of the larger research team, along with CW and KS, assisted with expert recruitment for the project: Dr. Teneille Gofton, Dr. Bryan Young, Dr. Lorina Naci, and Dr. Laura Gonzalez Lara. I was involved with all aspects of the project including: designing the methodology, writing the ethics application, creating the online surveys, collecting data, communicating with participants, analyzing data, creating and disseminating summary reports. Feedback and suggestions on the project and thesis were provided by the larger team and Dr. Greta Bauer.

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I would like to extend my gratitude to the members of the Neuroethics Research Group (NeRG) for their words of encouragement and ongoing advice regarding the project. In addition, I would like to thank Dr. Greta Bauer who provided valuable insight and constructive feedback during the writing process.

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Thank you to all the friends that I have made during my time in London, who became my support system and positively shaped my experience in this program.

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Chapter 1

1 Introduction and Overview

Researchers have demonstrated that functional magnetic resonance imaging (fMRI) can be used as a tool to detect covert consciousness in individuals with disorders of consciousness after severe brain injury (Owen et al., 2006). With the aid of this sophisticated technology, known as a brain-computer interface, select patients in a minimally conscious and covertly aware vegetative state have been able to communicate by modulating their brain activity (Monti et al., 2010). For the purpose of this thesis, these select patients are referred to as behaviourally nonresponsive because of their unique ability to communicate using a brain-computer interface but inability to communicate at the bedside. In the wake of these discoveries, some ethicists have argued that being vegetative and covertly conscious should be grounds for withdrawal of life-sustaining treatment to prevent needless suffering (Skene, Wilkinson, Kahane, & Savulescu, 2009). A few have gone as far as saying that these lives are not worth living. However, there is not enough information to make conclusive proclamations on the state of lives led by these patients. It has previously been demonstrated that some individuals who have a severe disability self-report their quality of life to be higher than assumed by external observers (Albrecht & Devlieger, 1999). Therefore, the brain-computer interface provides an opportunity for patients to directly provide information on their quality of life.

While quality of life instruments have been developed for most health conditions, to date no such measure has been developed for individuals with disorders of consciousness (Jenkinson, Peters, & Bromberg, 2011). Due to the profound injuries sustained by these patients, traditional techniques used to develop quality of life instruments cannot be used. Challenges to the development of a quality of life instrument in behaviourally nonresponsive patients include: the limited ability to interview patients; the brain-computer interface is limited to ‘yes’ or ‘no’ responses; and only a small number of questions may be posed during a scanning session. These circumstances present obstacles that have not been navigated by any developers of existing quality of life instruments. Nonetheless, such an undertaking is important because of society’s moral obligation to take the welfare interests of these patients into consideration, the insights that such research could provide into the vegetative and minimally conscious state, and the opportunity to learn about the well-being of behaviourally nonresponsive patients.

The challenges associated with evaluating quality of life in these patients requires an innovative approach. This study was conducted as the fundamental first step in developing a quality of life instrument specifically for behaviourally nonresponsive patients. The development of a quality of life instrument is a multistage process that requires extensive information regarding patients and their daily lives. Since there is a scarcity of knowledge regarding the lived experience of behaviourally nonresponsive patients, this thesis is the necessary next step in research into these patients’ well-being. Conventionally, such an undertaking is not required in instrument development studies because researchers are able to have a dialogue with patients. To determine the most relevant dimensions for evaluating quality of life in behaviourally nonresponsive patients, this study involved a systematic search of existing quality of life instruments along with consensus methodology using a panel of experts.

1.1 Objectives

The **aim** of this thesis is:

To generate foundational knowledge as the first step in the creation of an instrument to assess quality of life of patients in a minimally conscious and covertly aware vegetative state who are able to communicate with the assistance of a brain-computer interface (behaviourally nonresponsive patients).

The **specific objectives** of this thesis are:

1) To systematically identify relevant quality of life dimensions for behaviourally nonresponsive patients.

    (i) This will be accomplished by a systematic search of existing quality of life instruments designed for patient populations similar in some aspects to behaviourally nonresponsive patients.

2) To establish the key dimensions for assessing quality of life of behaviourally nonresponsive patients.

    (ii) This will be accomplished by designing and executing a consensus process with a multidisciplinary expert panel.

1.2 Thesis Structure

This thesis comprises the following chapters: Literature Review; Methods; Results; and Discussion. Chapter 2 (literature review) will discuss the target patient population in detail and review the research on communicating with select patients using a brain-computer interface. This will be followed by an explanation of quality of life and the conventional process for developing quality of life instruments. Finally, challenges related to measuring quality of life in behaviourally nonresponsive patients will be described and a novel approach will be explored. In Chapter 3 (methods), a detailed description of the methodology of the study conducted will be provided. Chapter 4 (results) will present the findings of our study. Lastly, in Chapter 5 (discussion), the implications of the study and the findings will be discussed, along with the strengths and limitations of the project. Suggestions for future directions for related research will be outlined as well.

The appendix includes the signed Research Ethics Board approval for this study and a list of the research team members. Furthermore, it includes the: informational material, letter of information, three online surveys, and three summary reports that were sent to the participants.

Chapter 2

2 Literature Review

This chapter begins with an overview of minimally conscious and vegetative states including their etiology, prevalence, diagnosis and prognosis. A brief review of neuroimaging research and how it led to the identification of behaviourally nonresponsive patients will be provided. Afterwards, a summary of the concept of quality of life and creation of instruments to measure it will be discussed. Additionally, the importance and challenges of measuring quality of life in the target population will be outlined. Finally, the chapter will present an alternative approach to creating a quality of life instrument for behaviourally nonresponsive patients.

2.1 Severe Brain Injuries

Acquired brain injury is one of the leading causes of death and disability among Canadians, with an incidence greater than that of breast cancer, spinal cord injury, multiple sclerosis, and HIV/AIDS combined (Brain Injury Association of Canada, 2012). An acquired brain injury can affect anyone, at any point in the life course. Although each brain injury is unique, the consequence is a modification of neuronal activity to one or more areas of the brain (Barnes & Good, 2013). An individual can suffer from a traumatic brain injury due to an external physical force or a non-traumatic brain injury as the result of a medical condition causing cerebral hypoxia. Of the nearly 165,000 Canadians who suffer an acquired brain injury each year, the majority will recover (Brain Injury Association of Canada, 2012). Many, however, will die and approximately 65,000 will be left with some form of permanent disability (Brain Injury Association of Canada, 2012). A subgroup of these injured individuals will enter into a state of impaired consciousness, also known as a disorder of consciousness. Categories of disorder of consciousness include: coma, vegetative state, and minimally conscious state (Greenwald & Nori, 1995).

2.2 Disorders of Consciousness

Consciousness is broadly defined as being awake and having awareness of oneself and one's environment (Bernat, 2006). After a severe brain injury, a patient is in a coma for a period of hours or days. A coma is characterized by lack of arousal, where the patient's eyes remain closed, and lack of awareness of self or environment (Greenwald & Nori, 1995). A coma can be brought on after a physical injury or can be medically induced to protect the brain from further damage (Greenwald & Nori, 1995). Within a period of days of entering a coma, a patient can regain full consciousness, enter into a vegetative state or minimally conscious state, or die (Laureys, Owen, & Schiff, 2004). Vegetative patients display sleep-wake cycles along with motor reflexes but fail to communicate, move volitionally, or show other signs of awareness (Laureys et al., 2004). There has been a long-standing consensus that vegetative state patients are unable to interact with others or their environment in a meaningfully way (Giacino, 1997). In contrast to vegetative patients, minimally conscious patients have low levels of intermittent awareness of themselves or their environment (Greenwald & Nori, 1995). To be classified as minimally conscious, a patient's volitional behaviour can be inconsistent but it must be reproducible or sustained long enough to be differentiated from automatic behaviour (Greenwald & Nori, 1995).

Globally, the prevalence of the vegetative state has been estimated at 0.2 to 6.1 patients per 100,000 people in the population (van Erp et al., 2014). Of the cases of severe head injury, 6-16% will result in the individual becoming vegetative (Cruzado & Elvira de la Morena, 2013). In the US, there is a wide discrepancy in the estimates of vegetative and minimally conscious patients. Estimates range from 12,000 to 54,000 vegetative patients and 112,000 to 280,000 minimally conscious patients (Beaumont & Kenealy, 2005; Hirschberg & Giacino, 2011). The fluctuation in the stated prevalence rates is partially due to dated statistical estimates and a high misdiagnosis rate.

2.3 Prognosis and Diagnosis

Prognosis in patients with disorders of consciousness is highly variable. While some patients rapidly emerge from coma and make a good recovery, some spend longer periods in the minimally conscious state before emerging with long-term impairments. Yet others remain in a vegetative or minimally conscious state permanently or succumb to their injuries. Adding to this complexity, many families choose to withdraw life-sustaining treatment in the days or weeks following brain injury, which is at a point where it is too early for a conclusive verdict about consciousness to be established in the patient (Kitzinger & Kitzinger, 2015).

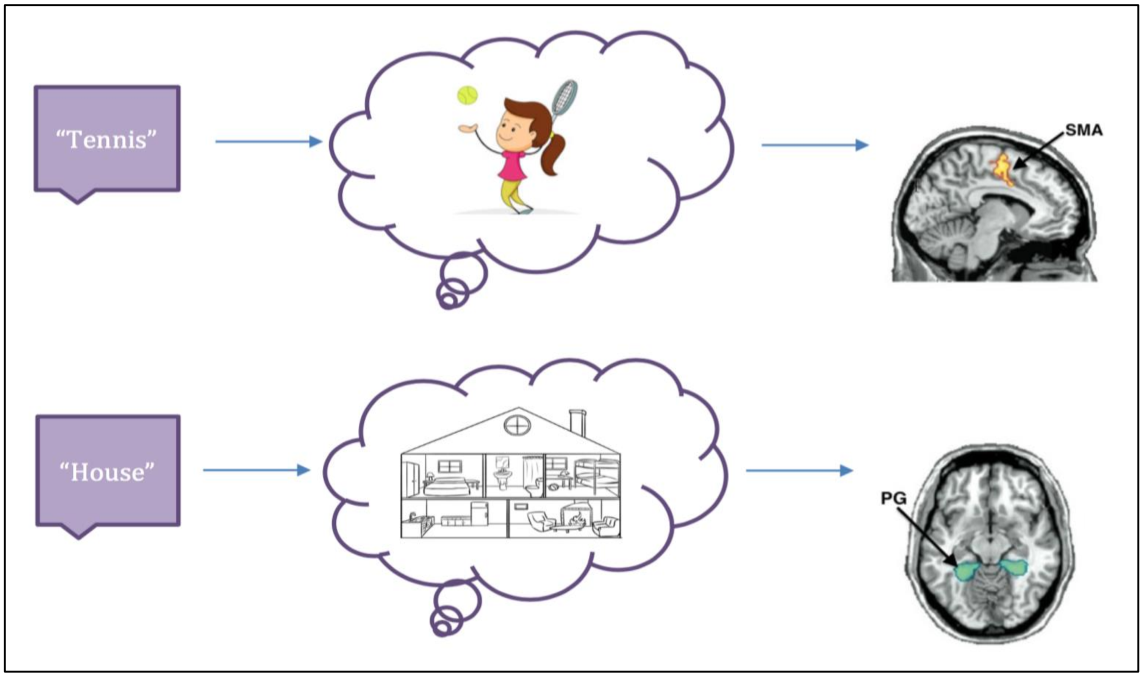
Recent advances in the neuroscience of consciousness have yet to result in major changes in the diagnosis and treatment of patients in the clinical setting. Indeed, the standard diagnostic procedures for disorders of consciousness have remained relatively unchanged for decades (Coleman et al., 2009). Traditionally, medical professionals review the clinical history of the patient and conduct a series of bedside examinations to determine whether the patient shows consistent signs of consciousness (von Wild, Laureys, Gerstenbrand, Dolce, & Onose, 2012). During the clinical assessment, auditory awareness, visual awareness, somatic awareness, and motor output are examined (Wade & Johnston, 1999). In each sensory domain, the clinician observes behavioural responses after a series of stimuli are applied to the patient (Wade & Johnston, 1999). To meet the diagnostic criteria for the vegetative state, a patient must exhibit: no evidence of awareness of oneself or the environment; no volitional response to any sensory stimuli; and no evidence of language comprehension (Wade & Johnston, 1999). A brain injured patient is diagnosed as being minimally conscious if he or she is able to perform one or more of the following to demonstrate awareness: purposeful behavior; gestural or verbal yes/no responses; intelligible verbalization; or following simple commands (von Wild et al., 2012). However, these patients remain unable to produce these behaviours consistently.

Diagnosis of disorders of consciousness can vary by clinician and location (Wade & Johnston, 1999). This can be partially attributed to the subjective nature of bedside examinations that are conducted. Diagnosis can be further complicated by the fact that patients can have motor impairment issues or fluctuating arousal states (Laureys et al., 2004). It is also possible that a patient could be unable to produce physical movement on command, but is in fact aware (Laureys et al., 2004). This ultimately can lead to a misdiagnosis; an individual who is conscious is diagnosed as being vegetative. The difficultly of diagnosis has led to a high rate of misdiagnosis in patients with disorders of consciousness, which can have serious consequences. Nearly 43% of patients who are minimally conscious are misclassified as being vegetative (Andrews, Murphy, Munday, & Littlewood, 1996). Previous research has suggested that patients who possess awareness can experience pain (Bernat, 2010). This means that a patient misdiagnosed as being vegetative, who in fact possesses awareness, could be suffering without receiving treatment to alleviate pain (Bernat, 2010). Furthermore, families use diagnostic and prognostic information to make end-of-life decisions for patients (Bernat, 2010). Since patients with awareness may have a more favourable prognosis, an accurate diagnosis could be the difference between life and death for a patient (Cullen, Park, & Bayley, 2008). With so much resting on the proper classification, researchers seek new ways to detect patient awareness that might not be displayed at the bedside.

2.4 Neuroimaging Research

In the last decade, functional magnetic resonance imaging (fMRI) has emerged as a tool to detect intact cognitive abilities in patients suffering from disorders of consciousness. In 2006, Owen and his colleagues were the first to explore if neuroimaging could detect awareness in patients who are vegetative or minimally conscious. The original study was conducted with a 23-year-old female patient, who met the clinical diagnosis of being in a vegetative state. To assess covert awareness in this patient, a specific imagery paradigm was used (Figure 1). The patient was verbally instructed to perform two mental imagery tasks while being scanned using fMRI. The first task was to imagine hitting a tennis ball back and forth, to activate the supplementary motor area (SMA) responsible for motor function. The second task was to imagine walking from room to room in her house, resulting in the parahippocampal cortices (PG) being activated, which are known to be associated with spatial navigation. While in the scanner, the patient was prompted to start imagining by the word ‘tennis’ or ‘house’ for a 30-second period. After this, the word ‘rest’ would signal for the patient to rest for 30-seconds. Each scan session involved a block of five imagery-rest cycles. The researchers found that the patient’s responses, displayed on a brain-computer interface, were indistinguishable from those of healthy controls who performed the same imagery paradigm.

Figure 1. Imagery Paradigm Conceptualization



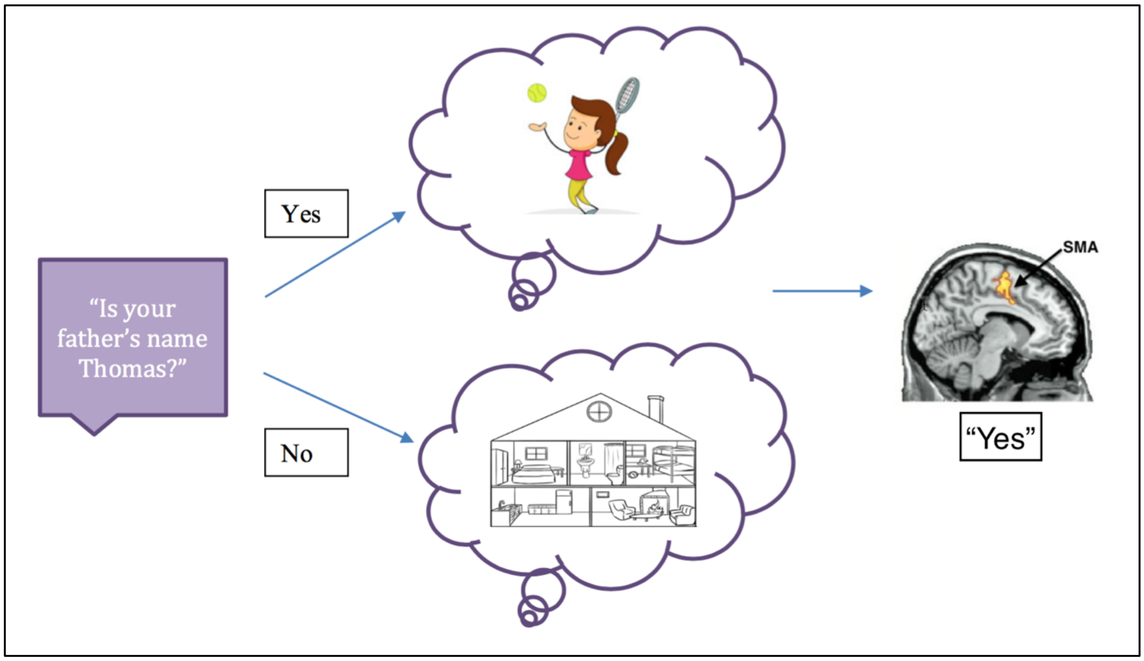
By performing the mental imagery task, the patient showed that she was able to remember instructions given at the start of scanning, comprehend verbal commands while in the fMRI, and respond correctly using her brain. Recall that during a standard bedside assessment clinicians give verbal commands and observe behavioural or speech responses. In the case of this fMRI study, the patient was following commands given to her verbally by willfully modulating her brain activity. The researchers argued that such neural activity linked to imagery motor action could be used as a proxy for physical motor behaviour. Hence, successful completion of the imagery paradigm confirmed that she was conscious.

The block experiment design used by the researchers ensured that what was being displayed was not the product of random brain activations associated with hearing certain words while in the fMRI (Fernández-Espejo & Owen, 2013). For patients to have a positive result during the imagery paradigm, they must willingly sustain their responses for a specified period of time and then switch between tasks as instructed.

This was the first study to demonstrate using fMRI that a clinically vegetative patient was in fact covertly aware (Owen et al., 2006). Furthermore, the findings from this study provide evidence that there are covertly aware patients who lack purposeful motor function during bedside examination. The imagery paradigm provides a means to detect cognitive function and awareness in select minimally conscious and vegetative state patients.

A follow-up study was conducted on a group of 54 patients diagnosed as vegetative or minimally conscious (Monti et al., 2010). After repeating the imagery paradigm, it was determined that one minimally conscious and four vegetative state patients were able to willfully modulate their brain activity, indicating conscious awareness. Furthermore, this study used a new communication paradigm to establish communication with a 22-year-old male vegetative state patient (Figure 2). Similar to the imagery paradigm, the same mental tasks were used to answer questions through modulation of brain activity. At the start of the scanning session, the patient was asked a biographical question that could be answered with a ‘yes’ or ‘no’ response (e.g. Is your father’s name Thomas?). To answer “yes” the patient was told to imagine playing a game of tennis; to answer “no” he was told to imagine walking from room-to-room in his home. While in the scanner, the verbal cue ‘answer’ would indicate the start of the imagery task for 30-seconds, followed by the cue ‘rest’ to signal a 30-second rest period. The patient was expected to imagine the mental task corresponding with the answer he wanted to convey. To avoid bias, the investigators were blinded to the correct answer to the question at time of scanning and analysis. The patient answered five of the six questions correctly (one answer could not be decoded by investigators).

Figure 2. Communication Paradigm Conceptualization



This study was the first to establish communication with a patient suffering from a disorder of consciousness using a brain-computer interface (Monti et al., 2010). To date, three patients with disorders of consciousness have been able to successfully perform the communication paradigm, despite not being able to overtly communicate at the bedside (Fernández-Espejo & Owen, 2013; Monti et al., 2010; Naci et al., 2012). All of these patients had a clinical diagnosis that did not reflect the true nature of their awareness and level of cognitive ability. A term used to describe this special subset of patients, which will be used for the remainder of this thesis, is behaviourally nonresponsive. Due to the complexity of the mental tasks, it can be concluded that patients able to complete the imagery paradigm and the communication paradigm possess a high-level of cognitive functioning beyond what is expected in their clinically diagnosed states (Fernández-Espejo & Owen, 2013). Preserved cognitive functions include sustained attention, language comprehension, working memory, and response selection.

2.5 Controversy

Legal cases regarding the withdrawal of treatment, specifically artificial nutrition and hydration, for patients in a vegetative state have sparked controversy and garnered media attention. Judges have been known to grant a family's request to withdraw treatment if it is demonstrated that the patient does not possess consciousness (Fine, 2005). It has been argued that the presence of consciousness is grounds for allowing a patient to live, and not doing so would be unethical (Fine, 2005). However, since the results of neuroimaging research have revealed that a subset of vegetative patients and minimally conscious patients are aware beyond what is expected, some philosophers have changed their stance (Skene et al., 2009). A few ethicists have stated that being conscious but unable to communicate could be "the worst form of solitary confinement" (Skene et al., 2009). Some have gone as far as saying that it would be in the best interest of those patients if treatment was withdrawn and they were allowed to die (Skene et al., 2009). Discussion surrounding the experience of these covertly conscious patients is warranted. However, missing from this discussion are those whose opinions (arguably at least) matter the most.

2.6 Patient-Reported Outcomes

Much of medical history has been documented through the lens of clinicians (Fayers & Machin, 2013). Patient physiology and biochemical information were analyzed to describe the illness and health of the patient, with minimal consideration of the patient's subjective experience (Fayers & Machin, 2013). The shift in recent years has led to health system reform that focuses on patients taking on a more active role in their health. This change to patient-centered care was largely due to the changing landscape of illnesses (Fayers & Machin, 2013). As the population continues to age, there has been an increase in the incidence of chronic diseases including cancers (Fayers & Machin, 2013). The traditional end-point of survival or disease-free survival was no longer necessarily of the utmost importance to patients (Garcia et al., 2007). Prolongation of life that would result in more suffering was seen as undesirable and inappropriate (Garcia et al., 2007). Patients and families of patients in palliative care were looking for enhancement of remaining life, not survival, as the ultimate goal of any treatment (Fayers & Machin, 2013). This led to the integration of patient reported outcomes, such as patient quality of life, into standard medical practice (Fayers & Machin, 2013).

2.7 Defining Quality of Life

The field of quality of life research has seen considerable growth in the last 20 years (Rapley, 2003). Quality of life has become the most widely used outcome in health research with widespread support for the position that it is the most important patient reported outcome (Guyatt, Feeny, & Patrick, 1993). The phrase "quality of life" has seeped into every discipline and even everyday language (Rapley, 2003). The extensive use of the term may mislead some into believing that the concept is relatively new. However, questions about what constitutes a good life can be traced back to ancient Greek philosophers (Cheung Chung, 1997). Various societies since have interpreted quality of life within the context of their culture and values (Cheung Chung, 1997). Despite the popularity of the phrase, no single universally accepted definition for quality of life exists (Rapley, 2003). The complexity of defining quality of life is attributable in part to its subjective nature; a good life means different things to different people (Carr, Gibson, & Robinson, 2001). It can encompass anything from optimal physical functioning to a low unemployment rate (Rapley, 2003). Many think of quality of life as an umbrella term that covers an assortment of physical and psychosocial constructs (Moons, Budts, & De Geest, 2006). Quality of life can be interpreted as individual evaluation of one's subjective well-being, achievement in life domains one considers important, or perceived health status compared to a desired reference (Dijkers, 1997).

In the literature, there are three major taxonomies of definitions used by researchers when discussing quality of life: global definitions, component definitions, and focused definitions (Farquhar, 1995). First, global or general definitions offer an all-encompassing concept of quality of life. The most widely cited definition of quality of life is a global definition developed by the World Health Organization:

> *"…an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's personal health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment."* (World Health Organization, 1995)

As can be seen, global definitions tend to lack specific details about quality of life and therefore issues can arise with how such a definition can be operationalized (Farquhar, 1995).

Second, component definitions break down quality of life into different components or dimensions. These specific types of definitions identify dimensions that are essential to consider when determining quality of life. For this reason, component definitions are easier to operationalize compared to global definitions of quality of life (Farquhar, 1995). One example would be Clark & Bowling's (1989) quality of life definition generated for elderly patients residing in nursing care facilities. They stated that the quality of life of these patients encompasses "privacy, freedom, respect for the individual, freedom of choice, emotional well-being, and maintenance of dignity" (Clark & Bowling, 1989). From their definition, quality of life is broken down into dimensions making it easier to measure in the target population.

Finally, focused definitions refer to only one or a couple of dimensions when trying to describe the concept of quality of life. A common example of this is when quality of life is addressed by focusing on health and/or function, also known as health-related quality of life. Specifically, health-related quality of life looks at how people perceive their lives, with the focus on their disease state and physical symptoms (Jia & Lubetkin, 2005). Similar to component definitions, focused definitions are more readily operationalized, however, they can be quite concentrated on singular aspects of life.

Since there is no information available on the reported quality of life of vegetative and minimally conscious state patients, it remains to be determined what quality of life means to these individuals. A global conceptualization of quality of life would lack the ability to be operationalized, and a focused definition would only provide a narrow view of quality of life. Therefore, this thesis sets out to explore quality of life in minimally conscious and covertly aware vegetative patients, who can communicate using a brain-computer interface, using a component definition. This will be accomplished by identifying the dimensions that are most relevant to the evaluation of quality of life in this patient population.

2.8 Dimensions of Quality of Life

To measure quality of life, both objective and subjective indicators are traditionally included as a part of instruments. Objective parameters are tangible and measureable aspects of life and usually center on social, economic, and health indicators (Costanza et al., 2007). Subjective parameters focus on personal reports of life experiences and are not usually directly observable (Costanza et al., 2007). Some have argued that the construct of quality of life is predominantly a subjective one because it is built upon a person’s perceived sense of well-being (Haas, 1999). However, individuals tend to rate their quality of life in comparison to peers and other relevant groups, so their perspective is sensitive to contextual influences (Schwarz & Strack, 1999). Furthermore, subjective answers can be shaped depending on the wording or phrasing of a question (Schwarz & Strack, 1999). To evaluate and obtain a fuller image of overall quality of life, both objective and subjective indicators must be included (Cummins, 2000).

Areas of life, or domains, are composed of objective and subjective dimensions of the same topic and can be grouped into categories like: physical, social, emotional, mental, economic, and productive well-being. Brown (1997) describes various domains that are conventionally included in quality of life instruments for individuals with disabilities. The physical domain encompasses dimensions such as: health status, physical fitness, mobility and other functional capabilities. Interpersonal relationships form the basis for social well-being and take the complexities of social networks and quality of relationships into account. Additionally, community support and engagement indicators usually fall under the domain of social well-being. Emotional well-being is influenced by mental state, self-esteem, religious faith, and sexual expression. Economic well-being is largely composed of income satisfaction but also includes one’s living environment, housing quality, and quality of the built environment. Productive quality of life is defined by development growth, self-determination, and exercise of choice or control. Life domains cannot be considered mutually exclusive; interdependency is inherent when evaluating overall quality of life (Brown, 1997). A change in one domain can lead to another domain being altered either positively or negatively. Accordingly, knowledge about an individual’s rating in one domain does not provide enough information to make conclusions about other areas in their life (Brown, 1997).

2.9 Generic versus Disease-Specific Instruments

The simplest way to gain insight into a communicative patient’s quality of life after illness is to ask directly (Fayers & Machin, 2013). Detailed questions can be asked of patients during in-person interviews, over the telephone, or in the form of a self-administered questionnaire (Rapley, 2003). Constructing standardized quality of life questionnaires has become the convention in research due to the ease of administration and standard methods to assess validity and reliability (Fayers & Machin, 2013). There are two main types of quality of life instruments: generic and disease-specific measures (Fayers & Machin, 2013).

Generic quality of life tools are broad instruments that can be applied to individuals irrespective of illness (Rapley, 2003). Furthermore, they can be used to determine quality of life in healthy individuals in the general population (Rapley, 2003).

Generic instruments can be advantageous when trying to compare quality of life among patients with different diseases, or comparing patients to healthy controls (Fayers & Machin, 2013). In contrast, disease-specific measures are designed with a particular disease group in mind (Rapley, 2003). This approach has merit, as it offers the ability to tailor questions to a particular condition (Rapley, 2003). In addition, various dimensions of quality of life can be emphasized or excluded in the questionnaire depending on the respective illness. The number of generic and disease-specific quality of life instruments has been on the rise since the incorporation of patient-reported outcomes in clinical research (Fayers & Machin, 2013).

2.10 Instrument Creation

With the explosion of quality of life instruments created in recent years, there has been a concomitant refinement of methods for quality of life tool development. The development of both generic and disease-specific instruments is a rigorous process that is time- and resource-consuming. The early stages of designing a questionnaire are focused on qualitative methods to ensure that scores accurately reflect the quality of life of patients (Fayers & Machin, 2013). Quantitative methods that follow after a measure has been created, like testing validity and reliability, rely on the assumption that all previous steps in the process of instrument development were carefully executed (Fayers & Machin, 2013). The established psychometric methods for scale development, which have been extensively used in neurodegenerative-specific instruments, use a three-step system: item generation, item reduction and scale generation, and psychometric evaluation (Jenkinson et al., 2011).

First steps in developing a quality of life instrument include: clarifying the objectives for measuring quality of life, generating a working definition of quality of life, stating the intended respondents, and selecting relevant dimensions of quality of life (Fayers & Machin, 2013). Objectives should state the intended purpose of collecting quality of life data from respondents and what will be done with the information obtained. To capture quality of life in respondents, what quality of life means to those subjects must be clarified. The working definition affects which dimensions of quality of life will be included in the instrument and which will be excluded (Fayers & Machin, 2013). Once the initial processes outlined are completed, items need to be generated for potential inclusion in the quality of life questionnaire (Fayers & Machin, 2013).

Item generation, the process of coming up with questions for patients to answer, is composed of reviewing the literature, interviewing patients with the condition of interest, and consulting with specialists (Jenkinson et al., 2011). First, a review of the literature is conducted to consider all relevant issues of quality of life for the patient population of interest (Fayers & Machin, 2013). This can include exploring existing quality of life instruments, information about the illness and its symptoms, or aspects of quality of life that would be impacted by a given health condition. This information is noted so it can be used to guide discussion with patients.

Second, selected patients with differing severity of illness participate in semi-structured interviews outlining how their condition has impacted their quality of life (Jenkinson et al., 2011). Patients can help to provide information that is not available in the literature or conveyed by specialists. Interviews are conducted until the data are saturated and no new information is introduced (Jenkinson et al., 2011). Focus groups are an alternative to conducting interviews with individual specialists or patients. In health research, a focus group is defined as a small group interview focused on specific topic and includes a moderator or facilitator (Fowler, 2002).

Third, specialists review interview transcripts independently and generate possible scale questions (Jenkinson et al., 2011). Specialists are usually health care professionals who work closely with the patient population of interest. They are able to use the material gathered from the previous two steps to address content validity, and consolidate the list of possible items for the questionnaire (Fayers & Machin, 2013). The generated questions are collectively discussed by exerts for overlap and importance until an initial questionnaire is developed (Jenkinson et al., 2011).

Item reduction and scale generation involve the preliminary questionnaire being piloted on a new sample of patients. After completed questionnaires are returned with feedback, standard item reduction approaches, such as exploratory factor analysis and Cronbach's alpha, are used to decide which questions were relevant and applicable (Williams, Weinberger, Harris, Clark, & Biller, 1999). The removal of items from the questionnaire occurs until a statistically sound scale is generated. The final step in instrument development involves the psychometric evaluation of the finished scale (Jenkinson et al., 2011). The instrument is administered to a large sample of patients and the validity and reliability of the measure are assessed or estimated (Jenkinson et al., 2011).

2.11 Gap in Knowledge

A gap in knowledge is evident when trying to establish the state of quality of life in individuals suffering from disorders of consciousness. While tools have been created for most health conditions, to date no such measure has been created to assess the welfare and lived experience of patients suffering from disorders of consciousness. To follow the procedures outlined for the development of quality of life instruments, like interviews and focus groups, requires consciousness, fluid speech, and the ability to describe experiences on the part of patients. With select vegetative and minimally conscious patients being conscious and able to communicate using a brain-computer interface, research on this patient population is anticipated to grow over the coming years. Ideally, quality of life should be a central patient-reported outcome in all populations regardless of patients' ability to communicate. It is essential to assess quality of life if health care professionals and caregivers are to do more to increase the quality of life experienced by those suffering severe brain injuries. Furthermore, measuring quality of life in patient populations is imperative to provide insight into how patients are faring and the extent to which they are satisfied with their existence.

2.12 Importance of Measuring Quality of Life in Behaviourally Nonresponsive Individuals

Little has been said about the importance of measuring quality of life in behaviourally nonresponsive patients. The complex tasks undertaken to develop a quality of life instrument are not only justified but also necessary. Quality of life should be evaluated in behaviourally nonresponsive individuals because these patients have moral status and there is a moral obligation to take their needs and interests into consideration.

Additionally, there is an opportunity to gain insight into the vegetative and minimally conscious state and to learn about the lived experience of these patients.

Graham (2015) has argued that patients in a minimally conscious or vegetative state with covert awareness have moral status because they are sentient. Sentience is simply the ability of an entity to suffer or experience pleasure (Graham et al., 2015). Previous research has established that minimally conscious patients experience pain similarly to healthy controls (Bernat, 2010). It has also been shown that patients in a vegetative state may retain the capacity to experience physical pain through responses in the pain matrix and pain-related brain activations (Kassubek et al., 2003). This provides strong evidence that covertly aware vegetative patients have the ability to experience pain and suffer but does not prove it with certainty. Nonetheless, it can be reasoned that prudence demands that we treat these patients as sentient (Graham et al., 2015). The alternative, possibly ignoring these patients' suffering, has far worse consequences.

It can be reasoned that all sentient entities have moral status and, therefore, are entitled to have their needs and interests considered equally (Graham et al., 2015). Moral status is a characteristic of entities, that means they matter morally for their own sake (Graham et al., 2015). Because of this status, other moral agents are obligated to weigh their interests and well-being equally to that of other moral agents. This does not mean that the interests of all entities with moral status are the same, but, rather that their individual interests must be given consideration. Since covertly aware patients have moral status, healthcare researchers and professionals have a moral obligation to take their welfare interests into account (Graham et al., 2015). To understand patient welfare interests, it first must be established what these interests are for behaviourally nonresponsive individuals. Quality of life instruments can help address this gap in knowledge.

Neuroimaging imagery and communication paradigms indicate possible higher-level cognition in patients with positive results (Fernández-Espejo & Owen, 2013). Given this information, it is conceivable that behaviourally nonresponsive patients have the capacity to experience more complex welfare interests and needs than simply avoidance of physical pain (Graham et al., 2015). In one study, it was found that behaviourally nonresponsive patients had brain activity that was highly synchronized with healthy controls, when watching a suspense-filled movie by Alfred Hitchcock while in fMRI (Naci, Cusack, Anello, & Owen, 2014). The synchronization of executive function in the two groups offers evidence that when exposed to the same information, they have a similar cognitive experience (Naci et al., 2014). Further understanding of the extent of complexity of needs in behaviourally nonresponsive individuals can be determined using a brain-computer interface. Imagery responses to quality of life questions can indicate the intricacies of their needs. Additionally, the information gained from evaluating quality of life can help clinicians and researchers better understand the vegetative and minimally conscious state. This can aid with the development of care guidelines for patients and future research into disorders of consciousness.

What constitutes a ‘good life’ for a vegetative or minimally conscious patient has yet to be determined. It would be erroneous to assume it is reasonable to apply the same definition to both healthy adults and these patients. Direct quality of life assessment is the only way to gain insight into whether behaviourally nonresponsive individuals are satisfied with their existence and how their care could be improved. If the existing opinion surveys of physicians and members of the general population are consulted for perspective on the lived experience of these patients, the situation seems dire (Payne, Taylor, Stocking, & Sachs, 1996). The majority of respondents fail to see how such a life could be worth living, stating that vegetative state patients are better off dead (Pearlman et al., 1993). It is important to know how patients with disorders of consciousness perceive their circumstances after suffering a life-altering injury. Quality of life is based on how an individual perceives his or her life, not what others attribute to it. Likewise, information pertaining to quality of life is essential for healthcare professionals and caregivers so they can modify or further enhance ongoing care.

2.13 Response Shift

Quality of life is a dynamic construct where values and expectations of self may change over the course of time and in response to life events and experiences (Carr et al., 2001). There is potential for instability in a person’s interpretation of what quality of life means to him or her. In the literature, the change individuals undergo in the way they conceptualize their quality of life as a result of internal changes in values or standards is referred to as response shift (Sprangers & Schwartz, 1999). The phenomenon of response shift has been observed in patients with severe disabilities (Livneh & Martz, 2015). People suffering from chronic and life threatening illnesses have been known to evaluate their quality of life differently post impairment (Wittink, Rogers, Sukiennik, & Carr, 2003). A person’s sense of self can be dramatically altered after a sudden acquired injury or change in health status (Bishop, 2005). To respond to the functional, psychosocial, and social changes occurring during such a time, the individual can undergo a process of adapting to his or her situation (Bishop, 2005). This can manifest in the form of changed values, beliefs, and expectations (Brown, 1997). Adaptation to one’s changing circumstances is not a new concept; an organism’s ability to adapt to change is not only desirable but also necessary for survival. The construct of evolution is built upon the foundation of species adjusting to their environment, or facing extinction.

Response shift can create challenges for measuring quality of life in patients with disabilities (Schwartz, Sprangers, & Fayers, 2005). Methodologists need to consider how adaptive behaviour results in certain values shifting and becoming more or less important in quality of life reporting (Schwartz et al., 2005). This is especially true of questions designed to measure objective quality of life. The individual may have learned to adapt to their limitation(s) in a certain dimension and including an objective indicator would needlessly result in a lower quality of life score. Both objective and subjective indicators are important to obtain an accurate picture of an individual’s quality of life, but considering one more favourable over the other may result in inaccuracies (Schwartz et al., 2005).

It is reasonable to assume that when considering patients with disorders of consciousness, some quality of life dimensions may be irrelevant because of the extent of their injuries (Wittink et al., 2003). Vegetative and minimally conscious state patients are dependent and bedridden, and would objectively have poor physical health and functioning. Using only these dimensions to evaluate quality of life in patients with a disorder of consciousness would be inappropriate. Additionally, due to response shift, behaviourally nonresponsive patients quite possibly have altered their values and weigh areas of their life differently post injury. Although designing a quality of life instrument tailored to include only relevant dimensions presents a challenge, it is critical for understanding life from the perspective of behaviourally nonresponsive patients.

2.14 Disability Paradox

It is a common misconception that those with severe disability have a lower quality of life (Albrecht & Devlieger, 1999). ‘Disability paradox’ is the term coined to refer to the phenomenon where the majority of individuals with moderate to serious disability rate themselves as having excellent or good quality of life (Albrecht & Devlieger, 1999). The concept may appear counter-intuitive to most external spectators, however many studies have documented this paradox. A noteworthy example included locked-in syndrome patients, a patient population that is comparable to behaviourally nonresponsive patients. The locked-in distinction is used to describe patients who are fully conscious and paralyzed (Laureys et al., 2005). Locked-in individuals are unable to produce speech, limb or facial movements, but retain vertical eye movement (Laureys et al., 2005). Patients can use coded eye movement to facilitate non-verbal communication with healthcare providers, researchers, and loved ones. In one study, locked-in syndrome patients self-scored their perceived well-being and their scores were not found to be significantly different than that of age-matched controls in the general population (Laureys et al., 2005). In a similar study of quality of life for 65 subjects, 47 (72%) reported that they were happy while only 18 stated they were unhappy (Bruno, 2011). Furthermore, very few locked-in patients report suicidal ideation after being in the state for 6 years or longer (Lulé et al., 2009).

The evidence suggests that the quality of life of someone who is severely disabled is not as bad as one may believe. The relationship between health and quality of life is not simple. It is possible that a behaviourally nonresponsive patient is satisfied with a level of quality of life that a healthy adult in the general population would not be (Graham et al., 2015). While physicians, ethicists, and family members can make assumptions about what it is like to be suffering from a disorder of consciousness, it is impossible for them to know definitively. Only an individual in a vegetative or minimally conscious state can “speak” to his or her lived experience. For this reason, a dialogue on what constitutes a life worth living should not be had without the patients themselves.

2.15 Existing Tools and Technologies

One of the greatest obstacles to determining quality of life in behaviourally nonresponsive patients is the lack of existing validated instruments that could be applied to these patients. Generic and disease-specific tools usually use a mixture of question formats and the majority include questions that are ordinal in nature (Fayers & Machin, 2013). Ordinal scales are composed of multiple response options that are inherently ordered or graded (Fayers & Machin, 2013). The most widely used ordinal scale in quality of life research is the Likert-type scale, which has response options labeled from ‘strongly disagree’ to ‘strongly agree’ with a neutral response in the middle (Fayers & Machin, 2013). These options are problematic because the available brain-computer interface and communication paradigm is designed to only support ‘yes’ or ‘no’ responses from patients.

A standard overall quality of life measure typically contains dozens of questions using ordinal response options. Using an existing lengthy quality of life measure, even if valid and reliable, is not feasible in behaviourally nonresponsive individuals. Due to the taxing nature of neuroimaging and command following, only a limited number of questions can be posed to patients during a scanning session. A longer questionnaire would allow for more details to be captured but a shorter questionnaire would ensure all the questions are answered. A balance must be struck when considering a quality of life instrument for patients that can only communicate using mental imagery in fMRI.

Furthermore, much research has focused on proxy-rated quality of life to determine if it can be an appropriate alternative to patient-rated quality of life. Bullinger (2002) employed a consensus meeting with a group of experts discussing the methods used to evaluated quality of life in patients who had suffered from a traumatic brain injury. It was agreed by the experts that proxies should not be used because their responses do not accurately reflect the patient's perspective. Proxies, especially physicians, tend to underestimate the quality of life of patients (Wilson, Dowling, Abdolell, & Tannock, 2000). It is difficult for healthy individuals to imagine what it would be like to be in a bedridden state with minimal mobility.

Finally, traditional methods to develop quality of life measures, like the ones previously outlined, cannot be applied to patients with disorders of consciousness. Regardless of the scale development technique, patient interviews are considered central to the process (Jenkinson et al., 2011). They are vital to the initial process of item generation to provide their personal experience. Currently, technology does not support an open dialogue format between researchers and behaviourally nonresponsive patients. This means that no interview process is possible and patients are unable to give their unique perspective directly.

These unique circumstances present obstacles that no other development process for a quality of life instrument has had to navigate. A novel approach needs to be considered if a measure to assess quality of life in this patient population is to be created.

2.16 A Novel Approach

In 2014, a study aimed at identifying the core dimensions of health-related quality of life was conducted in the Netherlands (Pietersma, De Vries, & Van Den Akker-Van Marle, 2014). Since the concept of quality of life used in an instrument is based on the definition used, there is no uniform set of dimensions used in every health-related quality of life measure. The researchers set out to establish the dimensions that are important, in the context of healthcare interventions, for inclusion in instruments to measure health-related quality of life. To accomplish this task, the researchers conducted an online three-stage Delphi consensus process with five stakeholder groups: patients, family members of patients, clinicians, scientific experts, and members of the general population. A non-systematic search was done in one database to identify existing disease-specific and generic instruments measuring health-related quality of life. They considered instruments that applied a global, component, or focused conceptualization of quality of life. The identified health-related quality of life instruments were used to generate an extensive list of dimensions of health-related quality of life. This list formed the basis of the Delphi process and the stakeholders were asked to select the dimensions they felt were essential for inclusion in health-related quality of life instruments. At the end, the researchers obtained a list of the top 10 dimensions that were selected by the stakeholders.

The study by Pietersma et al. (2014) provides a novel approach for how the first steps of instrument creation, mainly selecting relevant dimensions of quality of life, could be accomplished.

2.17 Proposed Study

To date the literature contains no instrument that can reliably assess quality of life in behaviourally nonresponsive patient, nor does it provide insight into which specific areas of life should be considered important. The purpose of this thesis is to generate the foundational knowledge necessary to complete the first step in developing a quality of life instrument for behaviourally nonresponsive patients who are able to communicate through a brain-computer interface. To accomplish this task, the Aware Study was designed to determine which dimensions of quality of life are the most relevant and important to behaviourally nonresponsive patients. Using similar methods undertaken by Pietersma et al. (2014), a systematic search and a multidisciplinary panel of experts was enlisted to help provide their expertise on the issue using consensus methodology. The end product of the Aware Study is a list of key dimensions of quality of life that experts have deemed essential in evaluating quality of life in behaviourally nonresponsive patients.

Chapter 3

3 Methods

The Aware Study set out to determine which dimensions of quality of life are the most relevant and important to minimally conscious and covertly aware vegetative state patients, who can communicate using a brain-computer interface (behaviourally nonresponsive patients). A two-pronged strategy was employed that included a systematic instrument search and a Delphi consensus process. This chapter describes the Aware Study including its design, recruitment strategies, and statistical analyses.

Approval was obtained from the Western University Health Science Research Ethics Board on July 22, 2016 (File Number: 108066; Appendix 1).

3.1 Consensus Methods

There are many instances in which decisions must be made in light of conflicting or scarce information. Consensus methodology was devised as a method to bring together experts on a particular issue with the goal to reach a convergence of opinion (Jacobsen, 2011). This differs markedly from a standard committee or focus group, due to the structured nature of consensus techniques. Furthermore, consensus methods use multiple iterations for experts to reach agreement, a feedback process for experts to see how others have responded, and the responses are analyzed statistically (Jones & Hunter, 1995). Although there is considerable variation in the methods employed, the basic approach typically requires participants to make independent judgments before and after exposure to the views of other participants (Jones & Hunter, 1995). Additionally, detailed guidelines have been developed to ensure that consensus techniques are carried out consistently across studies (Fink, Kosecoff, Chassin, & Brook, 1984).

The term ‘agreement’ takes on two distinct forms in consensus methodology research: (a) the degree to which individual experts agree with the issue or statement posed to them, and; (b) the degree to which the participants agree with each other on a particular issue or statement (Meijering, Kampen, & Tobi, 2013).

3.2 Delphi Method

The Aware Study employed the Delphi consensus technique, which involves the systematic gathering of information from participants within their domain of expertise, using a series of purposefully designed surveys (Keeney, Hasson, & McKenna, 2010). With the advancement of technology, geography is no longer an obstacle and the Delphi process is now almost exclusively conducted online. It is not necessary for participants to meet in person to reach consensus on an issue. Surveys are sent out to participants online and responses are collected. With each iteration of the questionnaire, called rounds, results from the previous survey are summarized and fed back to participants before the next survey is to be completed. The purpose of this feedback process is to allow the experts to reassess their original answers and possibly change their opinion in the next round (Keeney et al., 2010). Additionally, the feedback process is anonymous and only aggregate data are shown to participants as part of the summary report. Anonymity allows participants the equal opportunity to put forth ideas in an unbiased fashion with all opinions being weighted the same (Hsu & Sandford, 2007). In the Delphi process, participants are referred to as experts because these individuals have expertise in areas that are of interest to the researchers (Hsu & Sandford, 2007).

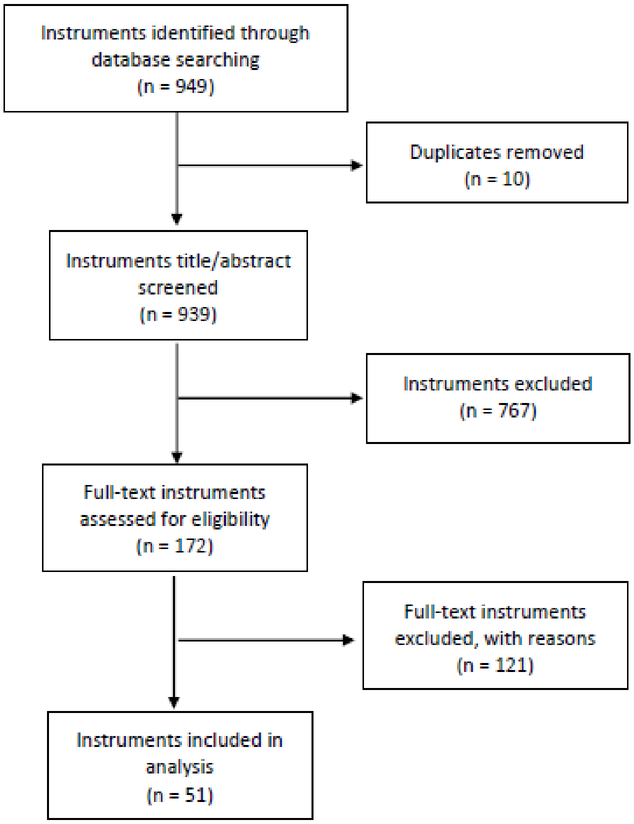
In the Aware Study, there were a total of three rounds with three online surveys, from September to November 2016. Invited study participants had expertise in at least one of the following areas: healthcare, neuroscience, quality of life methodology, philosophy (including bioethics), or patient advocacy. Experts who consented to study participation were emailed links to each survey and had a two-week deadline to complete the survey. Only those who participated in the first survey were sent the second and third iteration of the survey. After each round, the results were analyzed and a summary report with aggregate data was emailed to the participating experts. Experts were given the opportunity to see how other participants responded and reflect on their own responses before completing the next survey.

3.3 Systematic Search

To construct the first questionnaire for the Delphi process, a systematic literature search was conducted to identify dimensions of quality of life from existing quality of life instruments. Measures designed to be administered in patient populations similar in aspects to behaviourally nonresponsive patients were considered, such as: those with neurological or neurodegenerative conditions, disabilities or cognitive issues, along with patients with trauma or brain injury. These specific patient populations were selected because the aforementioned conditions can leave patients profoundly disabled with motor, cognitive, and language issues. The dimensions identified from the systematic search provided a starting point in assessing quality of life in behaviourally nonresponsive patients. The assumption was that dimensions used by researchers to evaluate quality of life in similar patients may have the potential to accurately capture quality of life in behaviourally nonresponsive patients. Additionally, since some of the instruments were developed for patients with life-changing injuries, the researchers likely accounted for response shift in patients when selecting dimensions.

A search of published quality of life instruments in the aforementioned patient populations was conducted in March 2016. The electronic databases Health and Psychosocial Instruments, PsycTests, and Mental Measurement Yearbook were searched using the following keywords: 1) quality of life OR well-being; 2) neurological OR neurodegenerative OR disability OR cognitive OR trauma OR brain injury; 3) #1 AND #2. Two levels of screening were performed to scan for keywords and relevance including title/abstract and full text review.

Figure 3. Dimension Search Strategy & Results



To meet the criteria for inclusion in this review, a quality of life instrument needed to: 1) be designed for the patient populations of interest; 2) employ a multidimensional definition of quality of life; 3) be developed to be completed by adult patients themselves, not proxies, children, or caregivers; 4) be available in English.

The search resulted in the identification of 51 instruments developed for assessing quality of life in patients who share characteristics with behaviourally nonresponsive patients. Each identified instrument was examined closely and the dimensions used to evaluate quality of life were extracted. If a particular dimension was unclear, the groupings of questions on the measure were inspected and the theme of the questions was identified as the dimension. The dimensions from each instrument were categorized as: physical well-being, mental well-being, social well-being, psychosocial well-being, economic well-being, overall quality of life, or other. Furthermore, dimensions were grouped and collapsed if they addressed the same construct, but no further modifications to the dimensions were made. In total, 42 unique dimensions of quality of life were identified from the instruments that were included in the review. A description was generated for each dimension by consulting the original instrument it was used in. This served as a quality check to ensure that groupings and naming of dimensions was not misconstrued from their initial meaning.

3.4 Questionnaire Development

The first round questionnaire used in the Delphi process was composed of the list of 42 dimensions of quality of life identified through the systematic search outlined in Section 3.3. Each dimension was provided with a description to allow participants to understand how the dimension(s) was used in the original quality of life instrument. The questionnaire contained close-ended questions, rather than open-ended questions as is more typical in the first round of Delphi studies. The use of closed-ended questions allowed the first questionnaire to be systematically generated with a defined structure. Several reasons support this approach. First, it has been reported previously that having open-ended questions in the first iteration can be too time consuming and cognitively demanding of experts (Skulmoski, Hartman, & Krahn, 2007). Second, since not all participants in the Aware Study were familiar with behaviourally nonresponsive patients, providing a list of dimensions currently in use in similar instruments provided some direction. However, participants were also instructed to add a dimension if they believed something was missing from the list of quality of life dimensions.

3.5 Participant Criteria

The Aware Study set out to recruit representatives from all stakeholder groups concerned with the care and welfare of minimally conscious and vegetative state patients. Therefore, five expert groups were recruited for this study: (a) healthcare professionals – frontline healthcare workers (neurologists, physiatrists, nurses) who have worked closely with vegetative or minimally conscious patients, for at least one year prior to this study; (b) neuroscientists – scientists who are actively conducting research with patients in a vegetative or minimally conscious state; (c) philosophers – individuals with expertise in well-being or bioethics *and* who have published research in peer-reviewed journals on welfare or disorders of consciousness *or* are on the editorial board of a prominent journal relevant to well-being or bioethics; (d) quality of life methodologists – researchers with experience in developing, and evaluating measures of quality of life *and* who have published research in peer-reviewed journals on the subject matter *or* are on the editorial board of a prominent journal on quality of life; and (e) patient advocates – family members of vegetative or minimally conscious patients, including those who are current or former participants in the Owen Lab’s research program on disorders of consciousness at Western University, *or* former patients who were diagnosed as being in a vegetative or minimally conscious state.

In the literature, there is no stated optional number of participants to compose a Delphi expert panel (Hsu & Sandford, 2007). However, recruiting too small of a sample can mean that the participating experts are not representative of the larger stakeholder group to which they belong, or having a sample too large can increase non-response bias. It has been recommended there be around 5-10 participants per each expert category (de Villiers, de Villiers, & Kent, 2005). In this study the aim was to recruit eight participants from each category to ensure that a heterogeneous group was selected with varying opinions.

3.6 Recruitment

To recruit healthcare professionals, neuroscientists, philosophers, and quality of life methodologists, an adaptation of the Borgiel recruitment method was utilized (Borgiel et al., 1989). Originally, the method was designed to use peer recruitment to overcome the traditionally low participation rates of physicians in research. Borgiel et al. (1989) enlisted physicians with high professional standing and influence to act as recruiters and encourage other physicians to participate in the study. The Aware Study used a similar approach to enroll experts into the study; professionals with experience dealing with patients that suffer from disorders of consciousness were invited to be a part of the Aware Study research team. These research team members would then act as recruiters and solicit professional peers to partake in the Aware Study. To determine which experts would participate, members of the research team nominated potential healthcare professionals, neuroscientists, philosophers, and quality of life methodologists who would be valuable to the study (list of research team members can be found in Appendix 2). These nominated experts were a part of the research team member's extended professional network. The research team individually generated a list of names of potential participants in their professional network and subsequently ranked these individuals. According to the rank, potential participants were informally contacted either in-person, through email, or telephone to introduce them to the study. Experts who expressed interest in the study were emailed the letter of information and informational package.

Patient advocates were identified through their current or former participation in research programs at Western University. More specifically, the relevant protocols from which some patient advocates were recruited from are: (a) EEG assessment of sensory and cognitive functioning in patients with disorders of consciousness (REB #18089 – Ethics File #100628); (b) Assessing residual cognitive function in patients with disorders of consciousness (REB #18124 – Ethics File #100963). The research coordinator for the above mentioned studies and Aware Study research team member, Laura Gonzalez Lara, contacted each of the patient advocates. She informed potential participants of this study and provided them with a letter of information and obtained informed consent. Only if a patient advocate signed and returned a consent form was his or her identity disclosed to the remainder of the Aware Study research team.

3.7 Study Procedure

All potential participants were emailed a letter of information about the Aware Study, an informational package about relevant research on behaviourally nonresponsive patients, and an overview of the Delphi process two weeks prior to the first round. The letter of information outlined the study's aims, time requirements, and participation expectations. Additionally, the letter of information was provided again as the preface to the first questionnaire and participants were instructed that they would be providing explicit consent by clicking to continue onto the survey. Participants completed a series of three iterative self-administered questionnaires using the online survey platform, *Qualtrics* (Qualtrics, 2016). For each round, participants were emailed a unique link to the questionnaire and given an initial deadline of one week to complete the survey. A single reminder email was sent out at the end of the one-week period offering an extension of an additional week to those participants who had not yet completed the questionnaire. Each of the three questionnaires took approximately 15-20 minutes to complete and were administered at three-week intervals. A summary report with aggregate data of the previous round accompanied the second and third round questionnaire links.

Questionnaires for all three rounds, including the informational package and summary reports, can found in Appendix 3-10.

Data Collection and Analysis

3.8 Round 1

The first questionnaire included the list of 42 dimensions of quality of life that were selected systematically from existing quality of life instruments in use in populations that share characteristics with behaviourally nonresponsive patients. Along with the dimensions, a description of each dimension was provided so that the participant was aware of how the dimension was used in the original instrument. These dimensions and descriptions were categorized into seven conventional domains: physical well-being, mental well-being, social well-being, psychosocial well-being, economic well-being, overall quality of life and other. There was an opportunity for the experts during this round to add dimensions, with a short description, that they felt were missing from the list. Participants were asked to rate the importance of each dimension in the assessment of quality of life in behaviourally nonresponsive patients, on a scale from 1 (not important) to 4 (very important). The questionnaire was available to all participants for two weeks. After one week had past, a reminder was sent to all participants who had not yet completed the questionnaire. A report summarizing the results of the first round was generated and the information in the report was anonymized so identities of participants could be concealed. The summary report was emailed to the experts along with the second iteration of the questionnaire.

3.9 Round 1 Analysis

The analysis plans for round one and subsequent rounds were largely modeled on the study conducted by Pietersma et al. (2014). This was done to maintain consistency with the methodology adapted from the study and because a general standard for measuring and determining consensus in Delphi studies does not yet exist (von der Gracht, 2012). The vast majority of researchers use different levels of agreements to indicate consensus in their studies.

A median score was calculated for each dimension. There were three possible outcomes for each dimension: consensus that the dimension is important, consensus that the dimension is not important, or no consensus reached on the dimension for its inclusion in an instrument to assess quality of life in behaviourally nonresponsive patients. Consensus on the importance, or lack there of, was considered reached if a particular dimension had a median score equal to 4 (very important) or 1 (not important), respectively. If the median score was less than 4 but greater than 1, it was deemed that no consensus was obtained.

Three researchers reviewed the suggested dimensions provided by the experts. Collectively, it was determined if the suggested dimension was novel. If so, a dimension name and description was generated jointly.

3.10 Round 2

The second survey was made available through an emailed link three weeks after the first questionnaire was sent out. Along with the survey, the summary report from the first round was emailed to experts for consideration before proceeding to the survey. The second round survey included the dimensions on which consensus had not been reached and the newly added dimensions that were suggested by the experts. Participants were informed of the dimensions on which consensus had been reached. Participants were instructed to rate the list of remaining dimensions, on a seven-point scale from 1 (not at all important) to 7 (extremely important). Experts were asked to consider their previous responses while keeping the summary report in mind. This gave experts the ability to change their ratings in light of the group's response. As per Delphi Method convention, participants were unable to suggest any further novel dimensions during this round (Hsu & Sandford, 2007). The second questionnaire was available to all participants for two weeks. After one week had past, a reminder was sent to all participants who had not yet completed the questionnaire. A report summarizing the results of the second round was generated and emailed to the experts along with the third iteration of the questionnaire.

3.11 Round 2 Analysis

Similar to the analysis in round one, median scores were calculated for each dimension and each dimension had three possible outcomes. The increase in the response options, from four to seven, allowed for more variance and a semi-interquartile range (SIR) analysis. The SIR is a measure of spread and is interpreted as half the distance needed to cover half the expert scores (Evans, 1996). Specifically,

$$SIR = \frac{Q_3 - Q_1}{2} = \frac{IQR}{2}$$

Consensus on the importance of a particular dimension was established if the SIR was less than or equal to 1 and the median score was higher than 5. Consensus on the lack of importance of a particular dimension was met if the SIR was less than or equal to 1 and the median score was 5 or less. No decisions about consensus were considered reached if the SIR was greater than 1.

3.12 Round 3

The third survey was made available through an emailed link three weeks after the second questionnaire was sent out. Along with the survey, the summary report from the second round was emailed to experts for consideration before proceeding to the survey. The third round survey included the dimensions of quality of life on which consensus had not been reached during the second round. Participants were instructed to rate the dimensions on the same seven-point scale used in the former questionnaire. Recognizing that patients can only be asked a very limited number of questions, the experts were also asked to select and order the five dimensions they deemed to be essential for evaluating quality of life in behaviourally nonresponsive patients. The third questionnaire was available to all participants for two weeks. After one week, a reminder was sent to all participants who had not yet completed the questionnaire. The final summary report was emailed to the experts six weeks after the completion of the third round.

3.13 Round 3 Analysis

Similar to round two, SIR and median scores were calculated for each dimension on the third survey. Furthermore, a mean rank score was generated for the five dimensions each expert selected. This allowed for a list to be generated of all dimensions that were mentioned, in the respective order of importance.

Subgroup analyses were conducted to reveal if there were similarities or differences in rating of dimensions between expert groups. The expert panel was split into two groups, patient advocates and remaining professionals (healthcare professionals, quality of life methodologists, philosophers or bioethicists, and neuroscientists). The panel was split in such a way because the patient advocate group differs the most from the other groups in the nature of their interaction with behaviourally nonresponsive patients. Patient advocates are more likely to have a personal relationship with patients, whereas the other expert groups have professional interactions with patients.

The first subgroup analysis examined differences in rating of dimensions that were deemed by the full panel to lack importance for assessing quality of life in behaviourally nonresponsive patients. The purpose of this analysis was to determine if there were any dimensions that patient advocates rated as being important but were ultimately labelled as not being important and excluded from subsequent rounds. The second subgroup analysis examined which dimensions patient advocates selected and ranked in their top five compared with the selections of the professionals. The findings from this analysis will illustrate if patient advocates favour particular dimensions in terms of importance for quality of life evaluation more or less than professionals.

3.14 Confidentiality and Data Security

Participants were asked to provide basic personal identifiers including: full name, email, and professional credentials. These identifiers were requested because email information was needed to send the unique link to complete the web survey, having the participant’s full name allowed for personalization of correspondence, and professional credentials allowed for classification of participants for subgroup analyses.

Qualtrics was used to create and distribute the online surveys for the Delphi process as part of the Aware Study. This platform differs from other major online survey development software because customers own and control their created or collected data

(Qualtrics, 2015). Furthermore, to address Western's privacy concerns, Qualtrics hosts all survey data in Ireland and not the United States. The servers are protected by various techniques: high-end firewall systems, regular vulnerability scans, quick failover points with redundant hardware, and nightly encrypted backups (Qualtrics, 2015).

Since unique links were generated for each participant, the completed online questionnaires did not contain personal identifiers and they were securely stored on the Qualtrics server. The server could only be accessed with the user name and password associated with the account. Additionally, Transport Layer Security (TLS) encryption enabled information transmitted between respondents and the Qualtrics servers to be protected (Qualtrics, 2015). A master list was created that included the participant's full name, email, and professional credentials. All digital data that were downloaded were encrypted with a password for storage. Digital files were stored on university network drives at Western University. Specifically, the digital files were stored on the Schulich School of Medicine and Dentistry network, a secure network located behind institutional firewalls.

Chapter 4

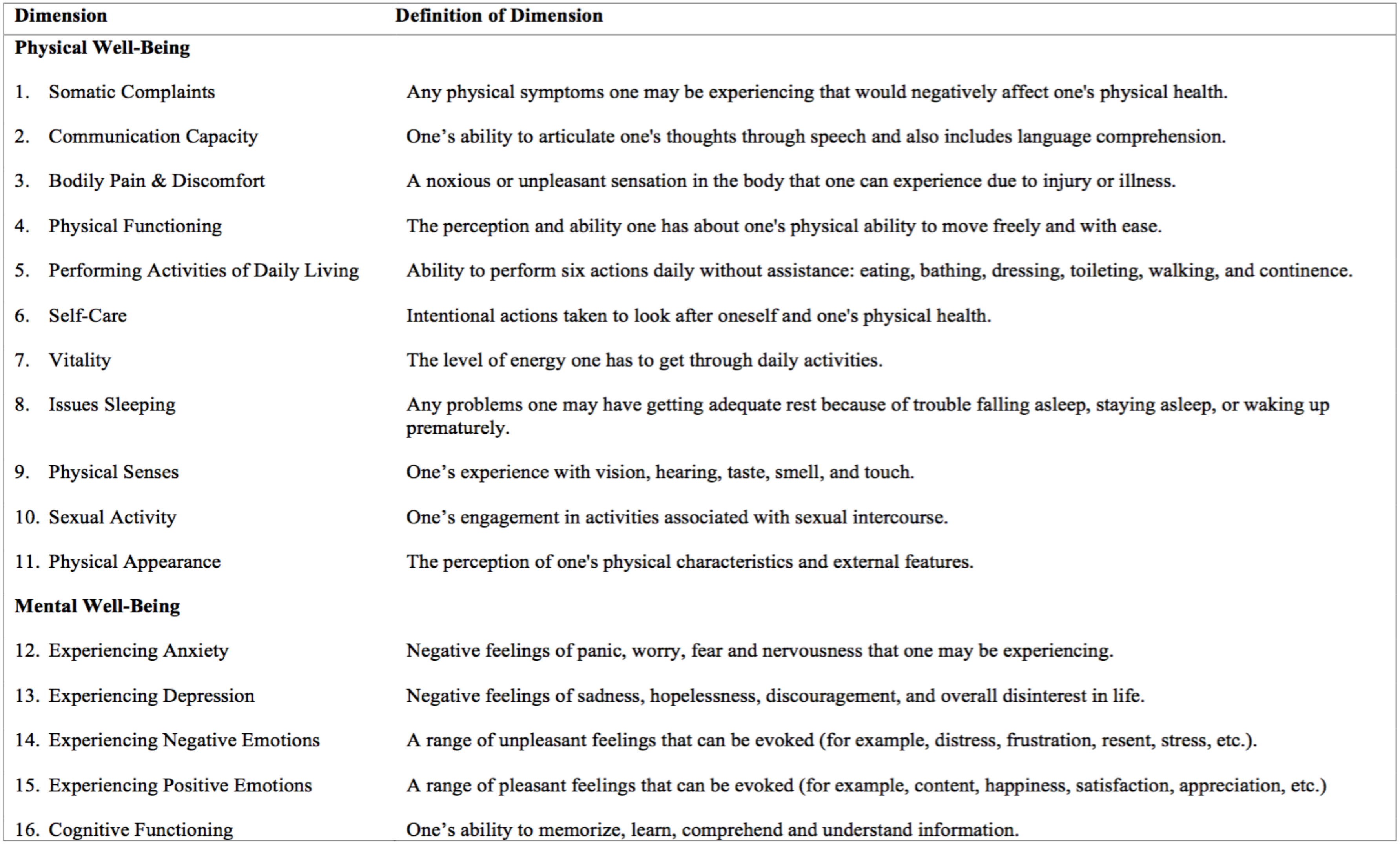
4 Results

In this chapter, the main findings of the Aware Study are reviewed. The chapter begins with the results from the systematic search for quality of life instruments designed for patients with similar characteristics to minimally conscious and covertly aware vegetative state patients, who can communicate using a brain-computer interface (behaviourally nonresponsive patients). This is followed by a description of the experts who composed the Delphi consensus panel, including their professional expertise, subgroup numbers, and participation throughout the three rounds of data collection. Next, the results of each individual round of the Delphi process are explained, including which dimensions of quality of life had consensus reached on importance, or lack of importance. Finally, subgroup analyses are presented to compare the extent of consensus on particular dimensions of quality of life and the rankings of dimensions among patient advocates and the other professionals.

4.1 Systematic Search

The systematic search of the literature identified 51 quality of life instruments developed for patients who share some characteristics with behaviourally nonresponsive patients. Each instrument was examined for dimensions used to assess quality of life in their respective patient populations. After exclusion of duplicates, 124 different dimensions were identified from all the instruments. Dimensions were grouped and collapsed if they addressed the same construct, which resulted in 42 unique dimensions of quality of life. The dimensions were categorized as: physical well-being (11), mental well-being (11), social well-being (4), psychosocial well-being (3), economic well-being (2), other (10), and overall quality of life (1). The final list of 42 dimensions along with their descriptions, is presented in Figure 4.

Figure 4. Dimensions of Quality of Life Identified from Systematic Search



Dimension	Definition of Dimension
Physical Well-Being	
1. Somatic Complaints	Any physical symptoms one may be experiencing that would negatively affect one's physical health.
2. Communication Capacity	One’s ability to articulate one's thoughts through speech and also includes language comprehension.
3. Bodily Pain & Discomfort	A noxious or unpleasant sensation in the body that one can experience due to injury or illness.
4. Physical Functioning	The perception and ability one has about one's physical ability to move freely and with ease.
5. Performing Activities of Daily Living	Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.
6. Self-Care	Intentional actions taken to look after oneself and one's physical health.
7. Vitality	The level of energy one has to get through daily activities.
8. Issues Sleeping	Any problems one may have getting adequate rest because of trouble falling asleep, staying asleep, or waking up prematurely.
9. Physical Senses	One’s experience with vision, hearing, taste, smell, and touch.
10. Sexual Activity	One’s engagement in activities associated with sexual intercourse.
11. Physical Appearance	The perception of one's physical characteristics and external features.
Mental Well-Being	
12. Experiencing Anxiety	Negative feelings of panic, worry, fear and nervousness that one may be experiencing.
13. Experiencing Depression	Negative feelings of sadness, hopelessness, discouragement, and overall disinterest in life.
14. Experiencing Negative Emotions	A range of unpleasant feelings that can be evoked (for example, distress, frustration, resent, stress, etc.).
15. Experiencing Positive Emotions	A range of pleasant feelings that can be evoked (for example, content, happiness, satisfaction, appreciation, etc.)
16. Cognitive Functioning	One’s ability to memorize, learn, comprehend and understand information.

Dimension	Definition of Dimension
17. Self-Acceptance	One’s ability to like oneself in light of one’s limits, failures, and circumstances.
18. Self-Esteem	The value one places on one's worth and capabilities.
19. Sense of Identity	The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.
20. Ability to Cope	One’s capacity to manage and overcome difficult situations and regulate one's unpleasant emotions.
21. Experiencing Loneliness	The feeling of being alone or isolated from others. It can also be the feeling of having been rejected by others.
22. Perception of One’s Health	One’s health refers to the positive and/or negative opinion or attitude one has about one's overall health.
23. Positive Future Outlook	Feeling that one’s life is heading in a good direction and one is striving towards positive outcomes.
24. Appreciation of Life	Being grateful for the life one has and deeming one’s existence as meaningful.
Social Well-Being	
25. Social Functioning	The level of interpersonal interactions with one’s environment.
26. Social Support	The physical and emotional comfort that one gives or receives from one’s personal network.
27. Personal Relationships	Having close positive connections with other people.
28. Relationship with Family	The close interaction and level of satisfaction one has with family members including spouses.
Psychosocial Well-Being	
29. Spirituality	One’s search for meaning in life events and desire for connectedness to the universe and/or some higher power.
30. Sense of Belonging	The feeling that one is a member of something without discrimination or stigmatization.
31. Community Integration	The opportunity to reside in a community and participate fully in aspects of community life.
32. Limitations in Life Roles	The inability to fulfill one's prescribed or expected responsibilities. This inability could be the result of physical or emotional problems
33. Autonomy and Independence	The perception and actuality that one has freedom to make one's decisions, without being pressured

Dimension	Definition of Dimension
34. Safety and Security	The perception one is free from harm or danger.
Economic Well-Being	
35. Satisfaction with Financial Resources	The level of contentment one has with one's total income, assets, and wealth.
36. Satisfaction with Employment	The level of contentment one has with one's occupation.
Other	
37. Pursuit of Goals	One's continued motivation to achieve personal aims or desires.
38. Satisfaction with Living Conditions	The level of contentment one has about one's living environment, including standard of living.
39. Satisfaction with Daily Activities	The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily
40. Satisfaction with Medical Treatment/Services	The level of contentment one has with the quantity and quality of care one receives for one's medical condition. Additionally, it includes any restriction or hardship one may experience when seeking care and the imposition this poses on one's life.
41. Effects of Medication	Any positive and/or negative results of taking medications for one's aliment(s). This can include adverse effects and symptom relief
Overall Quality of Life	
42. Overall Quality of Life	The broad satisfaction one has about one's life taking all aspects of well-being into consideration.

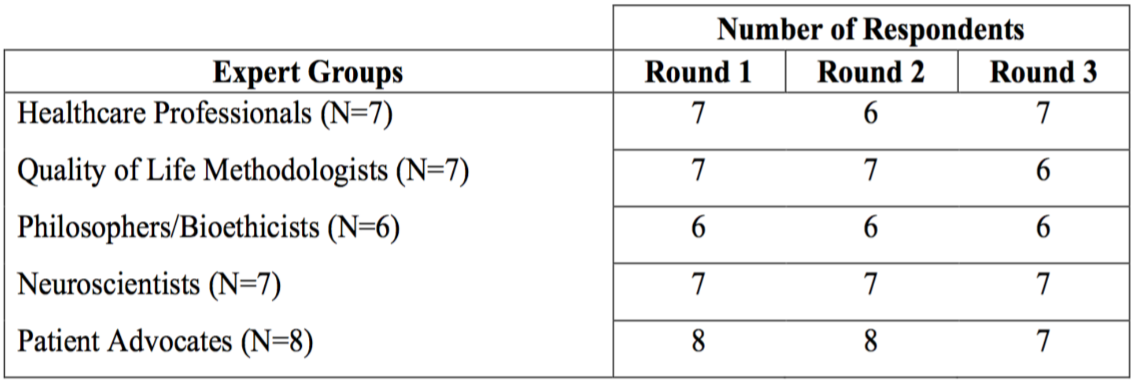
4.2 Expert Panel

Of the 42 experts nominated as potential participants, 37 expressed interest in participating in the Aware Study when approached by a member of the research team: seven healthcare professionals; eight quality of life methodologists; six philosophers/bioethicists; eight neuroscientists; and eight patient advocates. The first online survey was emailed to these potential participants and 35 individuals provided explicit consent to participate in the study. One quality of life methodologist withdrew from the study expressing a lack of expertise regarding behaviourally nonresponsive patients. Additionally, one neuroscientist did not provide explicit consent and was unable to be reached by email for follow-up.

The Delphi expert panel comprised 35 consenting participants: seven healthcare professionals; seven quality of life methodologists; six philosophers/bioethicists; seven neuroscientists; and eight patient advocates. The experts were located in Canada (n=24), the United States (n=4), the United Kingdom (n=5), the Netherlands (n=1), and Italy (n=1). Respondent participation in each Delphi round is displayed in Table 1.

The group of healthcare professionals consisted of physicians with backgrounds in neurology, neurocritical care, traumatology, and physiatry. The quality of life methodologists on the panel had considerable experience in the development and application of outcome measurement tools, with a focus on patient-reported outcomes. Additionally, the assembled philosophers and bioethicists had research interests in the nature of well-being, patient welfare, and ethics of neuroscience. The neuroscientists on the panel specialized in cognitive neuroscience, pathophysiology, neuropsychology, and brain-computer interfaces. Finally, the patient advocate group was made up of family members of former or current patients diagnosed as being minimally conscious or vegetative and one patient advocate who was a recovered patient.

Table 1. Respondents in Each Delphi Round



	Number of Respondents		
Expert Groups	**Round 1**	**Round 2**	**Round 3**
Healthcare Professionals (N=7)	7	6	7
Quality of Life Methodologists (N=7)	7	7	6
Philosophers/Bioethicists (N=6)	6	6	6
Neuroscientists (N=7)	7	7	7
Patient Advocates (N=8)	8	8	7

4.3 Round 1

The first online questionnaire was sent out on September 12, 2016. It was completed by 35 experts, for a response rate of 100%. A median score was calculated for each dimension, with each particular dimension having three possible outcomes: consensus that the dimension is important, consensus that the dimension is not important, or no consensus is reached on the importance of the dimension with respect to quality of life assessment in behaviourally nonresponsive patients.

In the first survey, consensus was reached on 16 of 42 dimensions. Thirteen dimensions had a median score equal to 4 indicating that a majority of experts (>50%) deemed these dimensions as very important:

1. Somatic Complaints
2. Communication Capacity
3. Bodily Pain & Discomfort
4. Experiencing Anxiety
5. Experiencing Depression
6. Experiencing Negative Emotions
7. Experiencing Positive Emotions
8. Experiencing Loneliness
9. Personal Relationships
10. Relationship with Family
11. Satisfaction with Medical Treatment/Services
12. Effects of Medication
13. Overall Quality of Life

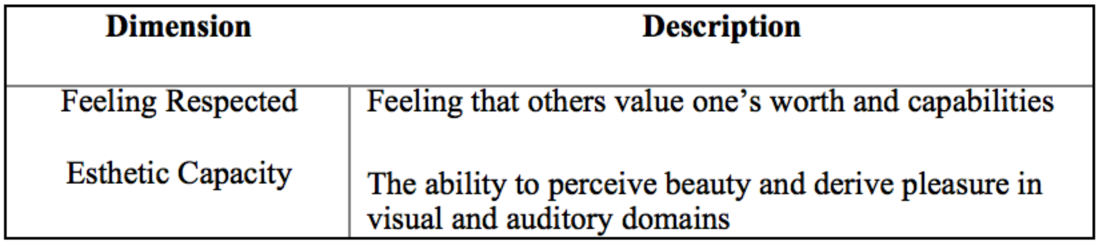
Three dimensions had a median score equal to 1 and were considered as lacking importance:

1. Sexual Activity
2. Satisfaction with Financial Resources
3. Satisfaction with Employment

Consensus was not reached on the remaining 26 dimensions and they moved forward to the second round for re-rating by the experts. The response counts, frequencies, and median scores for each dimension on the first survey are presented in Table 2.

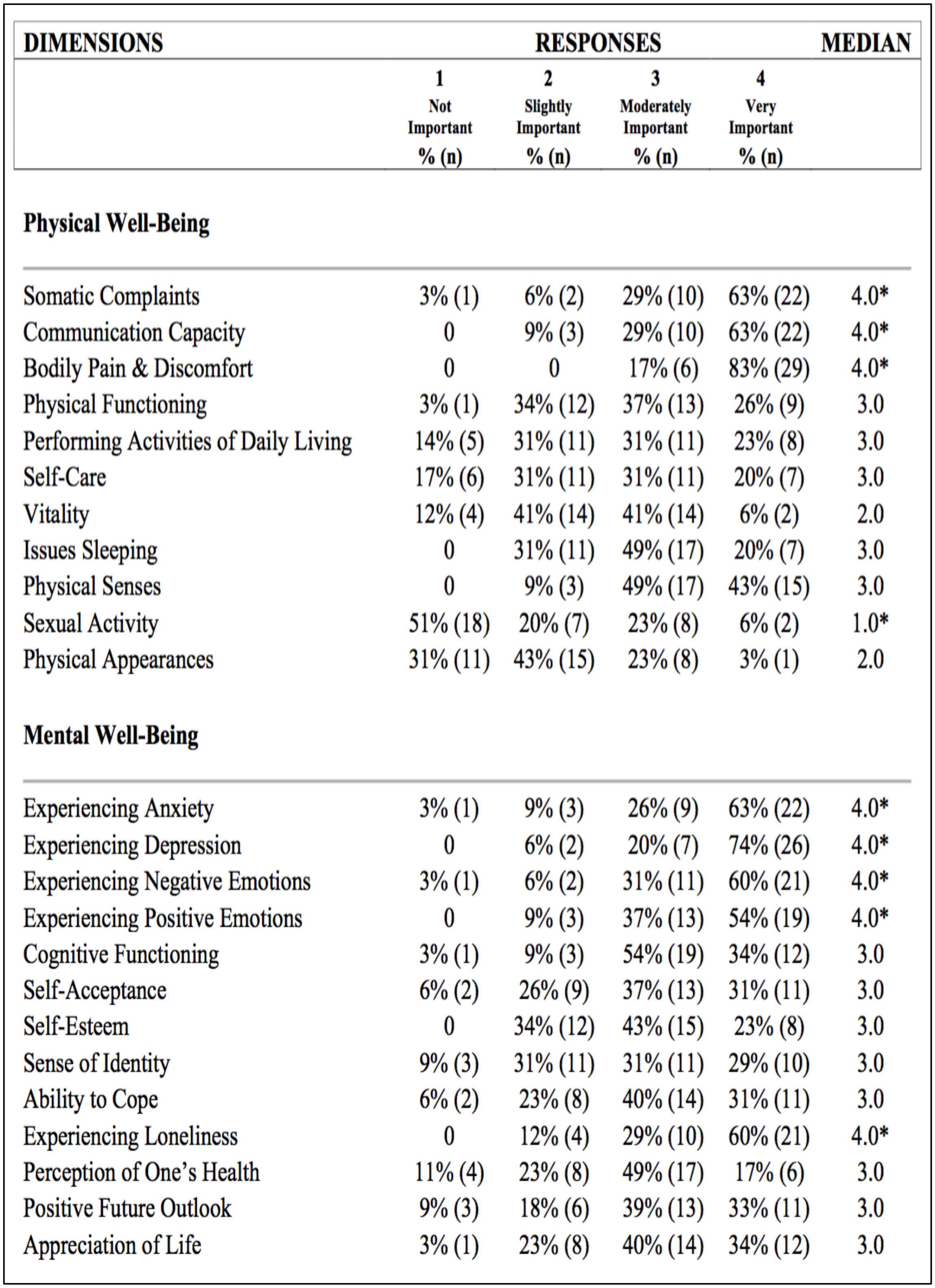
Experts were given an opportunity to suggest dimensions they felt might be missing from the systematically generated list of dimensions using existing quality of life measures. Nine dimensions or concepts were suggested for inclusion by four participants. The recommendations were reviewed by three members of the research team, and it was determined that two of the submitted dimensions were novel: ‘feeling respected’ and ‘esthetic capacity’ (Figure 5). These two dimensions were added to the second survey to be rated. The other seven dimensions suggested were each deemed to be addressed by a dimension included in the original set.

Figure 5. New Dimensions Added in Round One

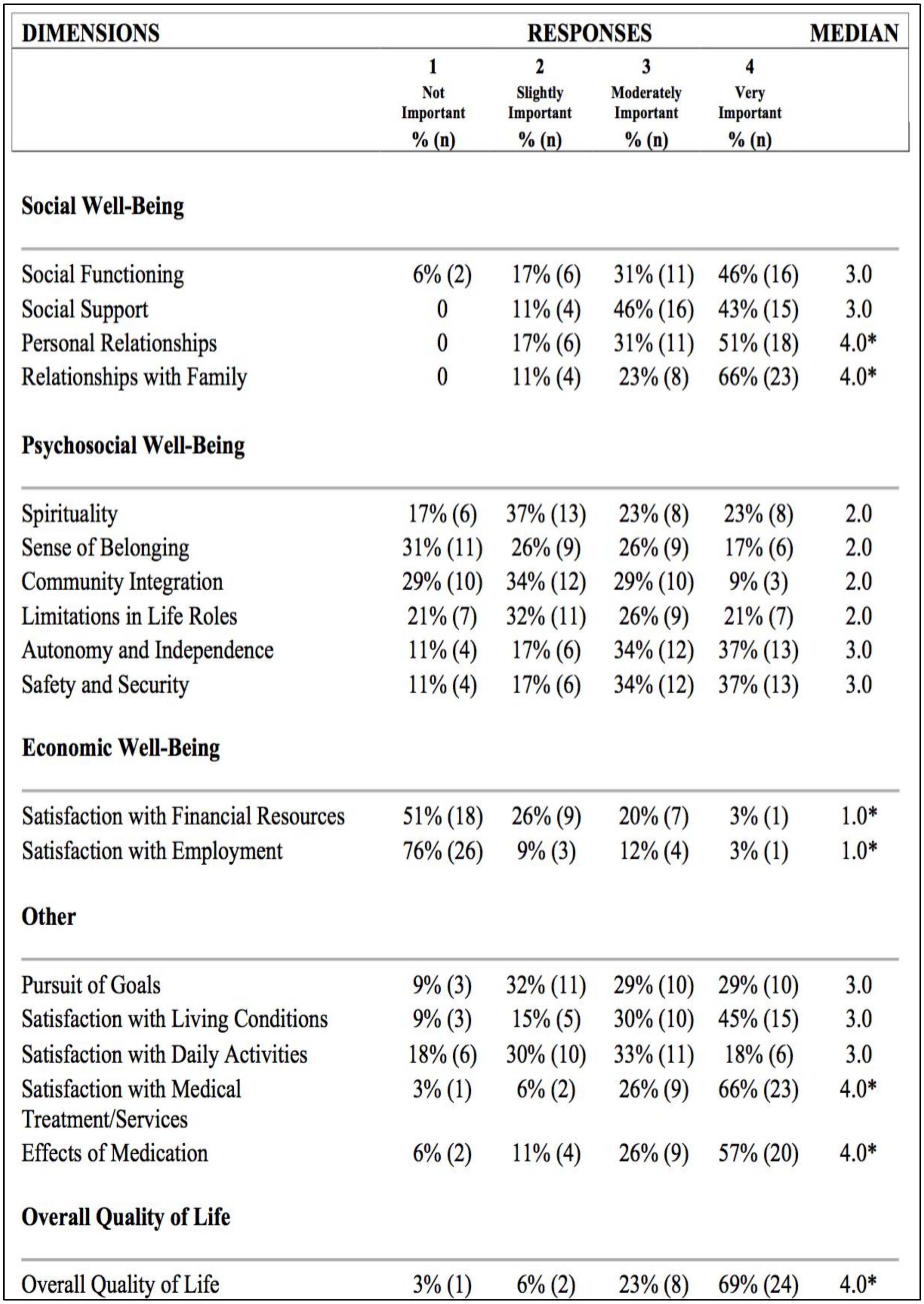


Dimension	Description
Feeling Respected	Feeling that others value one’s worth and capabilities
Esthetic Capacity	The ability to perceive beauty and derive pleasure in visual and auditory domains

Table 2. Round One Dimension Ratings



DIMENSIONS	RESPONSES				MEDIAN
	1 Not Important % (n)	2 Slightly Important % (n)	3 Moderately Important % (n)	4 Very Important % (n)	
Physical Well-Being					
Somatic Complaints	3% (1)	6% (2)	29% (10)	63% (22)	4.0*
Communication Capacity	0	9% (3)	29% (10)	63% (22)	4.0*
Bodily Pain & Discomfort	0	0	17% (6)	83% (29)	4.0*
Physical Functioning	3% (1)	34% (12)	37% (13)	26% (9)	3.0
Performing Activities of Daily Living	14% (5)	31% (11)	31% (11)	23% (8)	3.0
Self-Care	17% (6)	31% (11)	31% (11)	20% (7)	3.0
Vitality	12% (4)	41% (14)	41% (14)	6% (2)	2.0
Issues Sleeping	0	31% (11)	49% (17)	20% (7)	3.0
Physical Senses	0	9% (3)	49% (17)	43% (15)	3.0
Sexual Activity	51% (18)	20% (7)	23% (8)	6% (2)	1.0*
Physical Appearances	31% (11)	43% (15)	23% (8)	3% (1)	2.0
Mental Well-Being					
Experiencing Anxiety	3% (1)	9% (3)	26% (9)	63% (22)	4.0*
Experiencing Depression	0	6% (2)	20% (7)	74% (26)	4.0*
Experiencing Negative Emotions	3% (1)	6% (2)	31% (11)	60% (21)	4.0*
Experiencing Positive Emotions	0	9% (3)	37% (13)	54% (19)	4.0*
Cognitive Functioning	3% (1)	9% (3)	54% (19)	34% (12)	3.0
Self-Acceptance	6% (2)	26% (9)	37% (13)	31% (11)	3.0
Self-Esteem	0	34% (12)	43% (15)	23% (8)	3.0
Sense of Identity	9% (3)	31% (11)	31% (11)	29% (10)	3.0
Ability to Cope	6% (2)	23% (8)	40% (14)	31% (11)	3.0
Experiencing Loneliness	0	12% (4)	29% (10)	60% (21)	4.0*
Perception of One’s Health	11% (4)	23% (8)	49% (17)	17% (6)	3.0
Positive Future Outlook	9% (3)	18% (6)	39% (13)	33% (11)	3.0
Appreciation of Life	3% (1)	23% (8)	40% (14)	34% (12)	3.0



DIMENSIONS	RESPONSES				MEDIAN
	1 Not Important % (n)	2 Slightly Important % (n)	3 Moderately Important % (n)	4 Very Important % (n)	
Social Well-Being					
Social Functioning	6% (2)	17% (6)	31% (11)	46% (16)	3.0
Social Support	0	11% (4)	46% (16)	43% (15)	3.0
Personal Relationships	0	17% (6)	31% (11)	51% (18)	4.0*
Relationships with Family	0	11% (4)	23% (8)	66% (23)	4.0*
Psychosocial Well-Being					
Spirituality	17% (6)	37% (13)	23% (8)	23% (8)	2.0
Sense of Belonging	31% (11)	26% (9)	26% (9)	17% (6)	2.0
Community Integration	29% (10)	34% (12)	29% (10)	9% (3)	2.0
Limitations in Life Roles	21% (7)	32% (11)	26% (9)	21% (7)	2.0
Autonomy and Independence	11% (4)	17% (6)	34% (12)	37% (13)	3.0
Safety and Security	11% (4)	17% (6)	34% (12)	37% (13)	3.0
Economic Well-Being					
Satisfaction with Financial Resources	51% (18)	26% (9)	20% (7)	3% (1)	1.0*
Satisfaction with Employment	76% (26)	9% (3)	12% (4)	3% (1)	1.0*
Other					
Pursuit of Goals	9% (3)	32% (11)	29% (10)	29% (10)	3.0
Satisfaction with Living Conditions	9% (3)	15% (5)	30% (10)	45% (15)	3.0
Satisfaction with Daily Activities	18% (6)	30% (10)	33% (11)	18% (6)	3.0
Satisfaction with Medical Treatment/Services	3% (1)	6% (2)	26% (9)	66% (23)	4.0*
Effects of Medication	6% (2)	11% (4)	26% (9)	57% (20)	4.0*
Overall Quality of Life					
Overall Quality of Life	3% (1)	6% (2)	23% (8)	69% (24)	4.0*

*Dimensions where consensus was reached based on median score

4.4 Round 2

The second online questionnaire was emailed to all experts on September 30, 2016. The survey had a response rate of 97% with 34 experts returning the survey. The one participant who did not complete the survey was a healthcare professional who did not specify a reason for not responding. As described in the methods section, for the second survey the response format was expanded from a 4-point scale to a 7-point scale for rating the level of importance of each dimension. The semi-interquartile range (SIR) was calculated for each dimension along with the median score.

Consensus was reached on 17 of the 28 dimensions made available to the experts during the second round. Nine dimensions had a median score greater than 5 and a SIR of 1 or less, and were deemed to be important for ascertaining quality of life in behaviourally nonresponsive patients:

1. Issues Sleeping
2. Physical Senses
3. Self-Acceptance
4. Self-Esteem
5. Ability to Cope
6. Appreciation of Life
7. Social Support
8. Autonomy and Independence
9. Feeling Respected

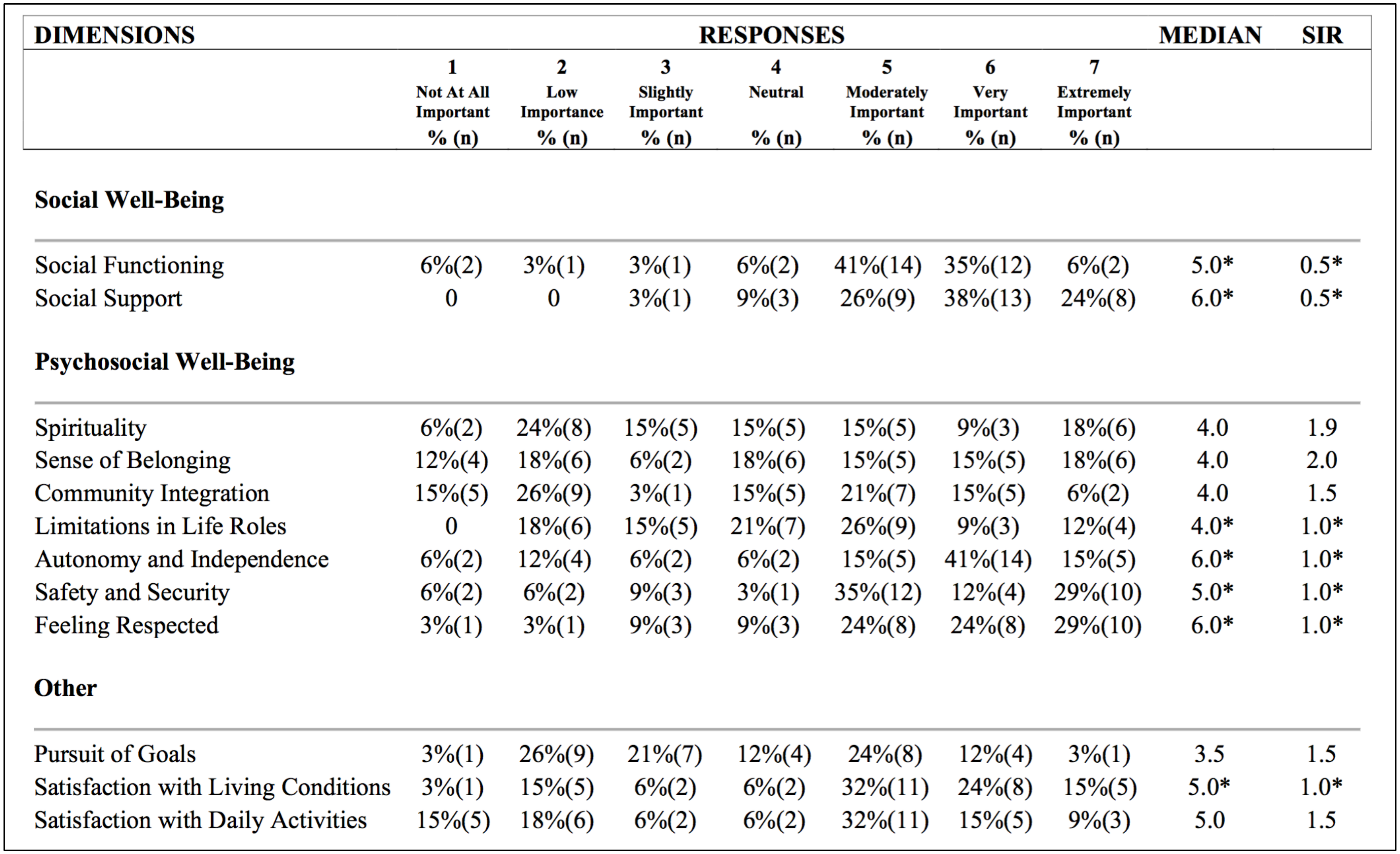
Eight dimensions had median scores of less than or equal to 5 and a SIR of less than 1, indicating the experts considered these dimensions to be not important:

1. Vitality
2. Cognitive Functioning
3. Perceptions of One’s Health
4. Positive Future Outlook
5. Social Functioning
6. Limitations in Life Roles
7. Safety and Security
8. Satisfaction with Living Conditions

Consensus was not reached on the remaining 11 dimensions and they moved forward to the third round for a final re-rating by the experts. The response counts, frequencies, and median scores for each dimension on the second survey are presented in Table 3.

Table 3. Round Two Dimension Ratings

DIMENSIONS	RESPONSES							MEDIAN	SIR
	1 Not At All Important % (n)	2 Low Importance % (n)	3 Slightly Important % (n)	4 Neutral % (n)	5 Moderately Important % (n)	6 Very Important % (n)	7 Extremely Important % (n)		
Physical Well-Being									
Physical Functioning	3%(1)	18%(6)	9%(3)	12%(4)	29%(10)	18%(6)	12%(4)	5.0	1.5
Performing Activities of Daily Living	18%(6)	18%(6)	9%(3)	6%(2)	24%(8)	15%(5)	12%(4)	4.5	1.9
Self-Care	9%(3)	26%(9)	3%(1)	15%(5)	24%(8)	21%(7)	3%(1)	4.0	1.5
Vitality	3%(1)	12%(4)	12%(4)	9%(3)	41%(14)	18%(6)	6%(2)	5.0*	0.9*
Issues Sleeping	3%(1)	6%(2)	6%(2)	6%(2)	29%(10)	35%(12)	15%(5)	5.5*	0.5*
Physical Senses	3%(1)	3%(1)	6%(2)	0	26%(9)	38%(13)	24%(8)	6.0*	0.5*
Physical Appearance	3% (1)	29%(10)	9%(3)	24%(8)	21%(7)	15%(5)	0	4.0	1.5
Mental Well-Being									
Cognitive Functioning	3%(1)	9%(3)	0	6%(2)	35%(12)	29%(10)	18%(6)	5.0*	0.5*
Self-Acceptance	6%(2)	12%(4)	6%(2)	9%(3)	18%(6)	35%(12)	15%(5)	5.5*	1.0*
Self-Esteem	3%(1)	3%(1)	9%(3)	3%(1)	24%(8)	41%(14)	18%(6)	6.0*	0.5*
Sense of Identity	6%(2)	9%(3)	12%(4)	9%(3)	15%(5)	32%(11)	18%(6)	5.5	1.4
Ability to Cope	3%(1)	6%(2)	6%(2)	6%(2)	24%(8)	24%(8)	32%(11)	6.0*	1.0*
Perception of One's Health	6%(2)	6%(2)	6%(2)	18%(6)	26%(9)	26%(9)	12%(4)	5.0*	1.0*
Positive Future Outlook	3%(1)	3%(1)	12%(4)	9%(3)	26%(9)	26%(9)	21%(7)	5.0*	0.9*
Appreciation of Life	3%(1)	6%(2)	6%(2)	6%(2)	15%(5)	38%(13)	26%(9)	6.0*	0.9*
Esthetic Capacity	3%(1)	21%(7)	12%(4)	12%(4)	24%(8)	26%(9)	3%(1)	5.0	1.5



DIMENSIONS	RESPONSES							MEDIAN	SIR
	1 Not At All Important % (n)	2 Low Importance % (n)	3 Slightly Important % (n)	4 Neutral % (n)	5 Moderately Important % (n)	6 Very Important % (n)	7 Extremely Important % (n)		
Social Well-Being									
Social Functioning	6%(2)	3%(1)	3%(1)	6%(2)	41%(14)	35%(12)	6%(2)	5.0*	0.5*
Social Support	0	0	3%(1)	9%(3)	26%(9)	38%(13)	24%(8)	6.0*	0.5*
Psychosocial Well-Being									
Spirituality	6%(2)	24%(8)	15%(5)	15%(5)	15%(5)	9%(3)	18%(6)	4.0	1.9
Sense of Belonging	12%(4)	18%(6)	6%(2)	18%(6)	15%(5)	15%(5)	18%(6)	4.0	2.0
Community Integration	15%(5)	26%(9)	3%(1)	15%(5)	21%(7)	15%(5)	6%(2)	4.0	1.5
Limitations in Life Roles	0	18%(6)	15%(5)	21%(7)	26%(9)	9%(3)	12%(4)	4.0*	1.0*
Autonomy and Independence	6%(2)	12%(4)	6%(2)	6%(2)	15%(5)	41%(14)	15%(5)	6.0*	1.0*
Safety and Security	6%(2)	6%(2)	9%(3)	3%(1)	35%(12)	12%(4)	29%(10)	5.0*	1.0*
Feeling Respected	3%(1)	3%(1)	9%(3)	9%(3)	24%(8)	24%(8)	29%(10)	6.0*	1.0*
Other									
Pursuit of Goals	3%(1)	26%(9)	21%(7)	12%(4)	24%(8)	12%(4)	3%(1)	3.5	1.5
Satisfaction with Living Conditions	3%(1)	15%(5)	6%(2)	6%(2)	32%(11)	24%(8)	15%(5)	5.0*	1.0*
Satisfaction with Daily Activities	15%(5)	18%(6)	6%(2)	6%(2)	32%(11)	15%(5)	9%(3)	5.0	1.5

*Dimensions where consensus was reached based on median score and SIR

4.5 Round 3

The third online questionnaire was sent out on October 21, 2016. The survey had a response rate of 94% with 33 experts completing the survey. One quality of life methodologist and one patient advocate did not participate in this round. The quality of life methodologist stated that other time commitments precluded completing the survey. A median score and a SIR were calculated for each dimension.

Of the 11 dimensions that experts were asked to re-rate, consensus was reached on only one of those dimensions. The dimension 'Sense of Identity' had a median score of 5 or less and a SIR of 1 or less, indicating the experts rated this dimension as lacking importance. The response counts, frequencies, and median scores for each dimension on the third survey are presented in Table 4.

In addition to calculating a median score and SIR for each dimension, for the third round a mean rank score was calculated to determine which dimensions were mentioned most often in the list of the five most important dimensions selected by experts. If an expert ranked a dimension as being the most important (number 1), it was coded as 5, if a dimension was ranked number 2, it was coded as 4, if a dimension was ranked number 3, it was coded as 3, if a dimension was ranked number 4, it was coded as 2, and if a dimension was ranked number 5, it was coded as 1. This conversion allows for ease of interpretation with higher scores indicating a greater level of importance. The frequencies and mean rank scores of the top 10 most highly rated dimensions are displayed in Table 5 and Table 6, respectively.

Table 4. Round Three Dimension Ratings

DIMENSIONS	RESPONSES							MEDIAN	SIR
	1 Not At All Important % (n)	2 Low Importance % (n)	3 Slightly Important % (n)	4 Neutral % (n)	5 Moderately Important % (n)	6 Very Important % (n)	7 Extremely Important % (n)		
Physical Well-Being									
Physical Functioning	12%(4)	24%(8)	21%(7)	0	18%(6)	21%(7)	3%(1)	3.0	1.5
Performing Activities of Daily Living	15%(5)	36%(12)	3%(1)	0	24%(8)	15%(5)	6%(2)	2.0	1.5
Self-Care	18%(6)	33%(11)	9%(3)	3%(1)	18%(6)	15%(5)	3%(1)	2.0	1.5
Physical Appearance	12%(4)	21%(7)	21%(7)	15%(5)	27%(9)	0	3%(1)	3.0	1.5
Mental Well-Being									
Sense of Identity	3%(1)	9%(3)	3%(1)	15%(5)	33%(11)	30%(10)	6%(2)	5.0*	1.0*
Esthetic Capacity	6%(2)	18%(6)	6%(2)	9%(3)	27%(9)	27%(9)	6%(2)	5.0	1.5
Psychosocial Well-Being									
Spirituality	3%(1)	24%(8)	12%(4)	21%(7)	9%(3)	18%(6)	12%(4)	4.0	2.0
Sense of Belonging	3%(1)	21%(7)	12%(4)	15%(5)	12%(4)	21%(7)	15%(5)	4.0	1.5
Community Integration	6%(2)	21%(7)	15%(5)	12%(4)	27%(9)	12%(4)	6%(2)	4.0	1.5
Other									
Pursuit of Goals	6%(2)	24%(8)	9%(3)	3%(1)	30%(10)	12%(4)	15%(5)	5.0	2.0
Satisfaction with Daily Activities	6%(2)	21%(7)	9%(3)	6%(2)	38%(13)	9%(3)	9%(3)	5.0	1.5

*Dimensions where consensus was reached based on median score and SIR

Table 5. Top 10 Highest Rated Dimensions: Frequency of Selection and Ranked Position

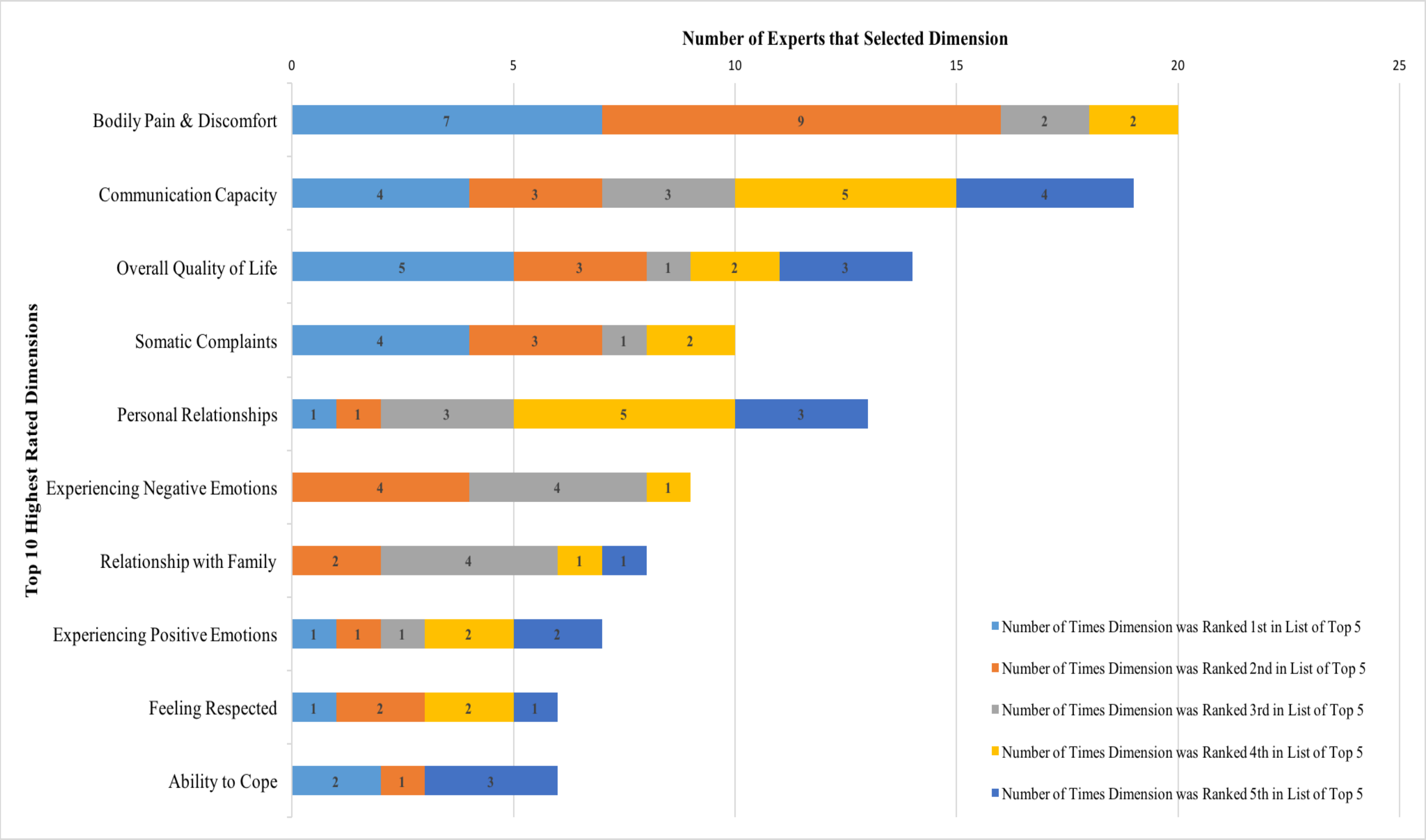
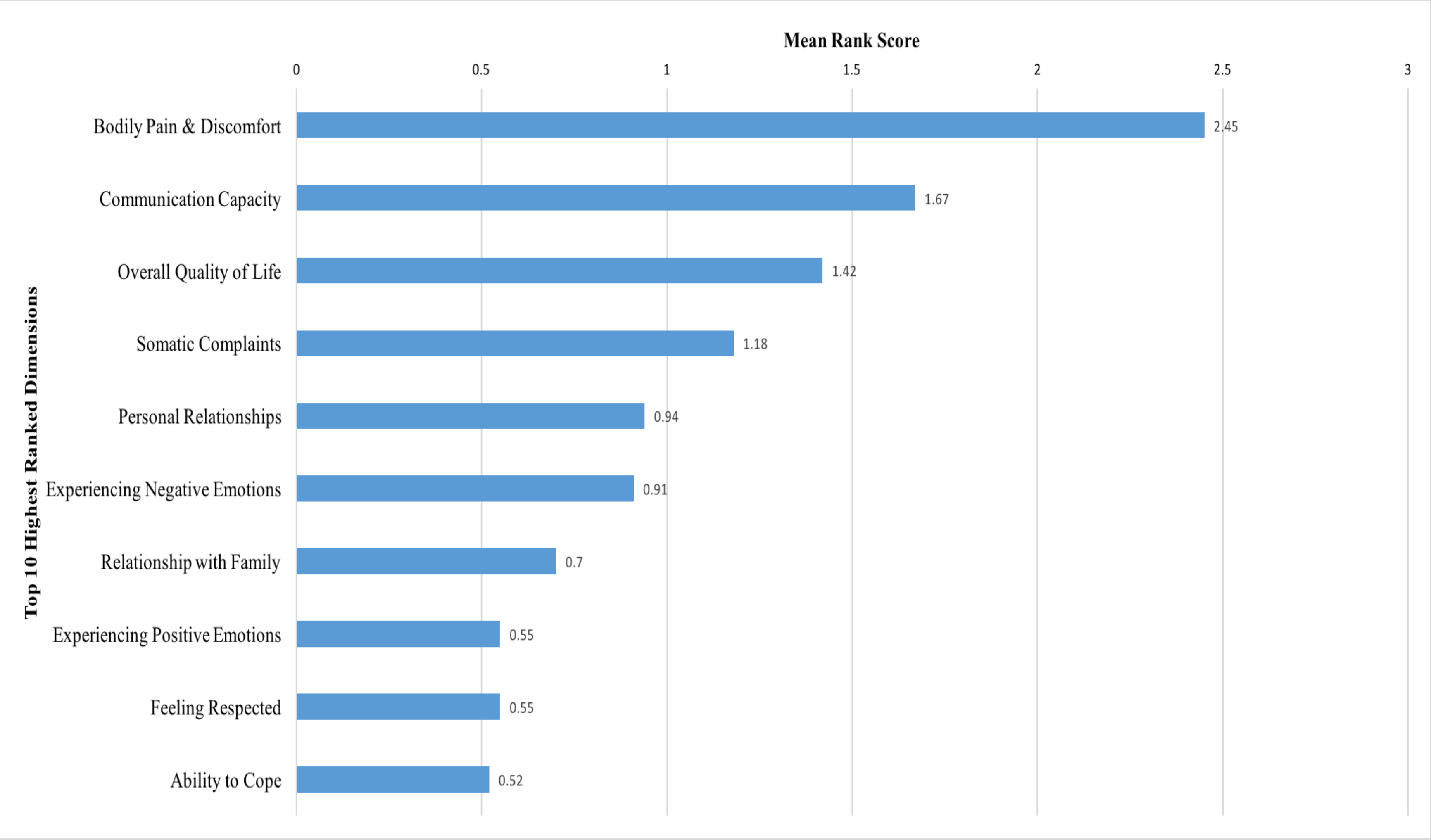


Table 6. Top 10 Highest Rated Dimensions: Mean Rank Scores



4.6 Subgroup Analyses

The first subgroup analysis assessed the extent to which the professionals (healthcare professionals, quality of life methodologists, philosophers and bioethicists, and neuroscientists) and patient advocates agreed in their ratings of dimensions that were ultimately deemed to have consensus reached on lack of importance (Table 7). A total of 12 dimensions, over the three rounds, were considered to be not important in assessing the quality of life of behaviourally nonresponsive patients. Examining the responses of the group of professionals revealed that all 12 dimensions, except one, had a median less than or equal to 5 and SIR of 1 or less (consensus reached on lack of importance). The one noteworthy exception was the dimension ‘Cognitive Functioning’, which had a consensus of importance among the group of professionals (median=6.0, SIR=0.5). This differed from the patient advocates who concluded that this dimension lacks importance.

There were a few differences between the patient advocate’s ratings of some of the 12 dimensions compared to the group of professionals. The patient advocates rated the level of importance of ‘Satisfaction with Employment’ much higher compared to their counterparts (median=3.0 versus median=1.0). Additionally, the dimensions ‘Positive Future Outlook’ and ‘Social Functioning’ had a consensus of importance among the patient advocates (median=6.5, SIR=0.9 and median=5.5, SIR=0.5, respectively). This result indicates that these two dimensions were considered important for evaluating quality of life in behaviourally nonresponsive patients among the patient advocates, but considered unimportant by the group of professionals. Furthermore, patient advocates were unable to reach consensus (SIR > 1) regarding the following dimensions compared to the professional group: ‘Limitations in Life Roles’, ‘Safety and Security’, and ‘Satisfaction with Living Conditions’.

For the second subgroup analysis, the selection and ranking of the experts’ top five most important dimensions were compared between the group of professionals and patient advocates (Table 8). The professionals ranked the following as their top five most important dimensions when a mean rank score was calculated: (1) Bodily Pain & Discomfort; (2) Communication Capacity; (3) Overall Quality of Life; (4) Somatic Complaints; and (5) Personal Relationships. The mean rank scores for the patient advocate group revealed an overlapping set of dimensions as being the most important: (1) Communication Capacity; (2) Feeling Respected; (2) Sense of Belonging; (4) Relationship with Family; and (5) Bodily Pain and Discomfort. It is noteworthy that the both patient advocates and professionals ranked the dimensions ‘Bodily Pain and Discomfort’ and ‘Communication Capacity’ highly. However, patient advocates included the dimension ‘Sense of Belonging’ which did not even appear in the top 10 most important dimensions rated by professionals. Additionally, ‘Feeling Respected’ was rated considerably higher among patient advocates than what was observed in the group of professionals. These results indicate there are both similarities and differences in the dimensions being selected and their order of importance being assigned by patient advocates compared to professionals.

Table 7. Subgroup Analysis of Dimensions Where Consensus Was Reached On Lack of Importance Comparing Patient Advocates and Professionals

	MEDIAN			SIR		
DIMENSIONS	Overall	Patient Advocates	Professionals	Overall	Patient Advocates	Professionals
Sexual Activity	1.0	1.0	2.0	n/a	n/a	n/a
Satisfaction with Financial Resources	1.0	2.5	1.0	n/a	n/a	n/a
Satisfaction with Employment	1.0	**3.0**	**1.0**	n/a	n/a	n/a
Vitality	5.0	5.0	5.0	0.9	1.0	0.9
Cognitive Functioning	5.0	**5.0**	**6.0**	0.5	0.8	0.5
Perception of One's Health	5.0	5.0	5.0	1.0	0.6	1.0
Positive Future Outlook	5.0	**6.5**	**5.0**	0.9	0.9	0.9
Social Functioning	5.0	**5.5**	**5.0**	0.5	0.5	0.5
Limitations in Life Roles	4.0	4.5	4.0	1.0	**1.1**	**1.0**
Safety and Security	5.0	6.0	5.0	1.0	**1.1**	**0.5**
Satisfaction with Living Conditions	5.0	6.0	5.0	1.0	**1.4**	**1.0**
Sense of Identity	5.0	5.0	5.0	1.0	0.5	1.0

Bolded: Meaningful differences between patient advocates and professionals

Table 8. Subgroup Analysis of Dimension Rankings Between Patient Advocates and Professionals

GROUP	RANK	TOP DIMENSIONS	COUNT	MEAN RANK SCORE
OVERALL (N=33)	1	Bodily Pain & Discomfort	20	2.45
	2	Communication Capacity	19	1.67
	3	Overall Quality of Life	14	1.42
	4	Somatic Complaints	10	1.18
	5	Personal Relationships	13	0.94
	6	Experiencing Negative Emotions	9	0.91
	7	Relationship with Family	8	0.70
	8	Experiencing Positive Emotions	7	0.55
	9	Feeling Respected	6	0.55
	10	Ability to Cope	6	0.52
PATIENT ADVOCATES (N=7)	1	Communication Capacity	4	1.57
	2	Feeling Respected	3	1.57
	2	Sense of Belonging	3	1.57
	4	Relationship with Family	4	1.43
	5	Bodily Pain & Discomfort	3	1.43
PROFESSIONALS (N=26)	1	Bodily Pain & Discomfort	17	2.73
	2	Communication Capacity	15	1.69
	3	Overall Quality of Life	13	1.65
	4	Somatic Complaints	9	1.35
	5	Personal Relationships	11	1.04

Chapter 5

5 Discussion and Conclusion

The aim of the Aware Study was to take the first step towards the development of a quality of life instrument for minimally conscious and covertly aware vegetative state patients, who can communicate using a brain-computer interface (behaviourally nonresponsive patients). A novel approach was needed because the limited ability to interview behaviourally nonresponsive patients presents a major obstacle to creating such a measure. The study utilized the combination of a systematic search of existing quality of life measures and a Delphi process because the traditional model used to develop a quality of life measure cannot be used. Assessing well-being in this patient population is important because it will allow insight into how patients are faring. Currently, we are only able to speculate about the lived experience of these patients but a quality of life instrument will provide more definitive answers.

This chapter will interpret and contextualize the key results of the Aware Study. Furthermore, the implications of the study and its methodology will be discussed. This is followed by recommendations for the next steps needed to assess quality of life in behaviourally nonresponsive patients. Finally, the strengths and limitations of the study are specified.

5.1 Overview of Findings

The systematic search of existing quality of life instruments, designed for patient populations similar to behaviourally nonresponsive patients, resulted in the identification of 42 dimensions. As part of the Delphi process, experts were also asked to suggest dimensions of quality of life that they thought were missing from the list. Only two new dimensions were added, which speaks to the rigour of the systematic search and its effectiveness in capturing relevant aspects of life in behaviourally nonresponsive patients. This also suggests the accuracy of the research team's selection of relevant patient populations that formed the basis of the systematic review.

The identified dimensions were rated on relative importance by five different groups of experts over the course of three Delphi rounds. Consensus was reached on 34 of the 44 dimensions: 22 dimensions were considered to be important and 12 dimensions were deemed to lack importance. It is not surprising that there was consensus on the importance of the majority of the dimensions. All but two of the dimensions in this study are included in existing quality of life instruments. These dimensions were previously selected by researchers to be important in shaping and defining quality of life in patients similar to behaviourally nonresponsive patients.

The dimensions considered by experts to lack importance were often intuitive. Dimensions such as 'Sexual Activity', 'Satisfaction with Employment', and 'Satisfaction with Financial Resources' are arguably inapplicable to bedridden patients incapable of volitional movement. Experts agreed early on in the process that their inclusion in a quality of life instrument would be inappropriate. However, other dimensions deemed to lack importance at first glance seemed to us quite applicable to behaviourally nonresponsive patients, such as 'Sense of Identity' and 'Satisfaction with Living Conditions'. However, their exclusion does not necessarily mean that experts did not think these dimensions were important. It is more likely that since only a limited number of questions can be posed to behaviourally nonresponsive patients, experts considered other dimensions to be relatively more important.

There were only 10 dimensions where consensus was not reached after the third and final round had concluded. They account for less than one quarter of the dimensions made available to the experts for rating. All of the remaining dimensions on which consensus was not reached had median scores of less than five, indicating a lack of importance, but there was variability in opinions beyond the allotted cut-off (SIR≤1). In the final round, consensus regarding importance was only reached on one dimension. A possible explanation for this might be that all clearly important or unimportant dimensions had been identified by the experts in the earlier rounds. It is unlikely that the experts would reach consensus on the remaining dimensions if additional rounds were added.

After analysis of experts' selections and rankings of their top five dimensions, a list of the top 10 highest ranked dimensions was generated (Table 6). The highest ranked dimension was 'Bodily Pain & Discomfort', which is a reassuring finding. The first welfare-related question ever asked of a communicating behaviourally nonresponsive patient was, "Are you in physical pain?". The patient in question, Scott Routley, responded by volitionally modulating his brain activity with the imagery task associated with the answer "no" (Walsh, 2012). The selection of 'Bodily Pain & Discomfort' as the most important dimension in this study is in line with previous research that has established that pain and discomfort have great weight in subjective quality of life evaluation and a profound effect on many other dimensions of quality of life in individuals (Skevington, 1998). Additionally, it is noteworthy that the final list of highest ranked dimensions included at least one dimension from each of the broader domains of physical well-being, social well-being, mental well-being, psychosocial well-being, and overall quality of life. For such a compilation to have been generated, means that the experts were likely working with a component definition of quality of life.

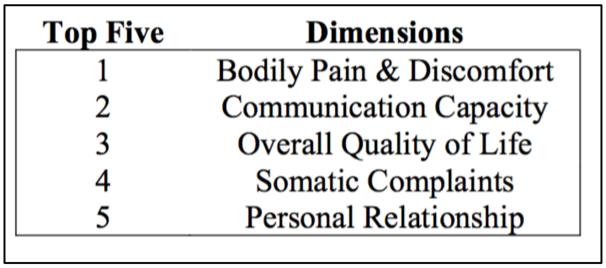
The subgroup analyses comparing the responses of professionals and patient advocates showcased both similarities and differences in consensus and dimension rankings. The decision to separate the expert panel in such a fashion was made to see if patient advocates, who are primarily family members of severely brain injured patients, have similar opinions to working professionals. Family members bring a distinct perspective since they have greater insight into the lives and values of patients prior to them suffering a severe brain injury. In the study, the patient advocates and professionals agreed on the majority of dimensions. Only three of the 12 dimensions where consensus was reached on lack of importance, had differences in responses by the patient advocates and professionals. Two of the dimensions, ‘Positive Future Outlook’ and ‘Social Functioning’, which were deemed to lack importance overall, were rated as being important by the patient advocates. These selections highlight that families tended to emphasize social aspects of well-being, including seeing patients as persons with valuable futures. Conversely, the professionals regarded the dimension ‘Cognitive Functioning’ as being important, but the patient advocates did not share their sentiment. It is possible that this occurred because professionals have a different understanding of the term cognitive functioning.

Both groups included the same two dimensions, ‘Bodily Pain & Discomfort’ and ‘Communication Capacity’, in their five highest rated dimensions. Additionally, professionals rated ‘Personal Relationships’ highly, while patient advocates selected ‘Relationship with Family’. However, these two dimensions can be thought of as overlapping concepts. Thus, the two groups came to the same conclusion on three of their five highest rated dimensions. On the other hand, patient advocates rated the dimensions ‘Sense of Belonging’ and ‘Feeling Respected’ higher than the professionals. The dimension ‘Feeling Respected’ made the top 10 highest ranked dimensions by the entire panel, but ‘Sense of Belonging’ did not. It remains unclear why the patient advocates picked and ranked ‘Sense of Belonging’ so highly compared to the professionals. As part of the Delphi process, experts were not required to provide rationale for choices or given an opportunity to discuss their selections with the other experts. However, a concurrent study may provide insight into the high rating of ‘Feeling Respected’ among patient advocates. An ongoing interview study of family members of patients who are minimally conscious or in a vegetative state conducted by other members of our research team revealed a lack of respect for patients as a reoccurring theme (personal communication: Charles Weijer, December 11, 2016). It is apparent that patient advocates bring an important perspective to the question of what well-being means for these patients. They humanize these patients and tend to see them as social beings. Furthermore, patient advocates are the closest we can get to including the perspective of the patients.

5.2 Implications of Findings

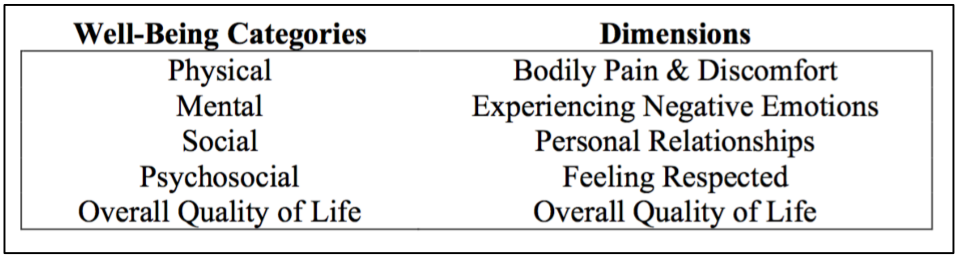
The Aware Study was able to accomplish its objectives and address a gap in knowledge. A short list of dimensions important for the evaluation of quality of life in behaviourally nonresponsive patients was produced, with a high degree of consistency in responses between professionals and patient advocates. The final product of this study, a list of 10 dimensions deemed highly important, allows for flexibility in its application. Depending on the exact number of questions that can feasibly be posed to behaviorally nonresponsive patients in a functional MRI setting, the whole list or just a part of it can be used. The complete list of 10 dimensions includes four of the five highest rated dimensions by patient advocates. Another option would be to select the top five from the list of 10 and create an instrument (Figure 6). However, a drawback would be that the top five dimensions are heavily focused on physical dimensions. Finally, a selection could be made of the highest rated dimension from each domain of quality of life to come up with a collection of five dimensions of maximum breadth (Figure 7). This approach would reasonably incorporate the choices made by patient advocates regarding the dimensions they believed to be the most important for assessing quality of life in behaviourally nonresponsive patients.

Figure 6. Final Dimension List Alternative (1)



Top Five	Dimensions
1	Bodily Pain & Discomfort
2	Communication Capacity
3	Overall Quality of Life
4	Somatic Complaints
5	Personal Relationship

Figure 7. Final Dimension List Alternative (2)



Well-Being Categories	Dimensions
Physical	Bodily Pain & Discomfort
Mental	Experiencing Negative Emotions
Social	Personal Relationships
Psychosocial	Feeling Respected
Overall Quality of Life	Overall Quality of Life

5.3 Future Research

The development of a quality of life instrument is a multistage process that requires extensive information regarding patients and their daily lives. Since there is a scarcity of knowledge regarding the lived experience of behaviourally nonresponsive patients, the Aware Study was the first step towards evaluating quality of life in these patients. The study was necessary because of the limited ability to have a dialogue with these patients. While the findings from this project aid in the developmental process, additional work is needed to produce a quality of life instrument. Before moving forward, critical questions need answering before the final selection of dimensions can be made and questions can be generated for the measure. Since the conceptualization of the Aware Study two years ago, many technological changes have occurred in the field of neuroimaging and brain-computer interfaces. Discussions need to occur among neuroscientists to determine: how many questions can be reasonably and reliably asked of behaviourally nonresponsive patients in a scanning session and, if new imagery tasks can be created to allow for questions on Likert-type scales to be answered.

After these issues are addressed, a selection of dimensions can be made and specific questions will need to be drafted for the instrument. Experts in quality of life methodology can be invited back to craft questions addressing the selected dimensions. Additionally, the larger group of panel experts should review these questions and provide feedback. A workshop format would be best to do this because it would serve to facilitate discussion among experts. After the creation of questions, the subsequent steps of development include pre-testing and validation. These steps will require access to behaviourally nonresponsive patients, a fMRI, and brain-computer interface specialists, which the research team of the Aware Study did not have. Healthy volunteers could be used to demonstrate that the drafted instrument can be administered in the fMRI environment. Furthermore, the validation phase could be conducted with other patient groups, with less severe forms of brain injury that can both perform the communication paradigm and provide verbal responses for confirmation.

5.4 Study Strengths

A key strength of the study was the high response rate obtained in each round of the study. The response rate observed, in each individual round and overall, was higher than typical in self-administered surveys or other Delphi studies (Paré, Cameron, Poba-Nzaou, & Templier, 2013). Furthermore, all groups of experts were well-represented in each round. This decreased the likelihood of response bias and skewed results. The sustained engagement on the part of participants was attributed to the enthusiasm of the panel. Experts stated that this was an “interesting”, “worthy”, and “thought provoking” project. Many expert panel members have already indicated a desire to contribute to subsequent phases of this project.

Another strength of the study was the decision to use only existing and validated quality of life measures to form the basis of the Delphi questionnaires. The systematic search resulted in a breath of dimensions being identified across a wide set of quality of life domains. Using a modified Delphi technique, and not strictly relying on experts to generate dimensions, avoided the possibility of experts producing a more limited list of dimensions. Furthermore, the identified dimensions were sufficient due to the fact that experts only suggested two additional dimensions.

The diversity of the expert groups included in the Delphi panel also strengthened the study. The Aware Study integrated representatives from relevant stakeholders concerned with the welfare of behaviourally nonresponsive patients. Such an approach is different from the traditional procedure of creating a quality of life instrument. Recall, aside from patients, traditionally researchers usually only seek advice from healthcare professionals when generating items for a quality of life measure. Having groups with different expertise and experiences allowed for the possibility of heterogeneity in opinions. Nonetheless, there was a high level of consistency in responses among the participating experts and between expert groups. The Aware Study was a novel effort to adapt and execute a method for instrument development. It was effective in achieving the fundamental initial phase of instrument development with a reasonable degree of consensus.

5.5 Study Limitations

While this project had strengths, it was not without limitations. The study design did not provide occasion for the patient advocates and professionals to engage in a direct dialogue to explain their views on dimensions to one another. Even though the level of agreement was high in this study, discussion may have enhanced the consensus reached. Additionally, the lack of discussion also gives research team members little insight into why experts made certain selections.

There are some widely recognized limitations with the Delphi technique. First, both the Delphi process and its outcomes are subjective. Consensus reached on a particular set of items does not equate to true or correct answers. The dimensions selected based on expert opinion may not be what patients would select for themselves.

Additionally, the judgments of this expert panel may not be representative of all experts who were qualified to participate in this study. Second, the consensus cut-offs in Delphi studies are somewhat arbitrary. Different Delphi studies use various levels of agreement to quantify consensus among their panel of experts. The results of this study may be altered if a different approach to consensus scoring was adopted. In the Aware Study, the level of agreement was adapted from the project done by Pietersma et al. (2014). However, using a measure of dispersion, like SIR, is generally accepted as an unbiased and rigorous way of determining agreement.

5.6 Implications for Study Design

The Aware Study is innovative because it applied an existing methodology in a novel way. The technique of systematically reviewing the literature in combination with a Delphi consensus process has previously been employed in health research to generate care guidelines, criteria for disease reporting, and clinical outcome priorities. To the best of our knowledge, this is the first time the two-pronged strategy has been used to assist in the creation of a new quality of life instrument where patient input is unavailable. The research team believes that this study design can be implemented in situations in which patients have a limited ability to communicate or provide reliable self-report, such as severe aphasia, late-stage Alzheimer’s, and dementia. Instruments designed to assess the quality of life of these patients are often administered to caregivers. Recall that previously, proxy-ratings have shown to not be the most reliable in reporting the quality of life of the patient in question (Bullinger et al., 2002). The technique used in the Aware Study brings together relevant stakeholders in a patient’s life and care to collectively decide which areas of life are important to the patient’s quality of life.

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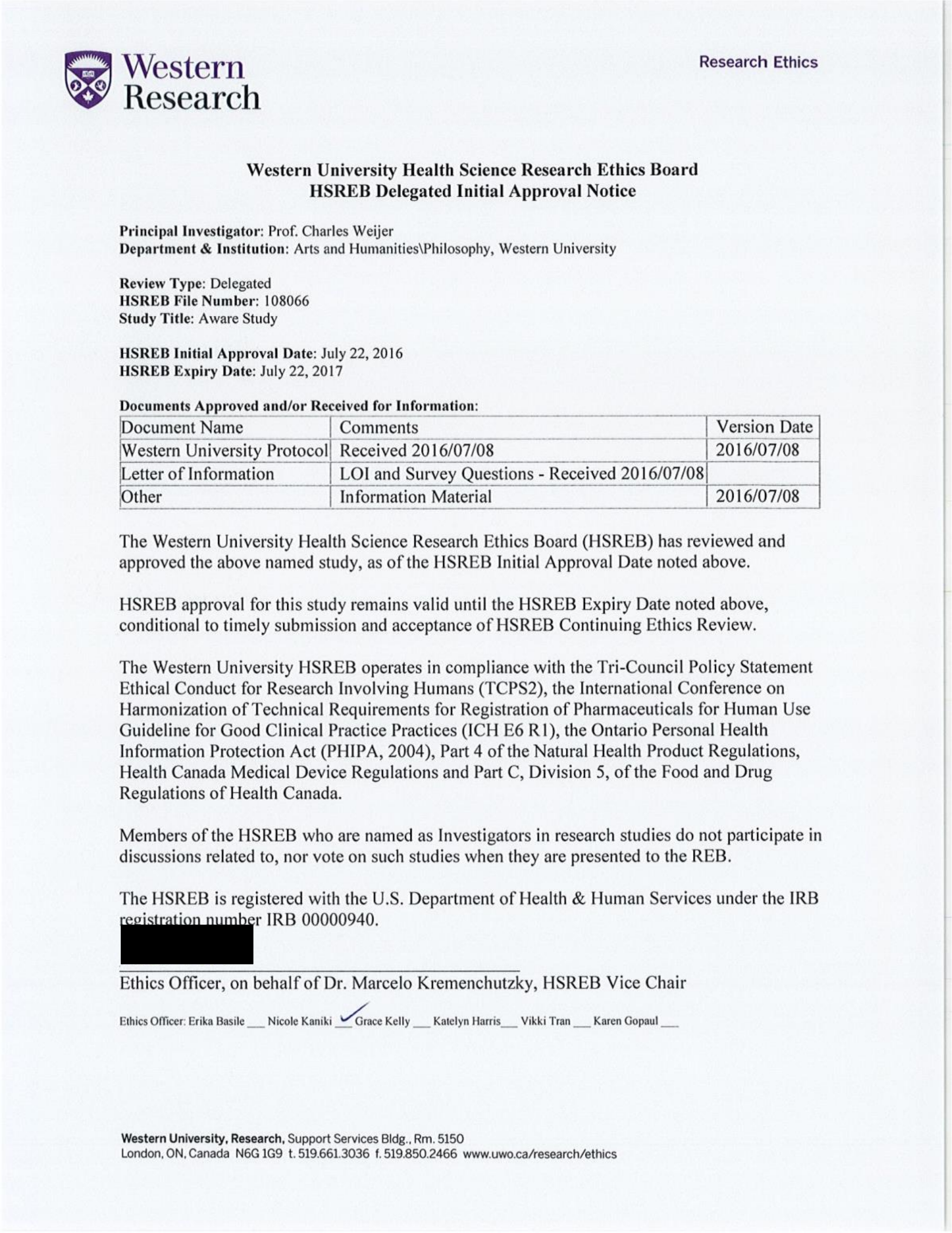
Appendices

Appendix 1. Western University Research Ethics Board Study Approvel



Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Prof. Charles Weijer
Department & Institution: Arts and Humanities\Philosophy, Western University

Review Type: Delegated
HSREB File Number: 108066
Study Title: Aware Study

HSREB Initial Approval Date: July 22, 2016
HSREB Expiry Date: July 22, 2017

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Western University Protocol	Received 2016/07/08	2016/07/08
Letter of Information	LOI and Survey Questions - Received 2016/07/08	
Other	Information Material	2016/07/08

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

Ethics Officer, on behalf of Dr. Marcelo Kremenchutzky, HSREB Vice Chair

Ethics Officer: Erika Basile ___ Nicole Kaniki ✓ Grace Kelly ___ Katelyn Harris ___ Vikki Tran ___ Karen Gopaul ___

Western University, Research, Support Services Bldg., Rm. 5150
London, ON, Canada N6G 1G9 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/ethics

Appendix 2. Aware Study Research Team Members

Last Name	**First Name**	**Affiliation**	**Role In Project**
Tung	Jasmine	Schulich School of Medicine and Dentistry\Epidemiology & Biostatistics	Study Coordinator
Speechley	Kathy	Schulich School of Medicine and Dentistry\Paediatrics	Co-Investigator & Recruiter
Weijer	Charles	Arts and Humanities\Philosophy	Co-Investigator & Recruiter
Gofton	Teneille	Schulich School of Medicine and Dentistry\Neurology	Participant & Recruiter
Young	Bryan	Schulich School of Medicine and Dentistry\Clinical Neurological Sciences	Participant & Recruiter
Naci	Lorina	Social Science\Psychology	Participant & Recruiter
Gonzalez Lara	Laura	Social Science\Psychology	Patient Advocate Recruiter
Owen	Adrian	Social Science\Psychology	Study Advisor

Appendix 3. Letter of Information and Consent Form

Letter of Information

Project Title:
Aware Study
Principal Investigators:
Dr. Charles Weijer
Rotman Institute of Philosophy, Western University
Dr. Kathy Nixon Speechley
Department of Epidemiology and Biostatistics, Western University

The purpose of the Aware Study is to determine which dimensions of quality of life are the most relevant and important to minimally conscious and covertly aware vegetative patients who lack the ability to functionally communicate at bedside. This study will enlist the help of a panel of 40 multidisciplinary experts and collect their beliefs and opinions using consensus methodology.

We want to hear your expert opinion and thoughts so we can improve our understanding of quality of life and how it pertains to minimally conscious and vegetative state patients. You're being invited to participate in this Delphi consensus panel because of your expertise in one or more of the following: quality of life methodology, philosophy of well-being, bioethics, healthcare, or patient advocacy.

Participation in this study is voluntary. You do not waive any legal rights by consenting to participate in this study. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your academic standing, employment status, or family's care. While no identifying information will be collected during the surveys and every possible step will be taken to protect confidentiality, there is always a risk of breach of privacy and confidentiality. You have the opportunity to be acknowledged in any publications or presentations that result from this study. All data collected will remain confidential and accessible only to the investigators of this study. Qualified representatives from the Western University Health Sciences Research Ethics Board may require access to study records for quality assurance purposes. All digital data will be encrypted and stored on secure university network drives at Western University behind institutional firewalls. Only an identification number will be associated with any information you give us. If the results of the study are published, your name will not be used without prior consent. You can decide to withdraw from the study at any time and your name will not be associated with any results produced from the study.

If consensus is reached at the end of the Delphi process, you may be invited back to help generate items for a quality of life instrument for minimally conscious and covertly aware vegetative patients.

If you agree to participate, you will be asked to complete three surveys about your expert opinions. The initial Informational Material package emailed to you will take about thirty minutes to read. Afterwards, you will be asked to complete the first of a total of three questionnaires about your expert opinions. The survey will take roughly twenty minutes to complete and the entire process of completing all three questionnaires is expected to take two months. Each one will be emailed to you separately about three weeks apart and will be available for one week. If you do not complete the survey in the allotted time frame, a reminder email will be sent to you. After each survey, the results will be analyzed and a summary report with aggregate data will be emailed to you. Your responses will be kept confidential and no personal information will be associated with your responses in any reports of the data.

If you require any further information regarding this research project or your participation in the Aware Study, you may contact Jasmine Tung (Study Coordinator) at [redacted]. If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics a[redacted]

This letter is yours to keep for future reference.

Consent Form

Project Title:
Aware Study
Principal Investigators:
Dr. Charles Weijer
Rotman Institute of Philosophy, Western University
Dr. Kathy Nixon Speechley
Department of Epidemiology and Biostatistics, Western University

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant's Name (please print): ____

Participant's Signature: ____

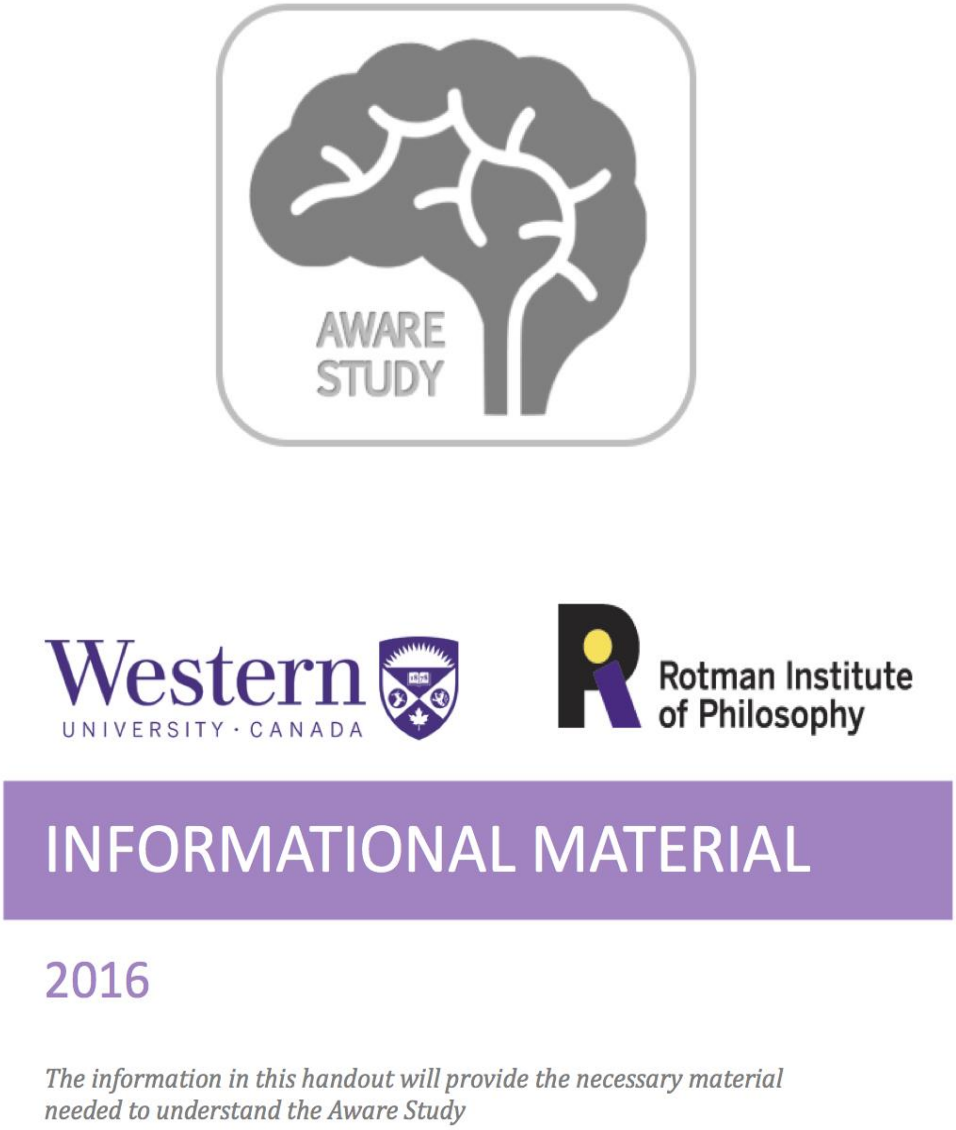
Date: ____

Person Obtaining Informed Consent (please print): ____

Signature: ____

Date: ____

Appendix 4. Informational Material



AWARE
STUDY

Western
UNIVERSITY · CANADA

Rotman Institute
of Philosophy

INFORMATIONAL MATERIAL

2016

The information in this handout will provide the necessary material needed to understand the Aware Study

TABLE OF CONTENTS

Contents

TO OUR EXPERTS

To Our Experts

STUDY OBJECTIVE

The purpose of the Aware Study is to determine which dimensions of quality of life are the most relevant and important to minimally conscious and covertly aware vegetative patients, known as behaviourally nonresponsive, who lack the ability to functionally communicate at bedside. If consensus is reached, the final product of this study will be a first draft of a quality of life instrument. We want to hear your expert opinion and thoughts so we can improve our understanding of quality of life for behaviourally nonresponsive patients.

TIME COMMITMENT

This Informational Material package will take about thirty minutes to read. Afterwards, you will be asked to complete the first of a total of three questionnaires about your expert opinions. The survey will take roughly twenty minutes to complete and the entire process of completing all three questionnaires is expected to take two months. Each one will be emailed to you separately about three weeks apart and will be available for one week. After each survey, the results will be analyzed and a summary report with aggregate data will be emailed to you.

CONFIDENTIALITY

Your responses will be kept confidential and no personal information will be associated with your responses in any reports of the data. Only an identification number will be associated with any information you give us. You can decide to withdraw from the study at any time and your name will not be associated with any results produced from the study. If you choose to withdraw from this study, your data will be removed and destroyed from our database. If the results of the study are published, your name will not be used without prior consent.

Disorders of Consciousness

Consciousness is broadly defined as being awake and having awareness of oneself and one's environment (1). After a severe brain injury a patient in a coma is characterized as lacking arousal, where the patient's eyes remain closed, and there is no awareness of self or environment (2). Within a period of days of entering a coma, a patient can regain consciousness, or enter into a vegetative state or minimally conscious state (3).

To meet the diagnostic criteria for the vegetative state, a patient must exhibit: no evidence of awareness of oneself or the environment, no volitional response to any sensory stimuli, and no evidence of language comprehension (4). A post-coma patient with is diagnosed as being minimally conscious if he or she is able to perform one or more of the following, even if inconsistently: purposeful behaviour, gestural or verbal yes/no responses, intelligible verbalization, or following simple commands (5).

Misdiagnosis

Diagnosis of patients suffering from a disorder of consciousness can vary by clinician and by treatment site (4). This can be partially attributed to the subjective nature of bedside examinations. Diagnosis can be further complicated by the fact that patients can have motor impairment issues or fluctuating arousal states (6). It is also possible that a patient could be unable to produce physical movement on command, but is in fact aware (6). This can lead to a variable diagnosis and possible misdiagnosis; that is, an individual who is aware is diagnosed as being vegetative.

Prevalence

Globally, the prevalence of the vegetative state has been estimated at 0.2 to 6.1 patients per 100,000 people in the population (7)*. Additionally, 6-16% of the cases of severe head injury will result in the individual becoming vegetative* (8)*. In the US, there is a wide discrepancy in the estimates of vegetative and minimally conscious patients. Estimates range from 12,000 to 54,000 vegetative patients and 112,000 to 280,000 minimally conscious patients* (9,10)*. The fluctuation in the stated prevalence rates is partially due to the high misdiagnosis rate, nearly 43%, among patients that are minimally conscious but misclassified as being vegetative* (11).

Neuroimaging Research

In the last decade, functional magnetic resonance imaging (fMRI) has emerged as a tool to detect intact cognitive abilities in patients suffering from disorders of consciousness. In 2006, Owen and his colleagues were the first to explore if neuroimaging could detect awareness in patients who are nonresponsive at the bedside. The original study was conducted with a 23-year-old female patient, who met the clinical diagnosis of being in a vegetative state. To assess awareness in this patient, an imagery paradigm was used (Diagram 1). The female patient's responses were found to be indistinguishable from those of healthy controls that performed the same imagery paradigm.

Diagram 1. Imagery Paradigm

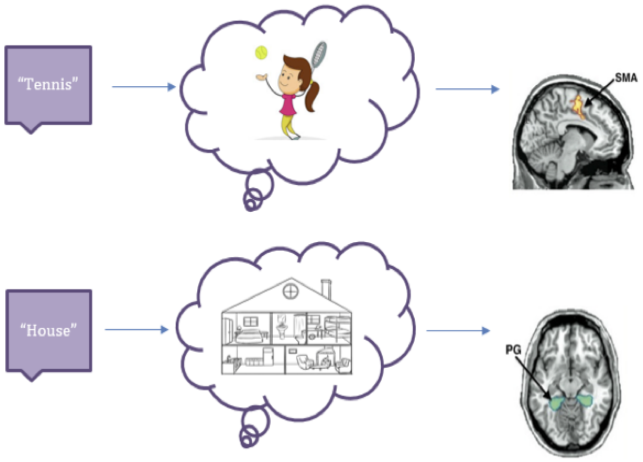


Diagram 1. *The patient is verbally instructed to perform two mental imagery tasks at the time of scanning. The first task is to imagine hitting a tennis ball back and forth, to activate the part of the brain responsible for motor function. The second task is to imagine walking from room to room in the patient's house, resulting in activation in parts of the brain known to be associated with spatial navigation. While in the scanner, the patient is prompted to start imagining by the word 'tennis' or 'house' for a 30-second period. After this, the word 'rest' signals for the patient to rest for 30-seconds.*

The patient being able to perform the mental imagery task showcases that she was able to remember instructions given at the start of scanning, comprehend verbal commands while in the fMRI, and respond using her brain. Successful participation in the imagery paradigm confirmed, beyond reasonable doubt, that all the necessary processes were intact in the patient and she was consciously aware of herself and her surroundings. Also, the block experiment design ensured that what was being displayed was not the product of random brain activations (12). This was the first study to demonstrate that despite a diagnosis of vegetative, there was covert awareness in a patient (13). Furthermore, the findings from this study provide evidence that there are covertly aware patients who lack purposeful motor function during bedside examination. The imagery paradigm provides a process for detecting signs of cognitive function and awareness in behaviourally nonresponsive patients.

A follow-up study was conducted in a similar fashion on a group of 54 patients in a vegetative or minimally conscious state (14). After repeating the imagery paradigm, it was determined that one minimally conscious and four vegetative state patients had brain activations patterns similar to those of healthy controls and therefore indicated covert awareness. Furthermore, this study introduced a new communication paradigm to establish a method to communicate with a 22-year-old male vegetative state patient, who successfully completed the imagery paradigm (Diagram 2). The patient answered five of the six questions correctly over six scanning sessions (one answer could not be correctly decoded by investigators).

This breakthrough study was the first to establish communication with a patient suffering from a disorder of consciousness using a brain-computer interface (14). To date, three patients with disorders of consciousness have been able to successfully perform the communication paradigm, despite not being able to functionally communicate at the bedside (12,14,15). All of these patients had a diagnosis that did not reflect the true nature of their awareness and level of cognitive ability. Due to the complexity of the mental tasks, it can be concluded that patients able to complete the imagery paradigm and the communication paradigm possess a high-level of cognitive functioning (12).

NEUROIMAGING RESEARCH

Diagram 2. Communication Paradigm

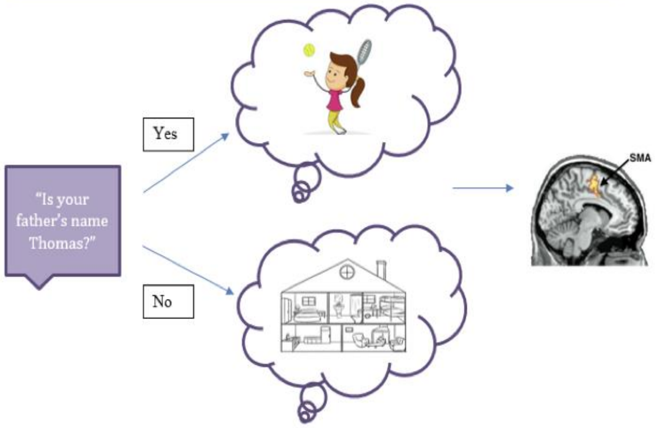


Diagram 2. *Similar to the imagery paradigm, the same mental tasks are used to answer questions through modification of brain activity. At the start of the scanning session, the patient is asked a personal question that could be answered with a 'yes' or 'no' response (e.g. is your father's name Thomas?). To answer "yes" the patient is told to imagine playing a game of tennis; to answer "no" they must imagine walking from room-to-room in their home. While in the scanner, the verbal cue 'answer' indicates the start of the imagery task for 30-seconds, followed by the cue 'rest' that signals a 30-second rest period. The patient is expected to imagine the mental task that corresponded with the answer they wanted to convey. To avoid bias, the investigators are blinded to the correct answer to the question at time of scanning.*

Quality of Life

The field of quality of life research has seen considerable growth in the last 20 years (16). The phrase has seeped into every discipline and even everyday language (16). The extensive use of the term may mislead some into believing that the concept is relatively new. However, questions about what constitutes a good life or optional existence can be traced back to ancient Greek philosophers (17). Different societies since have interpreted quality of life within the context of their culture and values (18). Despite the popularity of the phrase, no uniform definition for quality of life exists (16). The complexity of defining quality of life is attributable in part to its subjective nature; a good life means different things to different people (19). It can encompass anything and everything from optimal physical functioning to a low unemployment rate (16). Many think of quality of life as an umbrella term that covers an assortment of physical and psychosocial constructs (20). Quality of life can be interpreted as an individual's evaluation of their subjective wellbeing, achievement in life domains they consider important, or their perceived health status compared to a desired reference (21). The most widely cited definition for quality of life was developed by the World Health Organization:

> *"...an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's personal health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment." (WHO)*

Since there is no information on the reported quality of life of vegetative and minimally conscious state patients, it remains to be determined what quality of life means to these individuals.

DIMENSIONS OF QUALITY OF LIFE

To measure quality of life, both objective and subjective indicators are traditionally included as a part of instruments. Objective parameters are tangible and measureable aspects of life and usually center on social, economic, and health indicators (22). Subjective parameters focus on personal reports of life experiences and are not usually directly observable (22). Areas of life, or domains, are composed of objective and subjective dimensions of the same topic and can be grouped into categories like: physical, social, mental, emotional, and economic well-being. To evaluate and obtain a fuller image of overall quality of life, both objective and subjective dimensions must be included in quality of life instruments (23).

The dimensions of quality of life included in the questionnaires for the Aware Study were the result of a systematic review. A literature search strategy was designed to comply a list of dimensions from existing quality of life measures. There are properties that other patient populations share with individuals who suffer from disorders of consciousness. An instrument developed for a similar patient population was a starting point to assessing quality of life in the target population. Patients with the following conditions were included in the literature search: neurological conditions, neurodegenerative conditions, disabilities, cognitive issues, trauma, or brain injury. In the end, 42 unique dimensions of quality of life were isolated for investigation in this study.

INSTRUMENT CREATION

Instrument Creation

With the explosion of quality of life instruments created in recent years, there has been a concomitant refinement of methods for quality of life tool development. The development of instruments is a rigorous process that is time and resource consuming. The early stages of designing a questionnaire are focused on qualitative methods to ensure that scores accurately reflect the quality of life of patients (24). Quantitative methods that follow, testing validity and reliability, rely on the assumption that the instrument was diligently designed from the beginning (24). The established methods for scale development, which have been extensively used in neurodegenerative specific instruments, use a three-step system: item generation, item reduction and scale generation, and psychometric evaluation (25). Throughout the creation of a quality of life instrument patient input is sought many times.

While tools have been created for virtually every health condition, to date no such measure has been created to try to assess the welfare and lived experience of patients suffering from disorders of consciousness. The procedures for the development of quality of life instruments, like interviews and focus groups with patients, assumes consciousness on the part of patients. With select vegetative and minimally conscious patients being conscious and able to communicate through fMRI, research on this patient population is anticipated to grow over the coming years. A quality of life tool needs to be a central outcome in all patient populations regardless of their ability to communicate. It is essential to determine if health care professionals are to do more to increase the quality of life experienced by those suffering severe brain injuries.

Existing Tools & Technologies

One of the largest obstacles to determining quality of life in behaviourally nonresponsive patients is the lack of existing validated instruments that could be applied to these patients. Generic and disease-specific tools usually use a mixture of question formats and the majority include questions that are ordinal in nature (24). Ordinal scales are composed of multiple response options that are inherently ordered or graded (24). The most widely used ordinal scale in quality of life research is the Likert scale, which has response options labeled from 'strongly disagree' to 'strongly agree' with a neutral response in the middle (24). These options are problematic because the available brain-computer interface and communication paradigm is designed to only support 'yes' or 'no' responses from patients.

A standard overall quality of life measure can be numerous pages in length with dozens of questions. Using an existing lengthy quality of life, even if valid and reliable, is not feasible in behaviourally nonresponsive individuals. Due to the taxing nature of neuroimaging and command following, only a limited number of questions can be posed to patients during a scanning session. A longer questionnaire will allow for more details to be captured but a shorter questionnaire will ensure all the questions are answered. A balance must be struck when considering a quality of life instrument for patients that can only communicate using mental imagery in fMRI.

Finally, traditional quality of life tool development methods, like those previously outlined, cannot be applied to patients with disorders of consciousness. Regardless of the scale development technique, patient interviews are considered central to the process (25). They are vital to the initial item generation process to provide their personal experience. Currently, technology does not support an open dialogue format between researchers and behaviourally nonresponsive patients. This means that no interview process is possible and patients are unable to give their unique perspective directly.

Consensus Methodology

Consensus methods have been employed in health research to make decisions in situations where there is conflicting or scarce information (26). The aim of consensus methodology is to reach a convergence of opinion among the participating experts (26). Although there is considerable variation in the various methods, the basic approach typically requires participants to make independent judgments before, and then again after, exposure to the views of other participants (27). An example of a popular online consensus technique is the Delphi process.

The Delphi consensus technique involves the systematic gathering of information from participants within their domain of expertise, using a series of purposefully designed surveys (28). This study will employ this approach. The participants are not required to meet in person to reach consensus. Between iterations of the questionnaire, or rounds, the responses from earlier questionnaires are summarized and fed back to the participants. The feedback process is anonymous and it allows the experts to reassess their original opinions and possibly change judgments for the next iteration. Anonymity allows experts the equal opportunity to put forth ideas in an unbiased fashion (28). Additionally, remaining anonymous allows participants to know that their opinion carries the same weight as everyone else's.

DELPHI PROCESS

Delphi Process

Stage	***Description***
Initial Contact	Experts will be emailed a formal introduction to the study, timeline of the project, relevant research material and information on what is expected from them.
Round 1	First survey will include the list of dimensions of quality of life that have been systematically selected from existing measures in use. The experts will be asked to rate each domain on a scale from 1 (not important) to 4 (very important).
Round 1 Analyses	Median score analysis will be done on all dimensions. A summary report of responses will be generated and emailed out to participants.
Round 2	Second survey will include the dimensions for which consensus was not reached and the newly added dimensions from experts. Participants will be instructed to rate the list of dimensions but this time on a seven point scale (from 1-not at all important to 7-extremely important).
Round 2 Analyses	Median score and semi-interquartile range analysis will be done on all remaining dimensions. A summary report of responses will be generated and emailed out to participants.
Round 3	Third survey will be include all the original dimensions with the exception of dimensions that were judged to be not important by the experts from the first and second questionnaire. Participants will be instructed to rate the list of dimensions on a seven point scale The experts will be asked to select the five domains they deem the most relevant to quality of life and then rank them with 5 being the most important.
Round 3 Analyses	Median score, semi-interquartile range, and weighted means analysis will be done on remaining dimensions. A summary report of responses will be generated and emailed out to participants.

CONTACT INFORMATION

Contact Information

If you require any further information regarding this research project or your participation [redacted]

PRINCIPAL INVESTIGATORS

Dr. Charles Weijer
Rotman Institute of Philosophy
Western University
[redacted]

Dr. Kathy Nixon Speechley
Department of Epidemiology & Biostatistics
Western University
[redacted]

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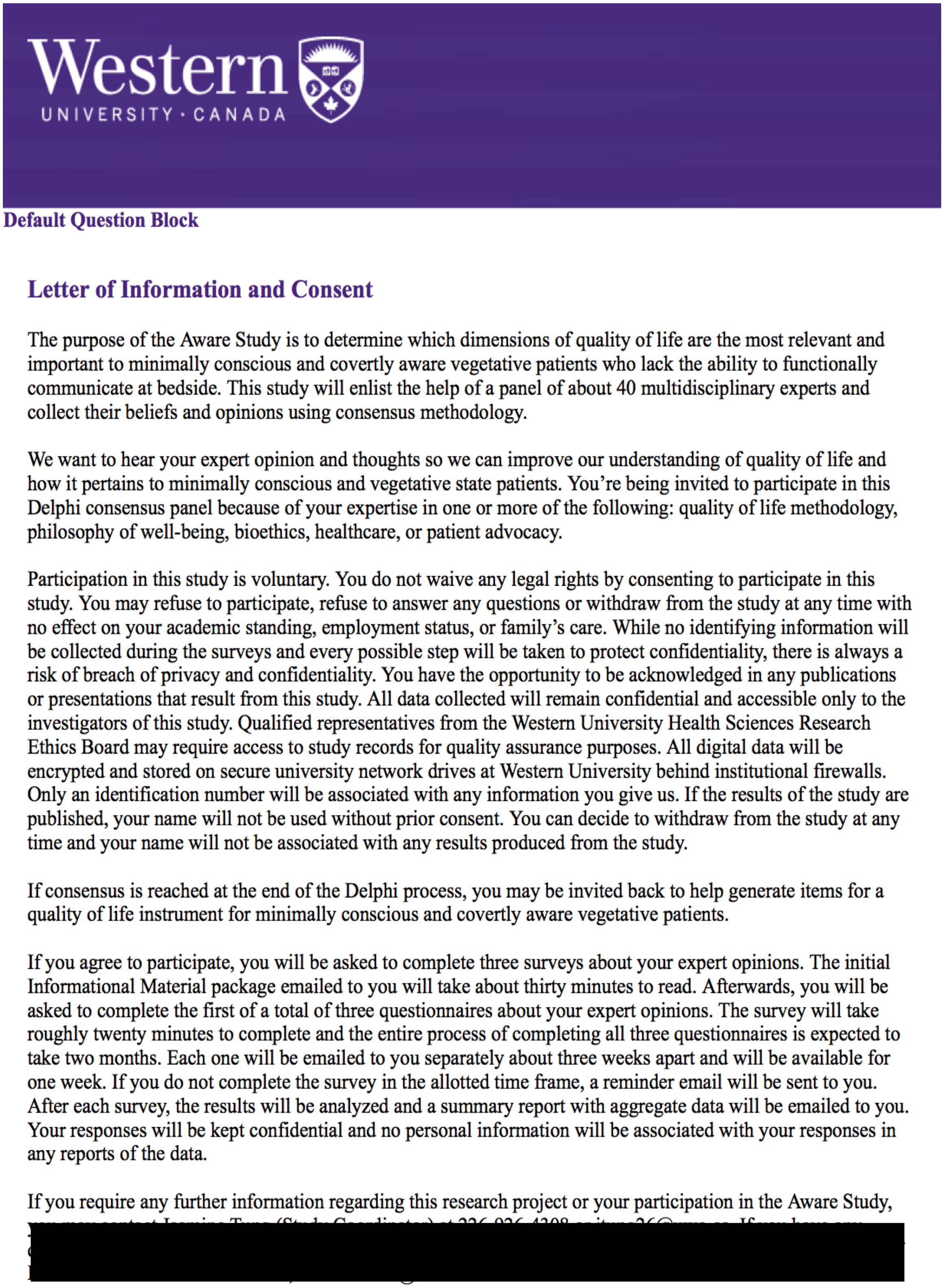
Appendix 5. Delphi Consensus Online Survey #1



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Letter of Information and Consent

The purpose of the Aware Study is to determine which dimensions of quality of life are the most relevant and important to minimally conscious and covertly aware vegetative patients who lack the ability to functionally communicate at bedside. This study will enlist the help of a panel of about 40 multidisciplinary experts and collect their beliefs and opinions using consensus methodology.

We want to hear your expert opinion and thoughts so we can improve our understanding of quality of life and how it pertains to minimally conscious and vegetative state patients. You're being invited to participate in this Delphi consensus panel because of your expertise in one or more of the following: quality of life methodology, philosophy of well-being, bioethics, healthcare, or patient advocacy.

Participation in this study is voluntary. You do not waive any legal rights by consenting to participate in this study. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your academic standing, employment status, or family's care. While no identifying information will be collected during the surveys and every possible step will be taken to protect confidentiality, there is always a risk of breach of privacy and confidentiality. You have the opportunity to be acknowledged in any publications or presentations that result from this study. All data collected will remain confidential and accessible only to the investigators of this study. Qualified representatives from the Western University Health Sciences Research Ethics Board may require access to study records for quality assurance purposes. All digital data will be encrypted and stored on secure university network drives at Western University behind institutional firewalls. Only an identification number will be associated with any information you give us. If the results of the study are published, your name will not be used without prior consent. You can decide to withdraw from the study at any time and your name will not be associated with any results produced from the study.

If consensus is reached at the end of the Delphi process, you may be invited back to help generate items for a quality of life instrument for minimally conscious and covertly aware vegetative patients.

If you agree to participate, you will be asked to complete three surveys about your expert opinions. The initial Informational Material package emailed to you will take about thirty minutes to read. Afterwards, you will be asked to complete the first of a total of three questionnaires about your expert opinions. The survey will take roughly twenty minutes to complete and the entire process of completing all three questionnaires is expected to take two months. Each one will be emailed to you separately about three weeks apart and will be available for one week. If you do not complete the survey in the allotted time frame, a reminder email will be sent to you. After each survey, the results will be analyzed and a summary report with aggregate data will be emailed to you. Your responses will be kept confidential and no personal information will be associated with your responses in any reports of the data.

If you require any further information regarding this research project or your participation in the Aware Study,

[redacted]

Principal Investigators:
Dr. Charles Weijer
Rotman Institute of Philosophy, Western University
[redacted]

Dr. Kathy Nixon Speechley
Department of Epidemiology and Biostatistics, Western University
[redacted]

Clicking on the “>>” button below indicates that:
*** you have read the above information**
*** you voluntarily agree to participate in the study**

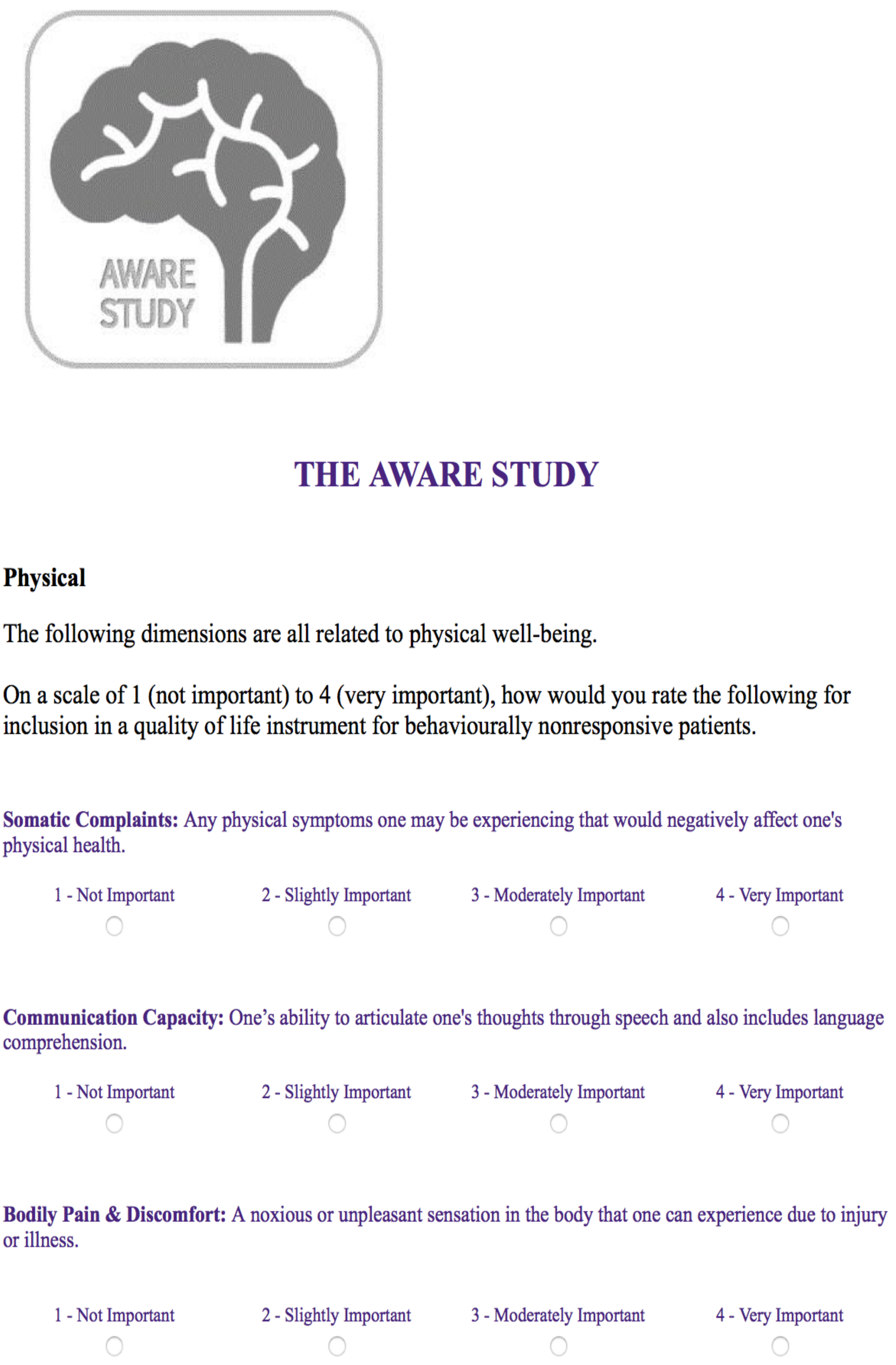
Welcome to the Expert Consensus Questionnaire

Thank you for participating in this important study.

Before beginning this survey, please ensure you have spent roughly thirty minutes to review the introductory material about the study and target population:
http://goo.gl/40lJM2

For the following survey, the dimensions of quality of life were identified from existing quality of life instruments used in patients that share characteristics with behaviourally nonresponsive individuals. The dimensions are organized into the following domains: physical, mental, social, psychosocial, economic, and other. In total, there are 42 dimensions of quality of life that you will be asked to rate.

For each dimensions please read the accompanying description to understand its application. For answers, click the value that is most similar to your opinion and continue to the next question. If you are unsure of a particular dimension, please avoid leaving the question blank and provide the answer that is closest to your belief. If necessary, at the end of the survey there will be an opportunity to add additional dimensions that should be included for consideration.



THE AWARE STUDY

Physical

The following dimensions are all related to physical well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Somatic Complaints: Any physical symptoms one may be experiencing that would negatively affect one's physical health.

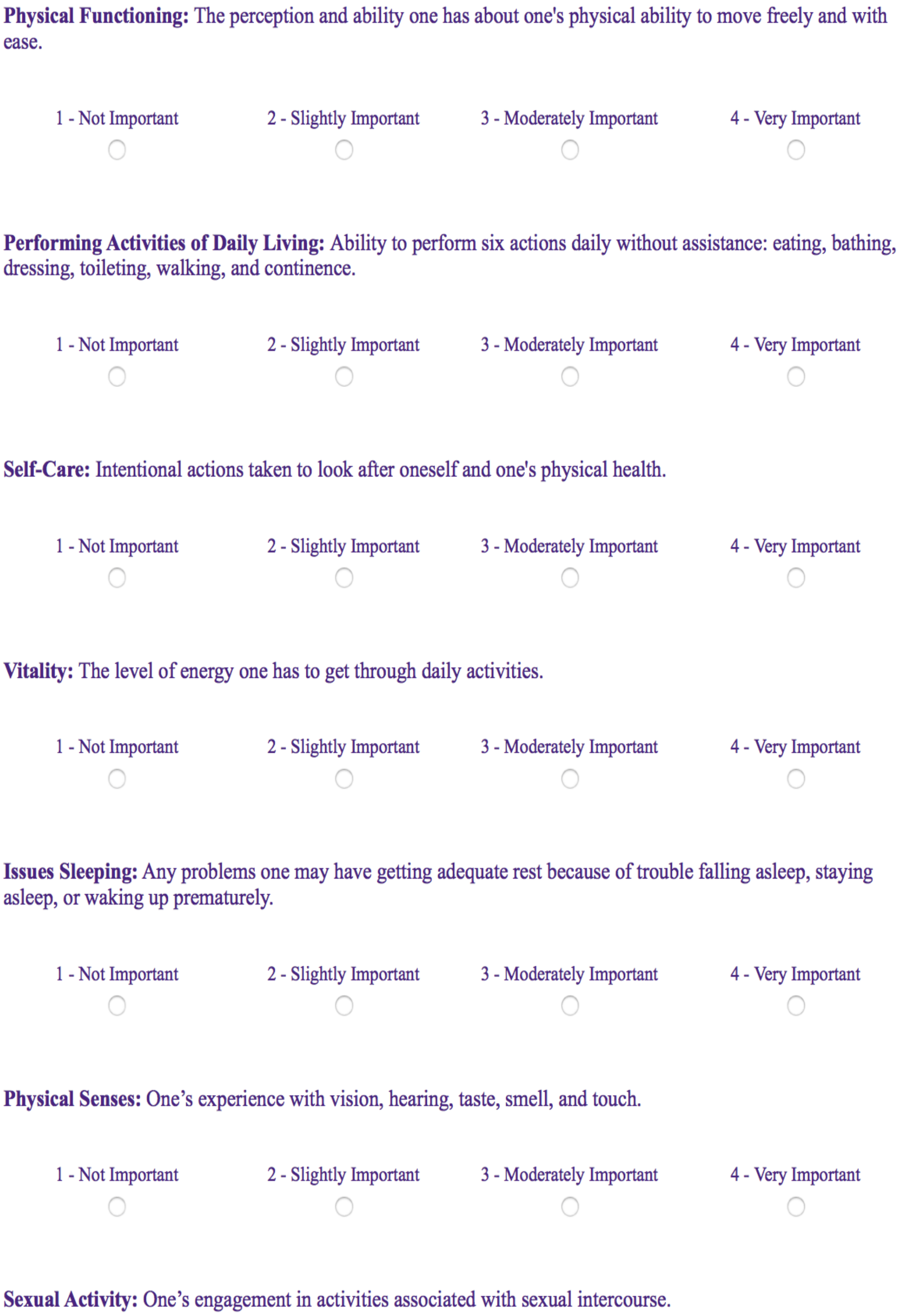
1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Communication Capacity: One's ability to articulate one's thoughts through speech and also includes language comprehension.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Bodily Pain & Discomfort: A noxious or unpleasant sensation in the body that one can experience due to injury or illness.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○



Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Self-Care: Intentional actions taken to look after oneself and one's physical health.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Vitality: The level of energy one has to get through daily activities.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Issues Sleeping: Any problems one may have getting adequate rest because of trouble falling asleep, staying asleep, or waking up prematurely.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Physical Senses: One’s experience with vision, hearing, taste, smell, and touch.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Sexual Activity: One’s engagement in activities associated with sexual intercourse.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Physical Appearance: The perception of one's physical characteristics and external features.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Mental

The following dimensions are all related to mental well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Experiencing Anxiety: Negative feelings of panic, worry, fear and nervousness that one may be experiencing.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Experiencing Depression: Negative feelings of sadness, hopelessness, discouragement, and overall disinterest in life.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

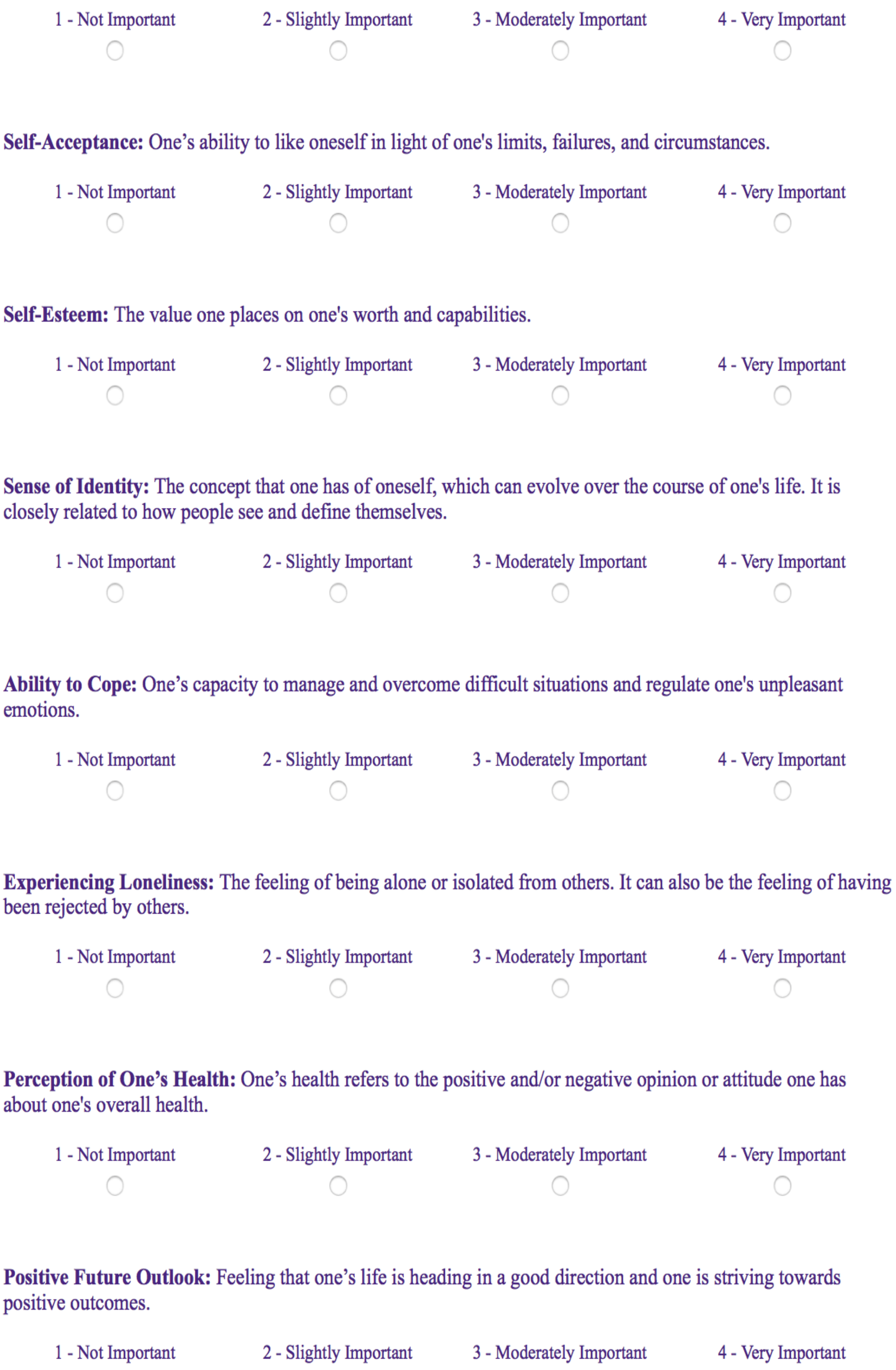
Experiencing Negative Emotions: A range of unpleasant feelings that can be evoked (for example, distress, frustration, resent, stress, etc.).

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Experiencing Positive Emotions: A range of pleasant feelings that can be evoked (for example, content, happiness, satisfaction, appreciation, etc.)

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Cognitive Functioning: One’s ability to memorize, learn, comprehend and understand information.



1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Self-Acceptance: One's ability to like oneself in light of one's limits, failures, and circumstances.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Self-Esteem: The value one places on one's worth and capabilities.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Sense of Identity: The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Ability to Cope: One's capacity to manage and overcome difficult situations and regulate one's unpleasant emotions.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Experiencing Loneliness: The feeling of being alone or isolated from others. It can also be the feeling of having been rejected by others.

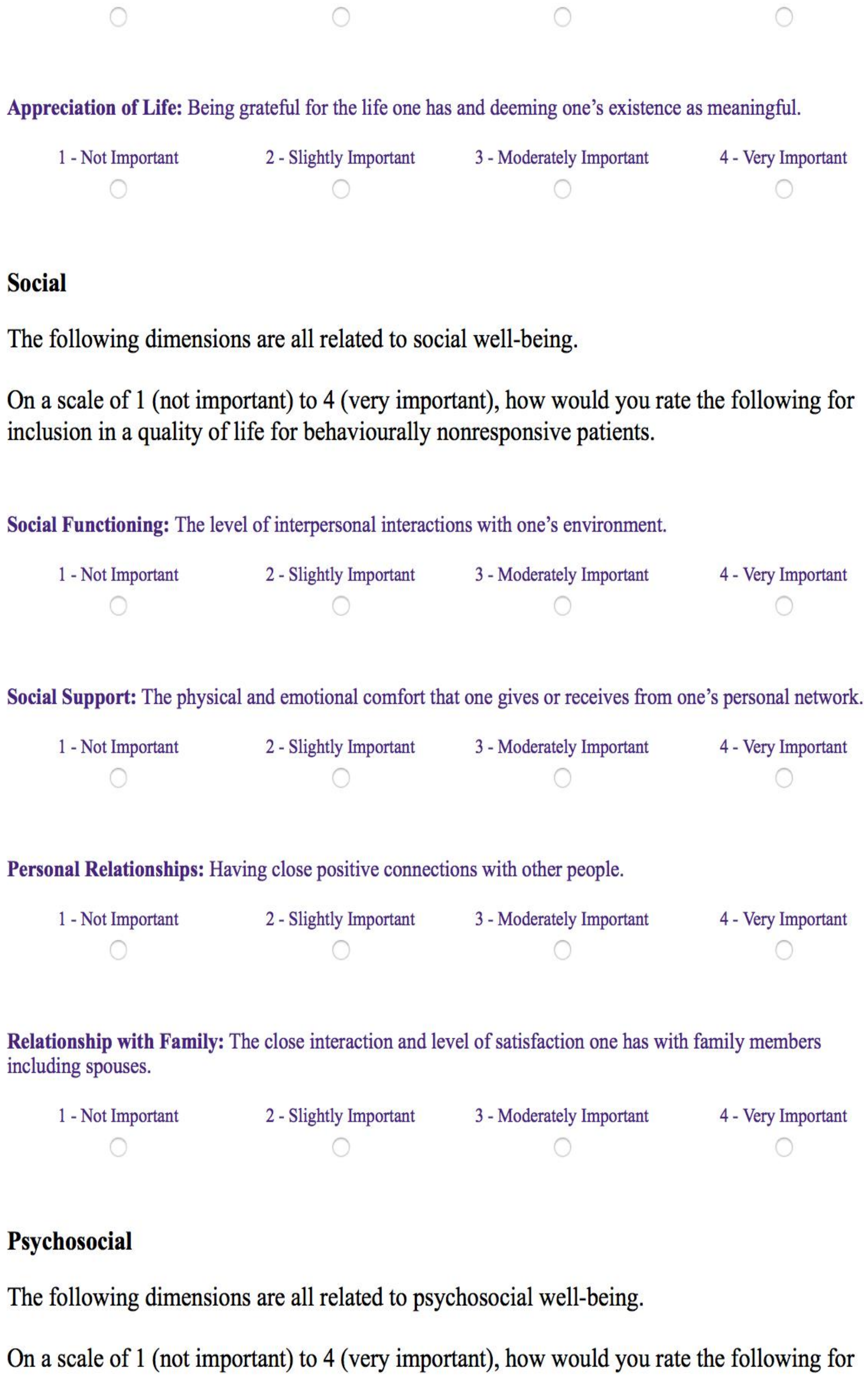
1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Perception of One's Health: One's health refers to the positive and/or negative opinion or attitude one has about one's overall health.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Positive Future Outlook: Feeling that one's life is heading in a good direction and one is striving towards positive outcomes.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important



○	○	○	○

Appreciation of Life: Being grateful for the life one has and deeming one's existence as meaningful.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Social

The following dimensions are all related to social well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life for behaviourally nonresponsive patients.

Social Functioning: The level of interpersonal interactions with one's environment.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Social Support: The physical and emotional comfort that one gives or receives from one's personal network.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Personal Relationships: Having close positive connections with other people.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

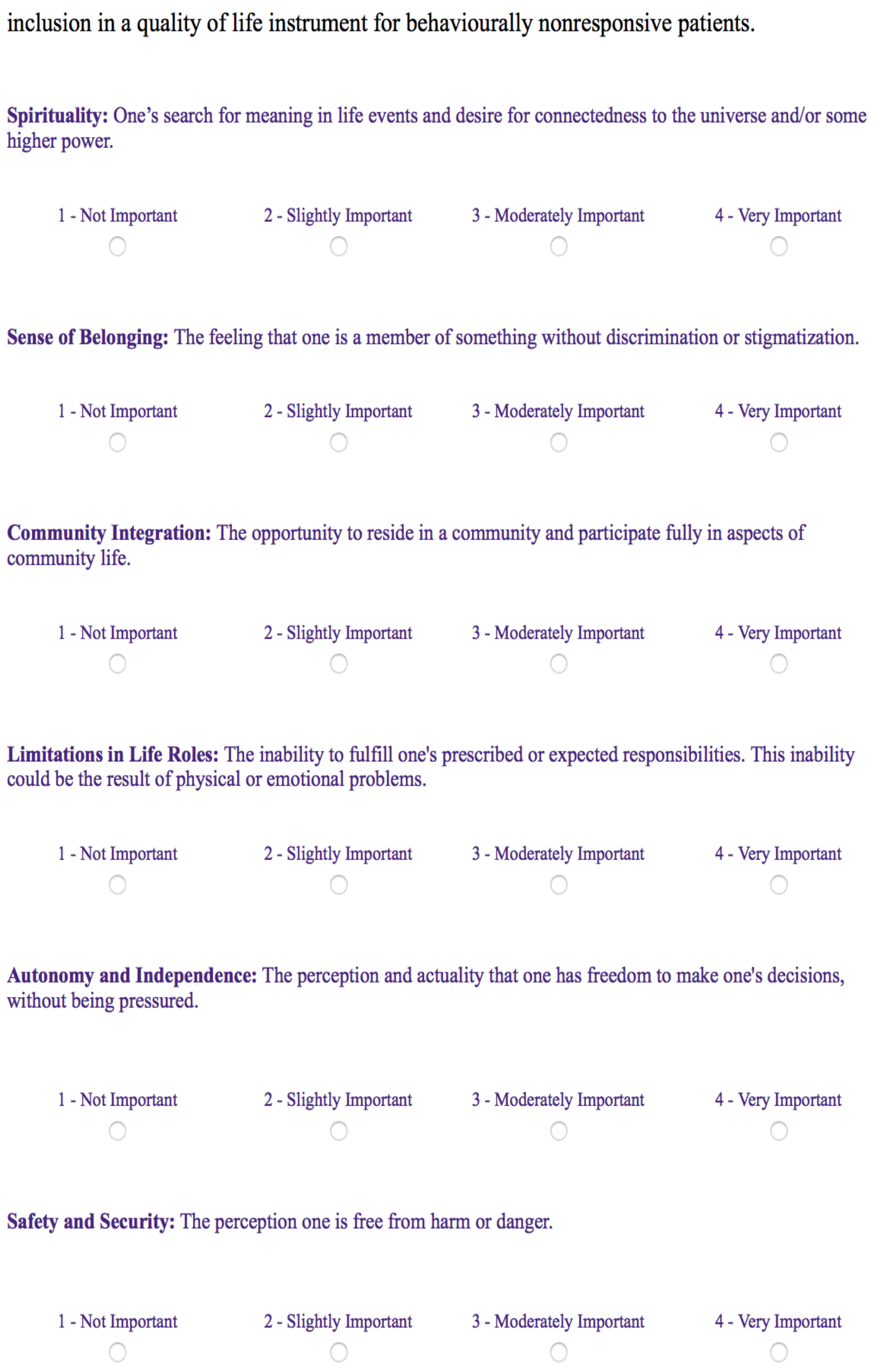
Relationship with Family: The close interaction and level of satisfaction one has with family members including spouses.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Psychosocial

The following dimensions are all related to psychosocial well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for



inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Spirituality: One’s search for meaning in life events and desire for connectedness to the universe and/or some higher power.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Limitations in Life Roles: The inability to fulfill one's prescribed or expected responsibilities. This inability could be the result of physical or emotional problems.

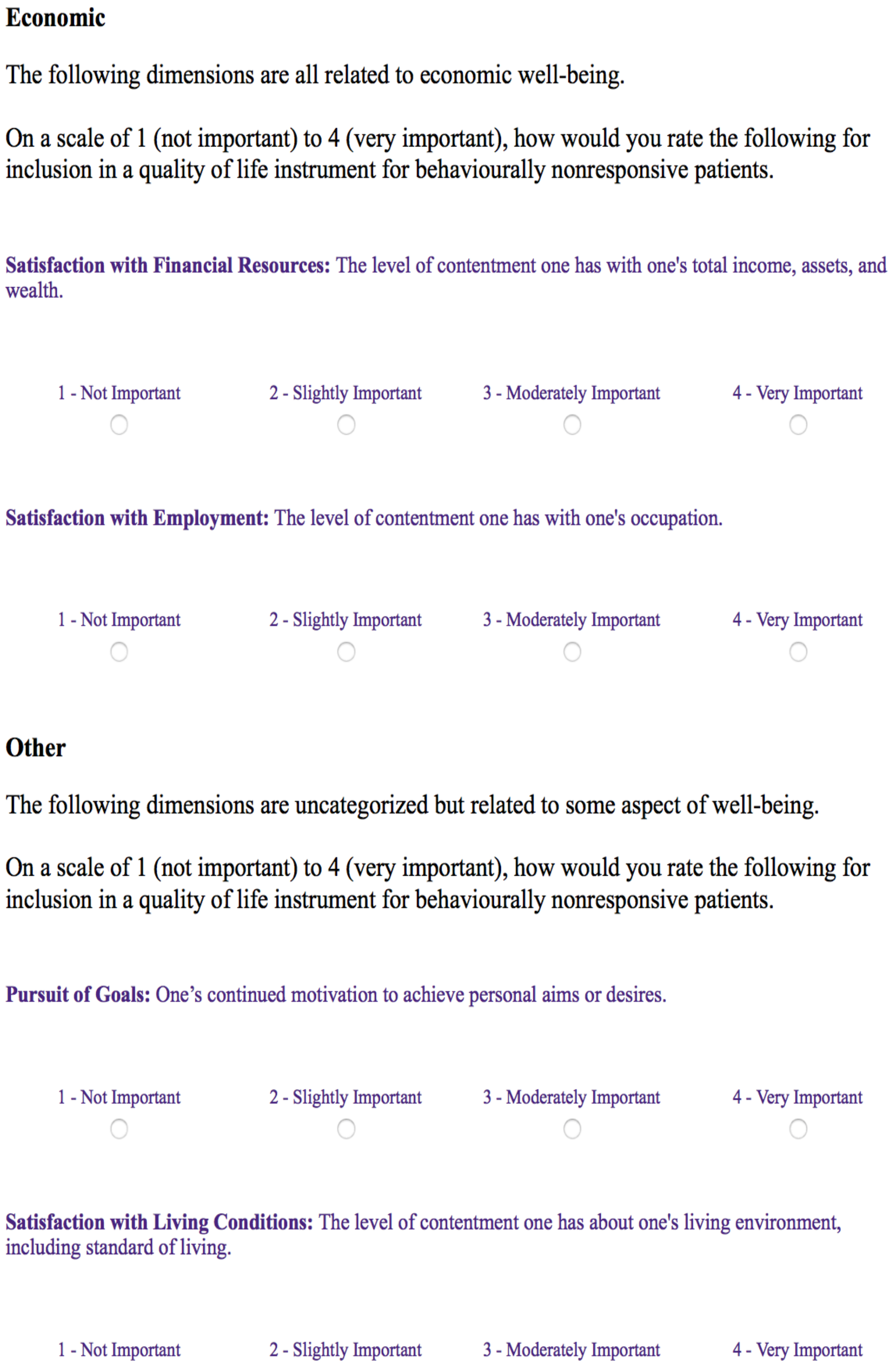
1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Autonomy and Independence: The perception and actuality that one has freedom to make one's decisions, without being pressured.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Safety and Security: The perception one is free from harm or danger.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○



Economic

The following dimensions are all related to economic well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Satisfaction with Financial Resources: The level of contentment one has with one's total income, assets, and wealth.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Satisfaction with Employment: The level of contentment one has with one's occupation.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Other

The following dimensions are uncategorized but related to some aspect of well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Pursuit of Goals: One’s continued motivation to achieve personal aims or desires.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Satisfaction with Living Conditions: The level of contentment one has about one's living environment, including standard of living.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important

○	○	○	○

Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Satisfaction with Medical Treatment/Services: The level of contentment one has with the quantity and quality of care one receives for one's medical condition. Additionally, it includes any restriction or hardship one may experience when seeking care and the imposition this poses on one's life.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Effects of Medication: Any positive and/or negative results of taking medications for one’s aliment(s). This can include adverse effects and symptom relief.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Overall Quality of Life

The following dimension is related to overall quality of life and well-being.

On a scale of 1 (not important) to 4 (very important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Overall Quality of Life: The broad satisfaction one has about one's life taking all aspects of well-being into consideration.

1 - Not Important	2 - Slightly Important	3 - Moderately Important	4 - Very Important
○	○	○	○

Additional Dimensions

If you feel that there is a dimension of quality of life that was missing from the list above, please add it below with a short description explaining its inclusion.

i)

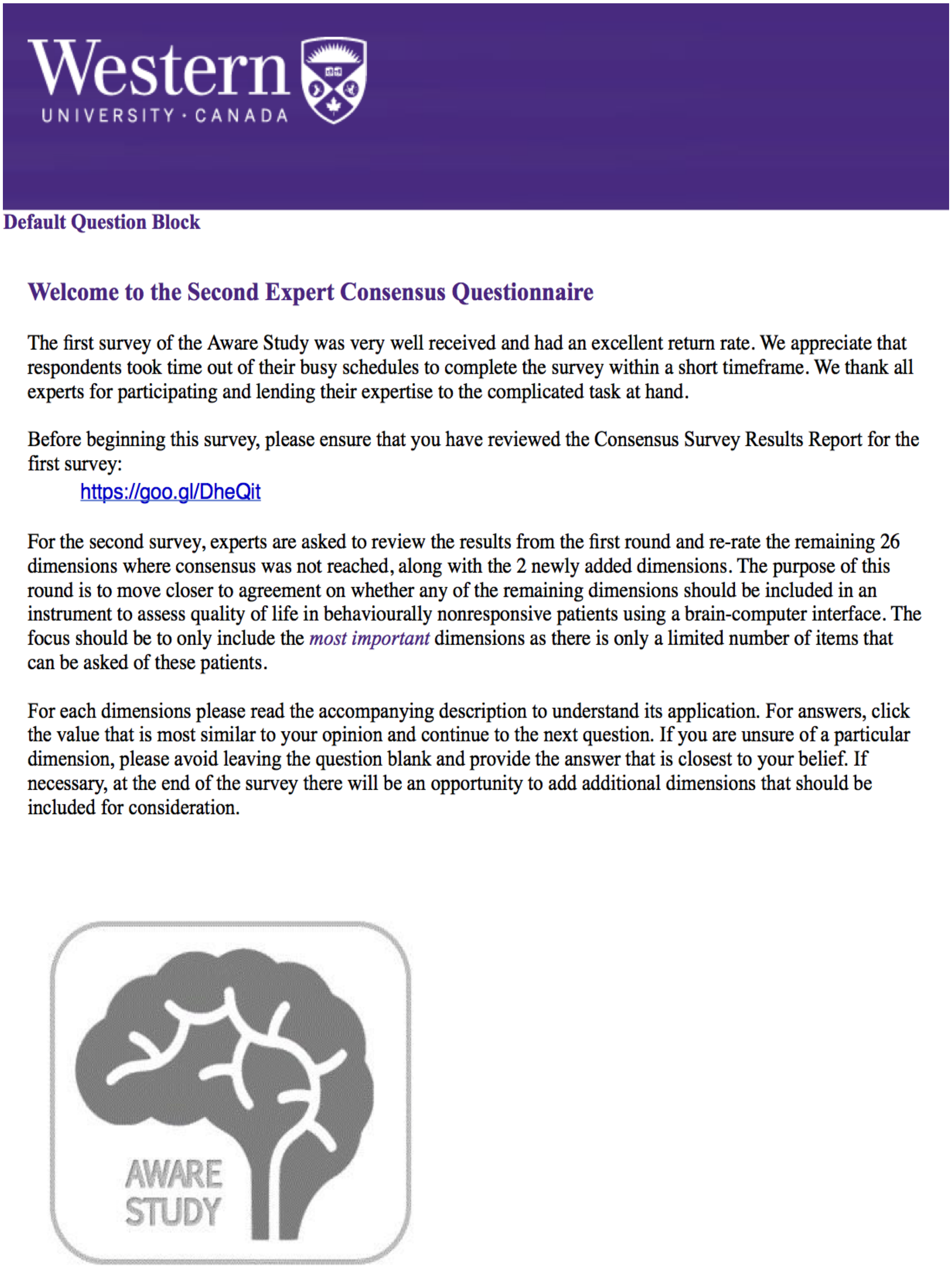
ii)

iii)

Feedback

Please use this space to leave any comments or concerns you may have.

Appendix 6. Delphi Consensus Online Survey #2



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Welcome to the Second Expert Consensus Questionnaire

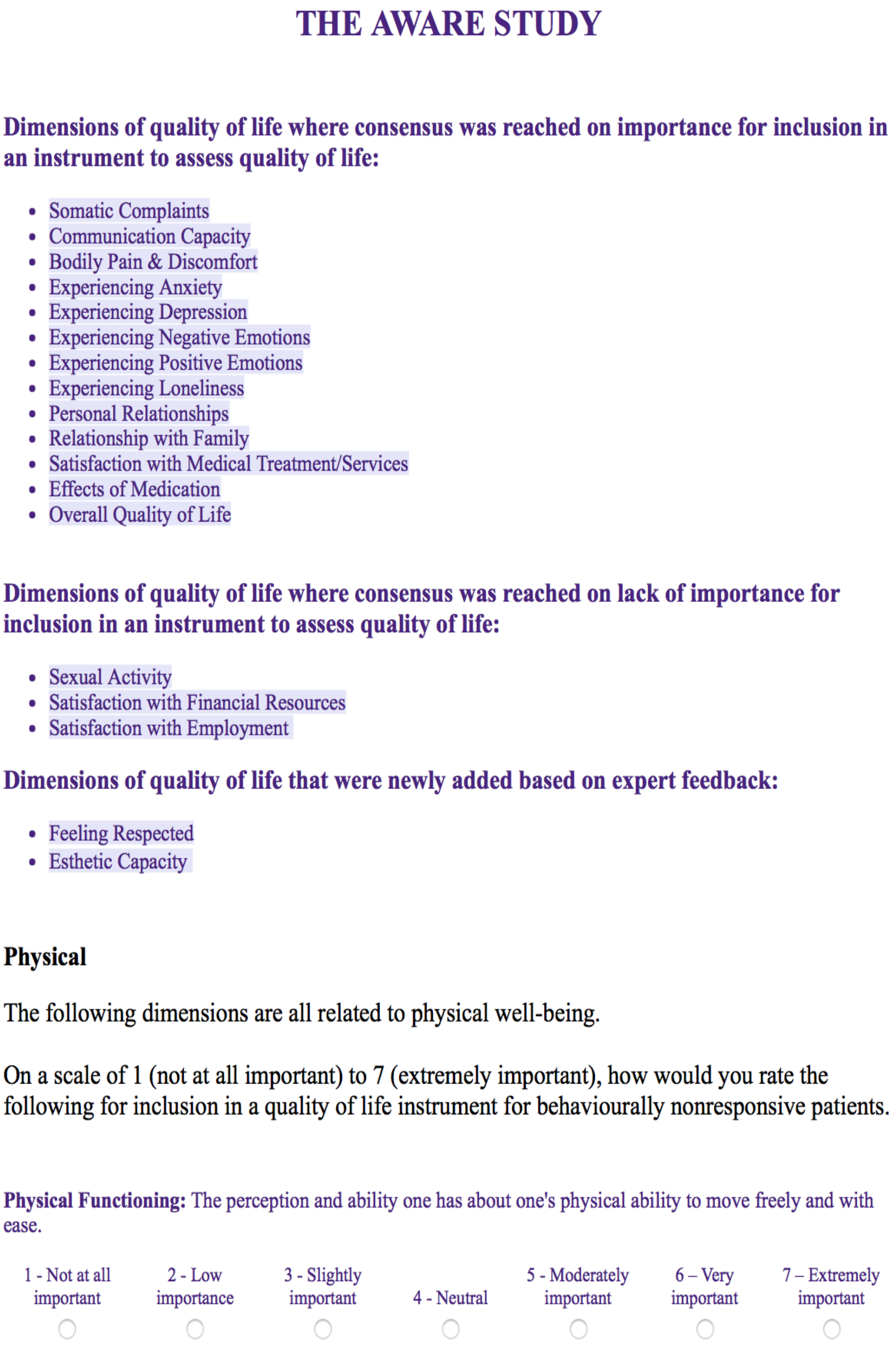
The first survey of the Aware Study was very well received and had an excellent return rate. We appreciate that respondents took time out of their busy schedules to complete the survey within a short timeframe. We thank all experts for participating and lending their expertise to the complicated task at hand.

Before beginning this survey, please ensure that you have reviewed the Consensus Survey Results Report for the first survey:

https://goo.gl/DheQit

For the second survey, experts are asked to review the results from the first round and re-rate the remaining 26 dimensions where consensus was not reached, along with the 2 newly added dimensions. The purpose of this round is to move closer to agreement on whether any of the remaining dimensions should be included in an instrument to assess quality of life in behaviourally nonresponsive patients using a brain-computer interface. The focus should be to only include the *most important* dimensions as there is only a limited number of items that can be asked of these patients.

For each dimensions please read the accompanying description to understand its application. For answers, click the value that is most similar to your opinion and continue to the next question. If you are unsure of a particular dimension, please avoid leaving the question blank and provide the answer that is closest to your belief. If necessary, at the end of the survey there will be an opportunity to add additional dimensions that should be included for consideration.



THE AWARE STUDY

Dimensions of quality of life where consensus was reached on importance for inclusion in an instrument to assess quality of life:

- Somatic Complaints
- Communication Capacity
- Bodily Pain & Discomfort
- Experiencing Anxiety
- Experiencing Depression
- Experiencing Negative Emotions
- Experiencing Positive Emotions
- Experiencing Loneliness
- Personal Relationships
- Relationship with Family
- Satisfaction with Medical Treatment/Services
- Effects of Medication
- Overall Quality of Life

Dimensions of quality of life where consensus was reached on lack of importance for inclusion in an instrument to assess quality of life:

- Sexual Activity
- Satisfaction with Financial Resources
- Satisfaction with Employment

Dimensions of quality of life that were newly added based on expert feedback:

- Feeling Respected
- Esthetic Capacity

Physical

The following dimensions are all related to physical well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Self-Care: Intentional actions taken to look after oneself and one's physical health.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Vitality: The level of energy one has to get through daily activities.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Issues Sleeping: Any problems one may have getting adequate rest because of trouble falling asleep, staying asleep, or waking up prematurely.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Physical Senses: One’s experience with vision, hearing, taste, smell, and touch.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Physical Appearance: The perception of one's physical characteristics and external features.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Mental

The following dimensions are all related to mental well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Cognitive Functioning: One’s ability to memorize, learn, comprehend and understand information.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Self-Acceptance: One’s ability to like oneself in light of one's limits, failures, and circumstances.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Self-Esteem: The value one places on one's worth and capabilities.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Sense of Identity: The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Ability to Cope: One’s capacity to manage and overcome difficult situations and regulate one's unpleasant emotions.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Perception of One’s Health: One’s health refers to the positive and/or negative opinion or attitude one has about one's overall health.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Positive Future Outlook: Feeling that one’s life is heading in a good direction and one is striving towards positive outcomes.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Appreciation of Life: Being grateful for the life one has and deeming one’s existence as meaningful.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Esthetic Capacity: the ability to perceive beauty and derive pleasure in visual and auditory domains

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Social

The following dimensions are all related to social well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life for behaviourally nonresponsive patients.

Social Functioning: The level of interpersonal interactions with one’s environment.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Social Support: The physical and emotional comfort that one gives or receives from one’s personal network.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Psychosocial

The following dimensions are all related to psychosocial well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Spirituality: One’s search for meaning in life events and desire for connectedness to the universe and/or some higher power.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Limitations in Life Roles: The inability to fulfill one's prescribed or expected responsibilities. This inability could be the result of physical or emotional problems.

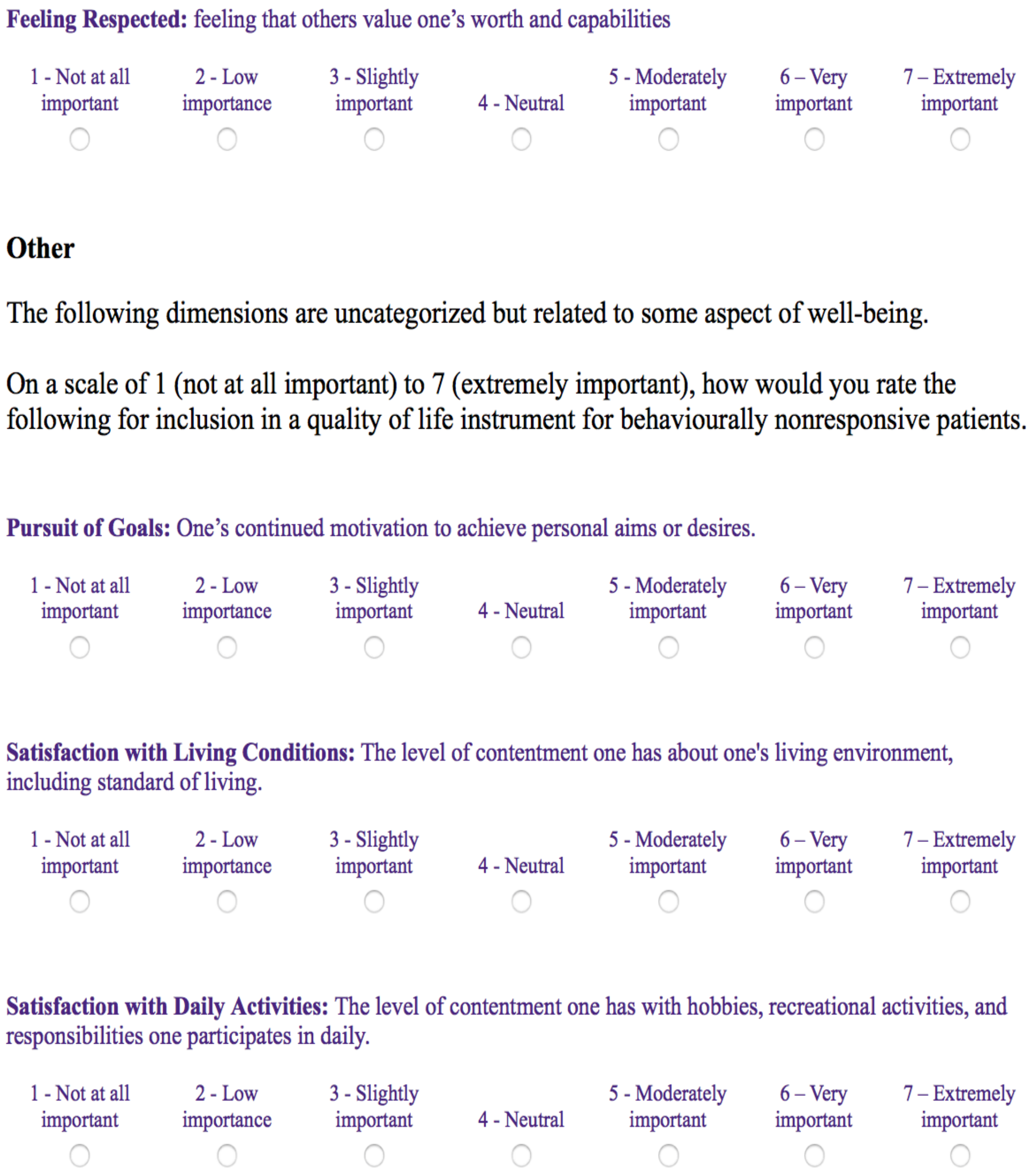
1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Autonomy and Independence: The perception and actuality that one has freedom to make one's decisions, without being pressured.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Safety and Security: The perception one is free from harm or danger.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○



Feeling Respected: feeling that others value one's worth and capabilities

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Other

The following dimensions are uncategorized but related to some aspect of well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Pursuit of Goals: One's continued motivation to achieve personal aims or desires.

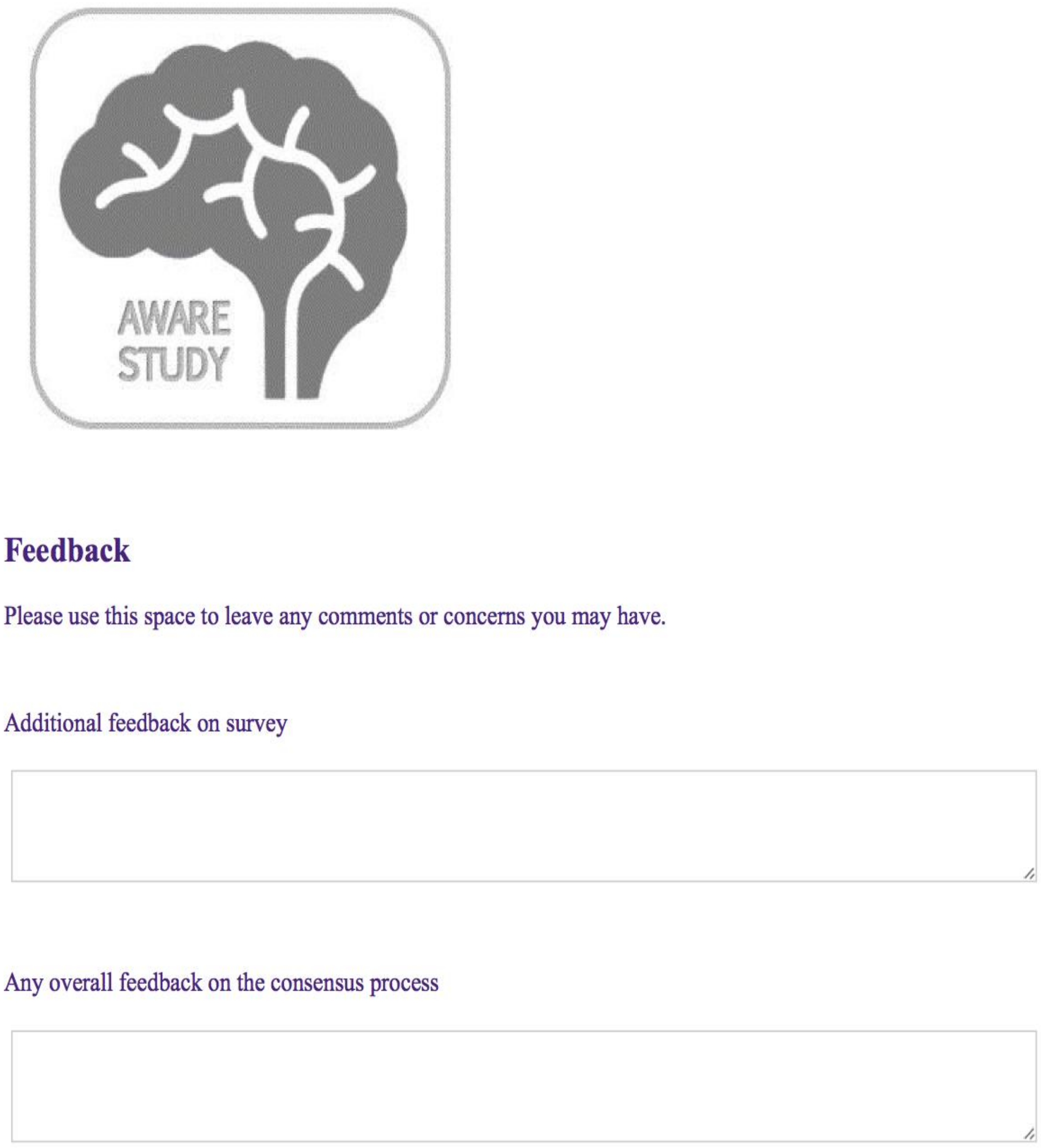
1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Satisfaction with Living Conditions: The level of contentment one has about one's living environment, including standard of living.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○



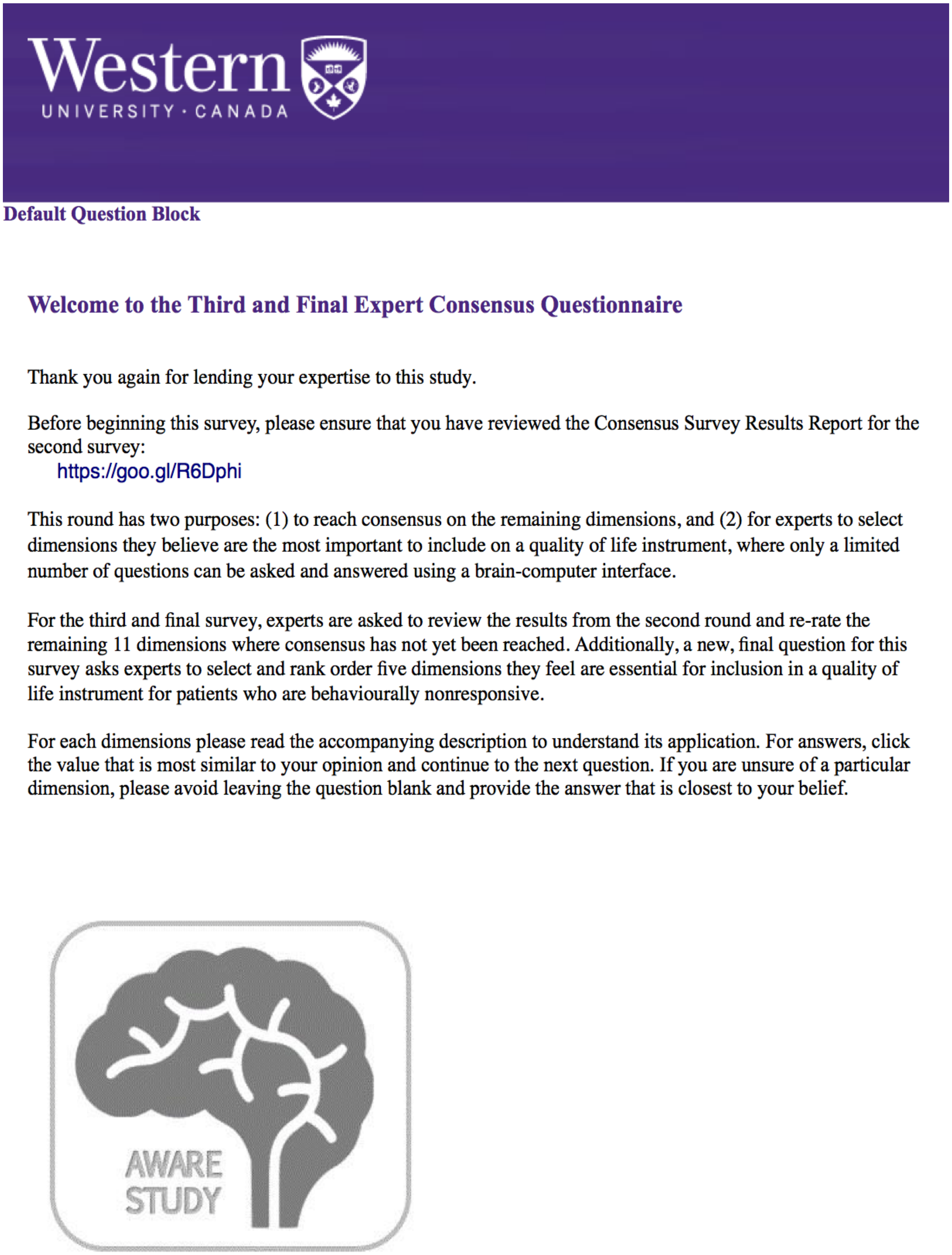
Feedback

Please use this space to leave any comments or concerns you may have.

Additional feedback on survey

Any overall feedback on the consensus process

Appendix 7. Delphi Consensus Online Survey #3



Default Question Block

Welcome to the Third and Final Expert Consensus Questionnaire

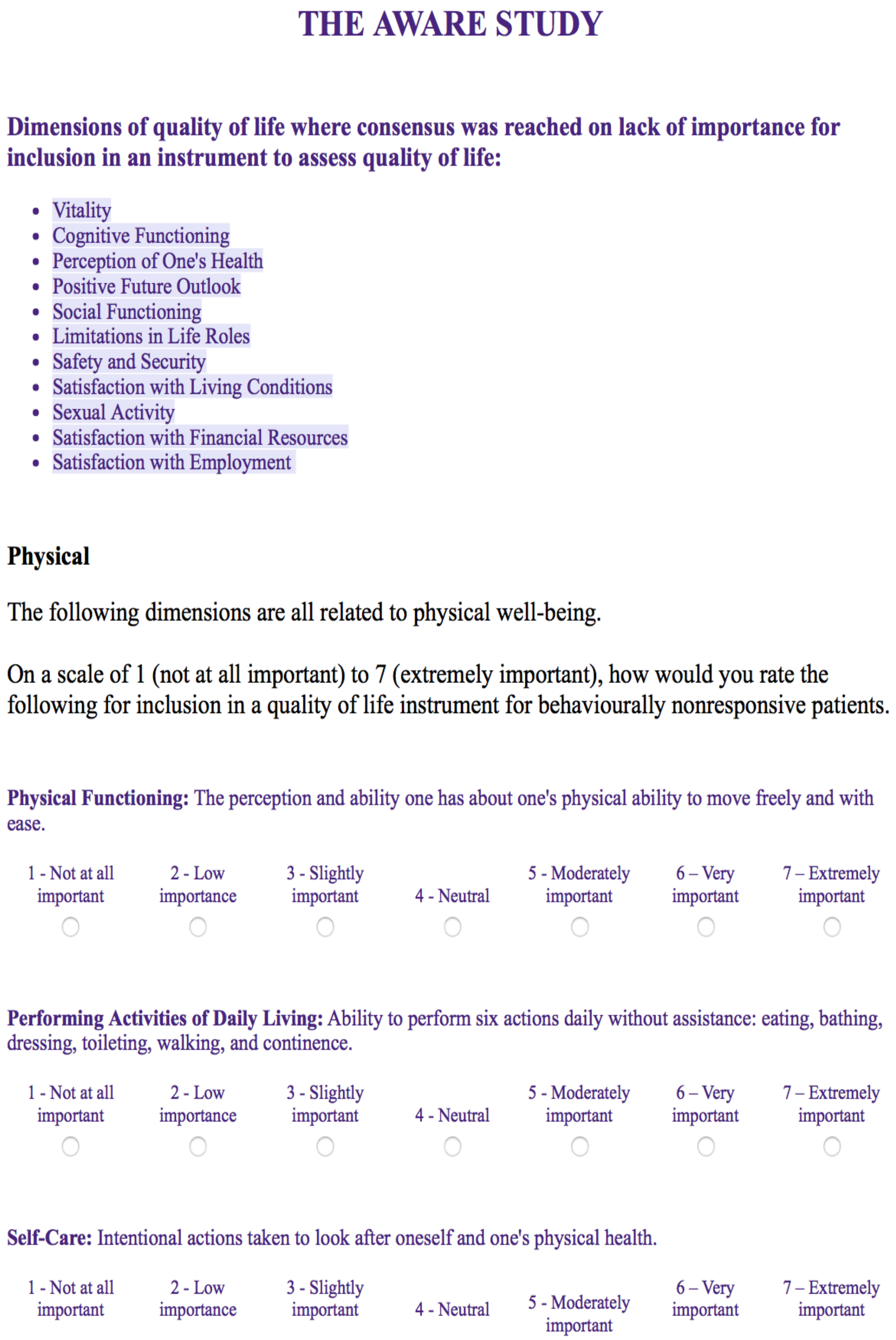
Thank you again for lending your expertise to this study.

Before beginning this survey, please ensure that you have reviewed the Consensus Survey Results Report for the second survey:
https://goo.gl/R6Dphi

This round has two purposes: (1) to reach consensus on the remaining dimensions, and (2) for experts to select dimensions they believe are the most important to include on a quality of life instrument, where only a limited number of questions can be asked and answered using a brain-computer interface.

For the third and final survey, experts are asked to review the results from the second round and re-rate the remaining 11 dimensions where consensus has not yet been reached. Additionally, a new, final question for this survey asks experts to select and rank order five dimensions they feel are essential for inclusion in a quality of life instrument for patients who are behaviourally nonresponsive.

For each dimensions please read the accompanying description to understand its application. For answers, click the value that is most similar to your opinion and continue to the next question. If you are unsure of a particular dimension, please avoid leaving the question blank and provide the answer that is closest to your belief.



THE AWARE STUDY

Dimensions of quality of life where consensus was reached on lack of importance for inclusion in an instrument to assess quality of life:

- Vitality
- Cognitive Functioning
- Perception of One's Health
- Positive Future Outlook
- Social Functioning
- Limitations in Life Roles
- Safety and Security
- Satisfaction with Living Conditions
- Sexual Activity
- Satisfaction with Financial Resources
- Satisfaction with Employment

Physical

The following dimensions are all related to physical well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Self-Care: Intentional actions taken to look after oneself and one's physical health.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important

○	○	○	○	○	○	○

Physical Appearance: The perception of one's physical characteristics and external features.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Mental

The following dimensions are all related to mental well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Sense of Identity: The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Esthetic Capacity: The ability to perceive beauty and derive pleasure in visual and auditory domains

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Psychosocial

The following dimensions are all related to psychosocial well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Spirituality: One’s search for meaning in life events and desire for connectedness to the universe and/or some higher power.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Other

The following dimensions are uncategorized but related to some aspect of well-being.

On a scale of 1 (not at all important) to 7 (extremely important), how would you rate the following for inclusion in a quality of life instrument for behaviourally nonresponsive patients.

Pursuit of Goals: One's continued motivation to achieve personal aims or desires.

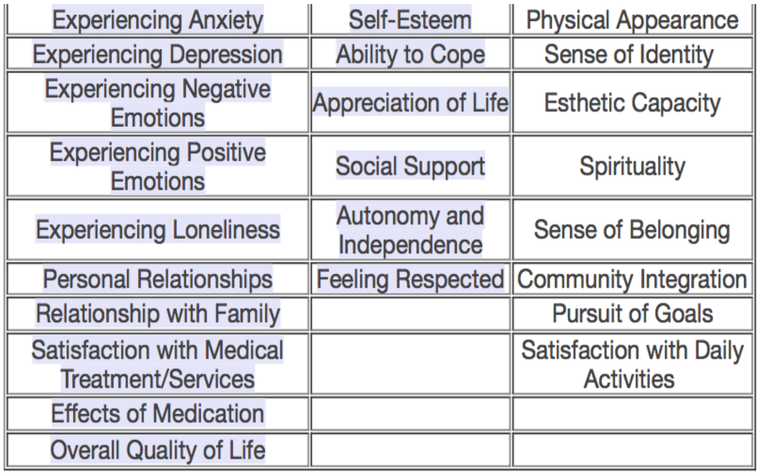
1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.

1 - Not at all important	2 - Low importance	3 - Slightly important	4 - Neutral	5 - Moderately important	6 – Very important	7 – Extremely important
○	○	○	○	○	○	○

The following table summarizes the dimensions on which consensus has been reached and in what respective round. Please note that in Round 3 no consensus has yet been reached regarding the listed dimensions.

Round 1	Round 2	Round 3
Somatic Complaints	Issues Sleeping	Physical Functioning
Communication Capacity	Physical Senses	Performing Activities of Daily Living
Bodily Pain & Discomfort	Self-Acceptance	Self-Care



Experiencing Anxiety	Self-Esteem	Physical Appearance
Experiencing Depression	Ability to Cope	Sense of Identity
Experiencing Negative Emotions	Appreciation of Life	Esthetic Capacity
Experiencing Positive Emotions	Social Support	Spirituality
Experiencing Loneliness	Autonomy and Independence	Sense of Belonging
Personal Relationships	Feeling Respected	Community Integration
Relationship with Family		Pursuit of Goals
Satisfaction with Medical Treatment/Services		Satisfaction with Daily Activities
Effects of Medication		
Overall Quality of Life		

Final Question: Top Dimensions & Rankings

The following list consists of all dimensions where consensus has been reached on importance or has yet to be reached.

From the list provided, select 5 dimensions of quality of life that you believe are ***the most important*** for inclusion in a quality of life instrument for behaviourally nonresponsive patients. Additionally, organize the dimensions on a scale of importance with (1) being the most important and (5) being the least important.

Please recall that such a quality of life instrument could only include a limited number of questions and would be administered to patients using a brain-computer interface.

Drag and drop the dimension into the text box and organize them by moving the dimension up or down.

Items

- Somatic Complaints
- Communication Capacity
- Bodily Pain & Discomfort
- Experiencing Anxiety
- Experiencing Depression
- Experiencing Negative Emotions
- Experiencing Positive Emotions
- Experiencing Loneliness
- Personal Relationships
- Relationship with Family

Top 5 Dimensions of Quality of Life Essential for Inclusion in an Instrument for Behaviourally Nonresponsive Patients

Satisfaction with Medical Treatment/Services

Effects of Medication

Overall Quality of Life

Issues Sleeping

Physical Senses

Self-Acceptance

Self-Esteem

Ability to Cope

Appreciation of Life

Social Support

Autonomy and Independence

Feeling Respected

Physical Functioning

Performing Activities of Daily Living

Self-Care

Physical Appearance

Sense of Identity

Spirituality

Sense of Belonging

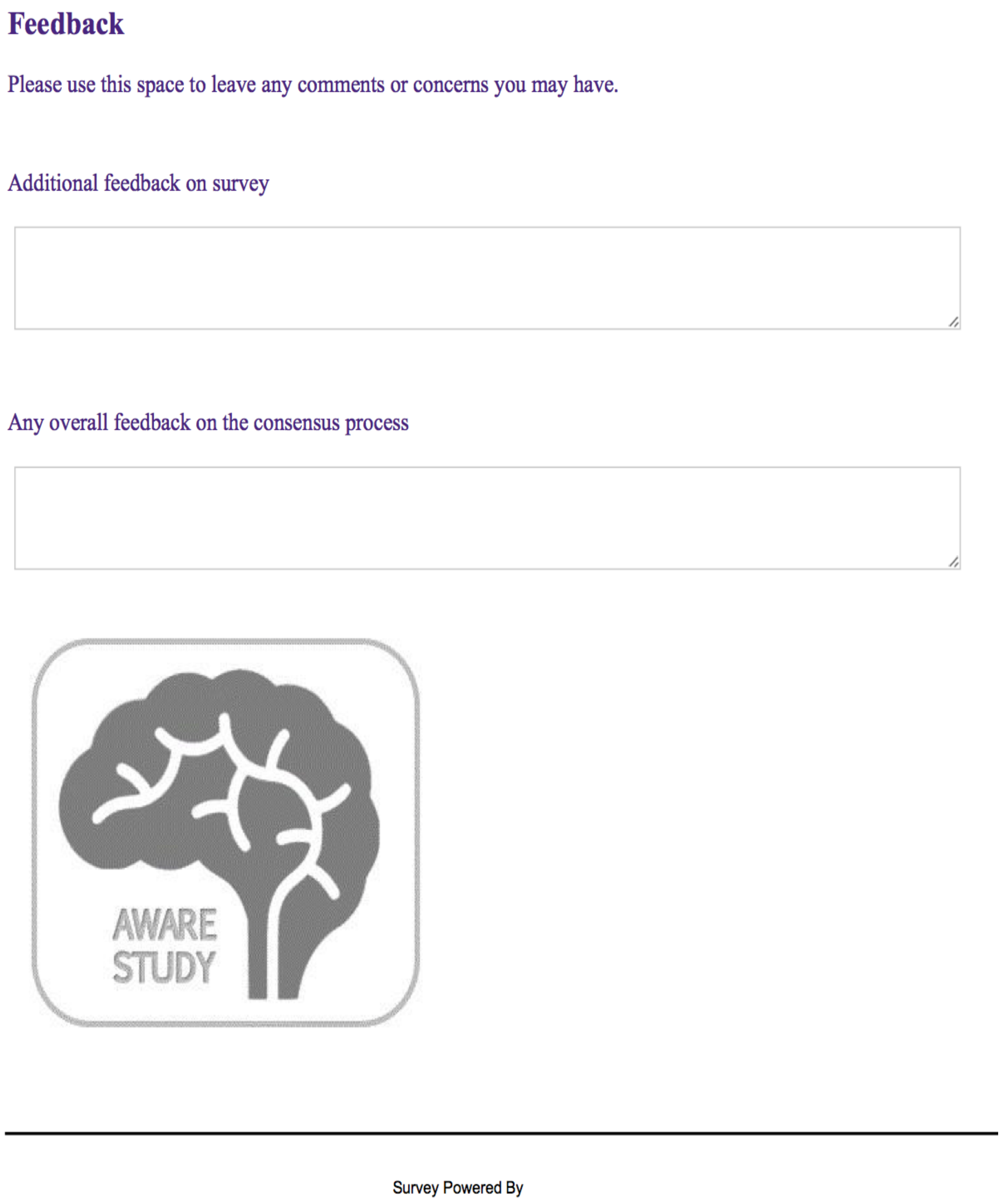
Community Integration

Esthetic Capacity

Pursuit of Goals

Satisfaction with Daily Activities

AWARE
STUDY



Feedback

Please use this space to leave any comments or concerns you may have.

Additional feedback on survey

Any overall feedback on the consensus process

Survey Powered By

Appendix 8. Summary Report of Survey #1

CONSENSUS SURVEY ROUND #1
RESULTS

2016

The report summarizes the results from the round #1 of the Delphi consensus survey for the Aware Study

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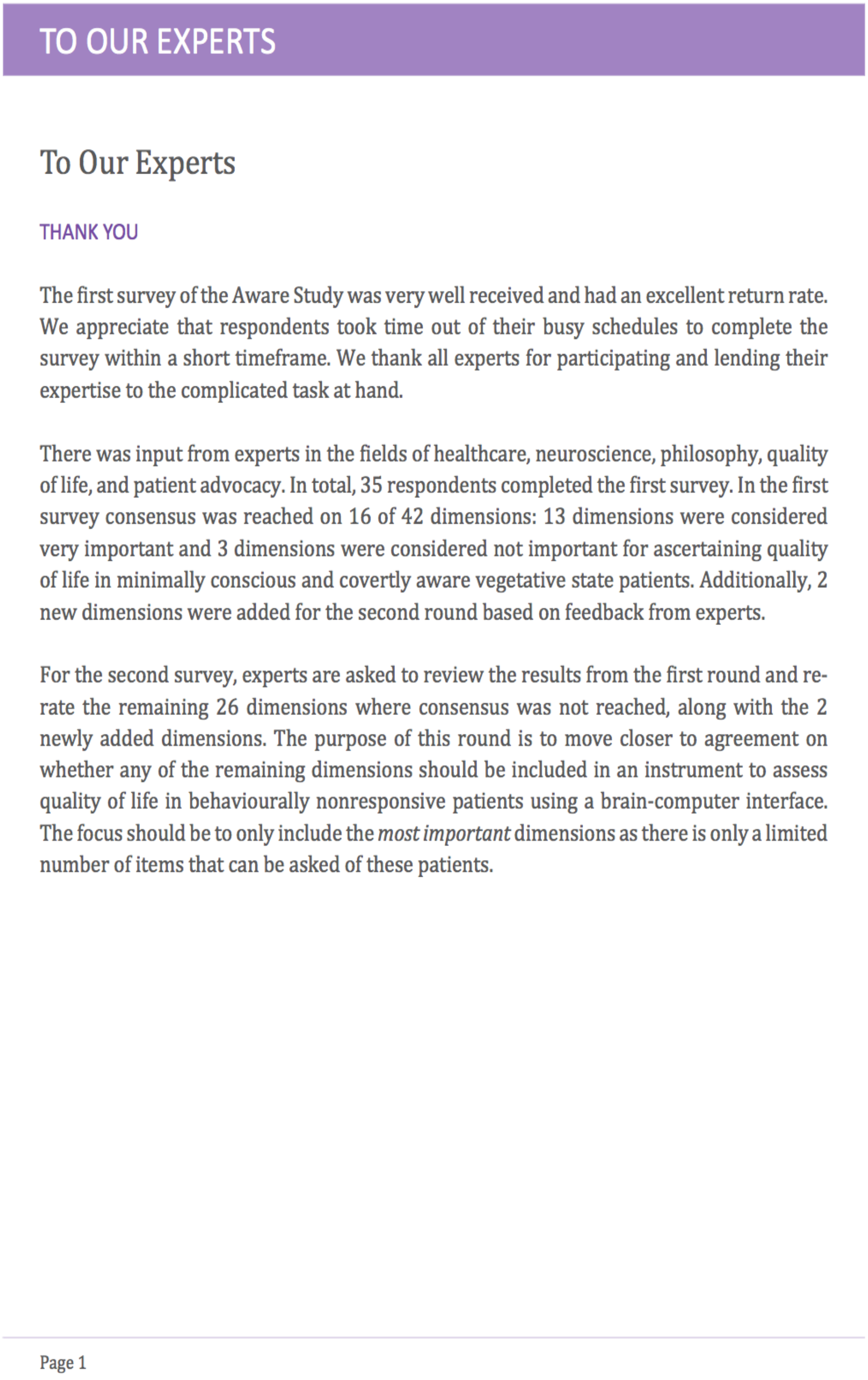


TO OUR EXPERTS

To Our Experts

THANK YOU

The first survey of the Aware Study was very well received and had an excellent return rate. We appreciate that respondents took time out of their busy schedules to complete the survey within a short timeframe. We thank all experts for participating and lending their expertise to the complicated task at hand.

There was input from experts in the fields of healthcare, neuroscience, philosophy, quality of life, and patient advocacy. In total, 35 respondents completed the first survey. In the first survey consensus was reached on 16 of 42 dimensions: 13 dimensions were considered very important and 3 dimensions were considered not important for ascertaining quality of life in minimally conscious and covertly aware vegetative state patients. Additionally, 2 new dimensions were added for the second round based on feedback from experts.

For the second survey, experts are asked to review the results from the first round and re-rate the remaining 26 dimensions where consensus was not reached, along with the 2 newly added dimensions. The purpose of this round is to move closer to agreement on whether any of the remaining dimensions should be included in an instrument to assess quality of life in behaviourally nonresponsive patients using a brain-computer interface. The focus should be to only include the *most important* dimensions as there is only a limited number of items that can be asked of these patients.

SUMMARY OF RESULTS

Summary of Results

A median score was calculated for each dimension to determine consensus. There were three possible outcomes for each dimension: consensus that the dimension is important, consensus that the dimension is not important, or no consensus reached on the dimension. Additionally, two new dimensions were added based on respondent feedback.

Dimensions where consensus was reached on importance

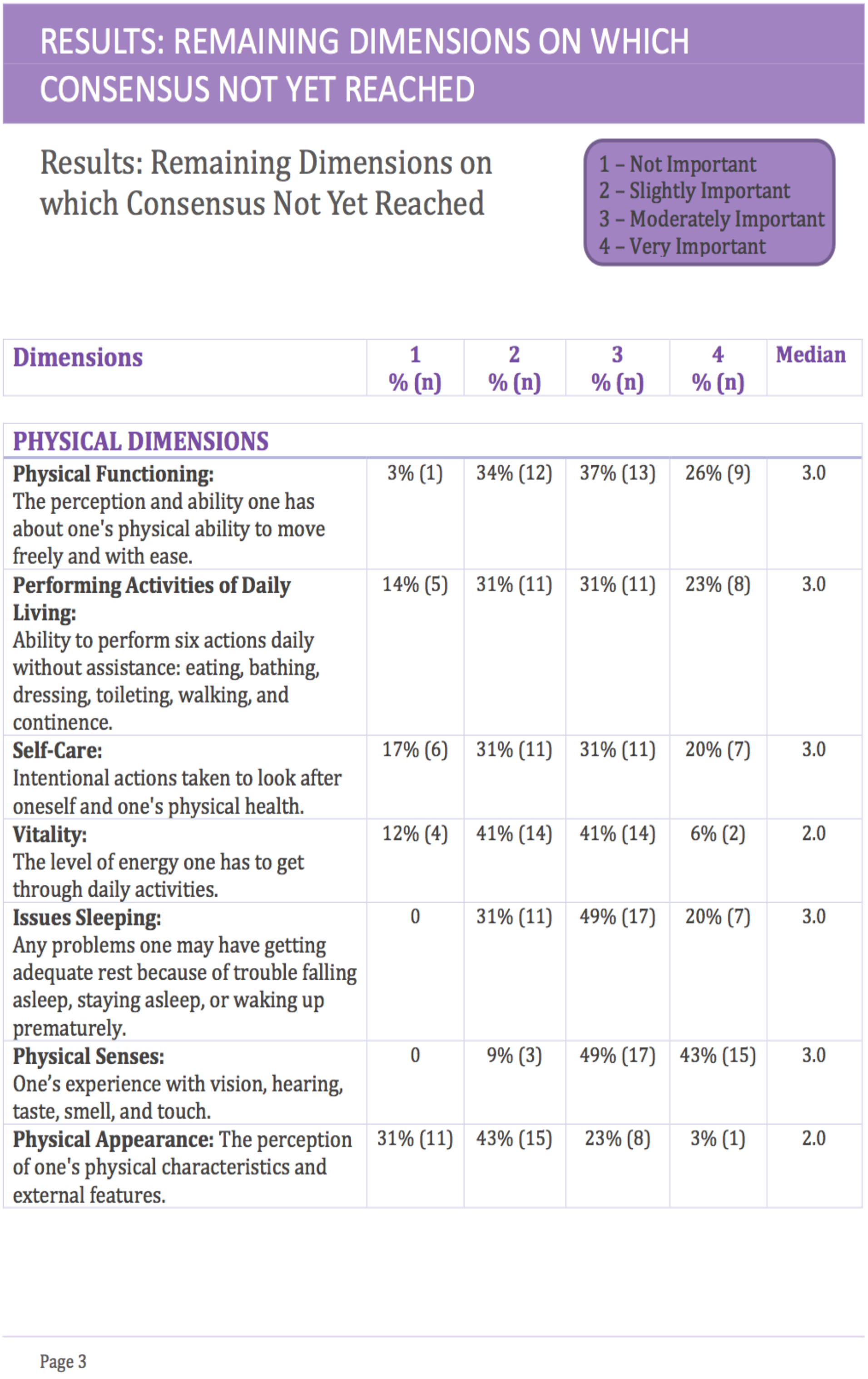
- Somatic Complaints
- Communication Capacity
- Bodily Pain & Discomfort
- Experiencing Anxiety
- Experiencing Depression
- Experiencing Negative Emotions
- Experiencing Positive Emotions
- Experiencing Loneliness
- Personal Relationships
- Relationship with Family
- Satisfaction with Medical Treatment/Services
- Effects of Medication
- Overall Quality of Life

Dimensions where consensus was reached on lack of importance

- Sexual Activity
- Satisfaction with Financial Resources
- Satisfaction with Employment

Newly added dimensions for round #2 survey

1. **Feeling Respected:** feeling that others value one's worth and capabilities
2. **Esthetic Capacity:** the ability to perceive beauty and derive pleasure in visual and auditory domains



RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Results: Remaining Dimensions on which Consensus Not Yet Reached

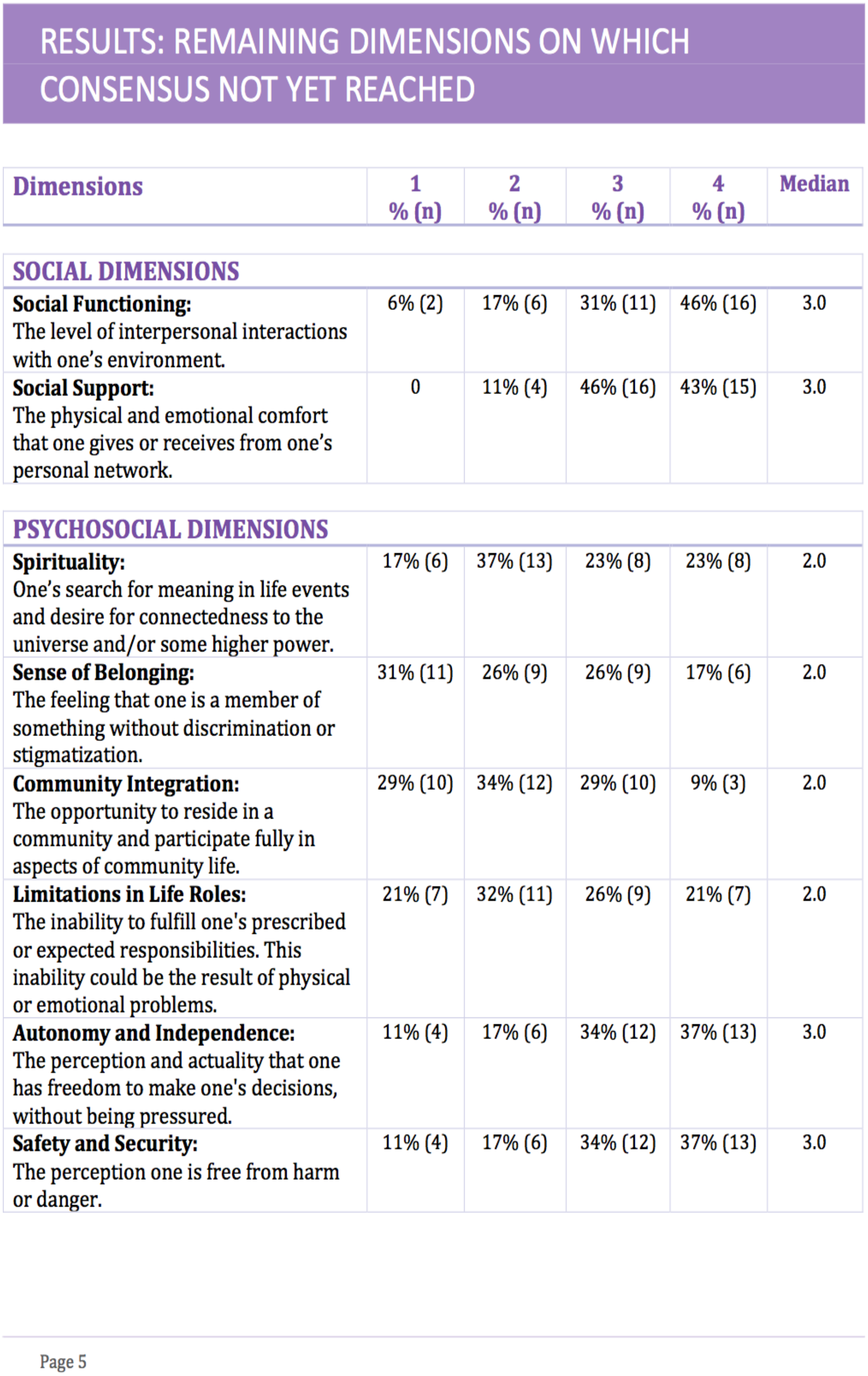
1 – Not Important
2 – Slightly Important
3 – Moderately Important
4 – Very Important

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	Median
PHYSICAL DIMENSIONS					
Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.	3% (1)	34% (12)	37% (13)	26% (9)	3.0
Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.	14% (5)	31% (11)	31% (11)	23% (8)	3.0
Self-Care: Intentional actions taken to look after oneself and one's physical health.	17% (6)	31% (11)	31% (11)	20% (7)	3.0
Vitality: The level of energy one has to get through daily activities.	12% (4)	41% (14)	41% (14)	6% (2)	2.0
Issues Sleeping: Any problems one may have getting adequate rest because of trouble falling asleep, staying asleep, or waking up prematurely.	0	31% (11)	49% (17)	20% (7)	3.0
Physical Senses: One's experience with vision, hearing, taste, smell, and touch.	0	9% (3)	49% (17)	43% (15)	3.0
Physical Appearance: The perception of one's physical characteristics and external features.	31% (11)	43% (15)	23% (8)	3% (1)	2.0

Page 3

RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	Median
MENTAL DIMENSIONS					
Cognitive Functioning: One's ability to memorize, learn, comprehend and understand information.	3% (1)	9% (3)	54% (19)	34% (12)	3.0
Self-Acceptance: One's ability to like oneself in light of one's limits, failures, and circumstances.	6% (2)	26% (9)	37% (13)	31% (11)	3.0
Self-Esteem: The value one places on one's worth and capabilities.	0	34% (12)	43% (15)	23% (8)	3.0
Sense of Identity: The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.	9% (3)	31% (11)	31% (11)	29% (10)	3.0
Ability to Cope: One's capacity to manage and overcome difficult situations and regulate one's unpleasant emotions.	6% (2)	23% (8)	40% (14)	31% (11)	3.0
Perception of One's Health: One's health refers to the positive and/or negative opinion or attitude one has about one's overall health.	11% (4)	23% (8)	49% (17)	17% (6)	3.0
Positive Future Outlook: Feeling that one's life is heading in a good direction and one is striving towards positive outcomes.	9% (3)	18% (6)	39% (13)	33% (11)	3.0
Appreciation of Life: Being grateful for the life one has and deeming one's existence as meaningful.	3% (1)	23% (8)	40% (14)	34% (12)	3.0



RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	Median
SOCIAL DIMENSIONS					
Social Functioning: The level of interpersonal interactions with one's environment.	6% (2)	17% (6)	31% (11)	46% (16)	3.0
Social Support: The physical and emotional comfort that one gives or receives from one's personal network.	0	11% (4)	46% (16)	43% (15)	3.0
PSYCHOSOCIAL DIMENSIONS					
Spirituality: One's search for meaning in life events and desire for connectedness to the universe and/or some higher power.	17% (6)	37% (13)	23% (8)	23% (8)	2.0
Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.	31% (11)	26% (9)	26% (9)	17% (6)	2.0
Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.	29% (10)	34% (12)	29% (10)	9% (3)	2.0
Limitations in Life Roles: The inability to fulfill one's prescribed or expected responsibilities. This inability could be the result of physical or emotional problems.	21% (7)	32% (11)	26% (9)	21% (7)	2.0
Autonomy and Independence: The perception and actuality that one has freedom to make one's decisions, without being pressured.	11% (4)	17% (6)	34% (12)	37% (13)	3.0
Safety and Security: The perception one is free from harm or danger.	11% (4)	17% (6)	34% (12)	37% (13)	3.0

RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	Median
OTHER/UNCATEGORIZED DIMENSIONS					
Pursuit of Goals: One's continued motivation to achieve personal aims or desires.	9% (3)	32% (11)	29% (10)	29% (10)	3.0
Satisfaction with Living Conditions: The level of contentment one has about one's living environment, including standard of living.	9% (3)	15% (5)	30% (10)	45% (15)	3.0
Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.	18% (6)	30% (10)	33% (11)	18% (6)	3.0

CONTACT INFORMATION

Contact Information

If you require any further information regarding this research project or your participation in the [redacted]

PRINCIPAL INVESTIGATORS

Dr. Charles Weijer
Rotman Institute of Philosophy
[redacted]

Dr. Kathy Nixon Speechley
Department of Epidemiology & Biostatistics
[redacted]

AWARE STUDY

APPENDIX: DELPHI PROCESS

Appendix: Delphi Process

Stage	***Description***
Initial Contact	Experts will be emailed a formal introduction to the study, timeline of the project, relevant research material and information on what is expected from them.
Round 1	First survey will include the list of dimensions of quality of life that have been systematically selected from existing measures in use. The experts will be asked to rate each domain on a scale from 1 (not important) to 4 (very important).
Round 1 Analyses	Median score analysis will be done on all dimensions. A summary report of responses will be generated and emailed out to participants.
Round 2	Second survey will include the dimensions for which consensus was not reached and the newly added dimensions from experts. Participants will be instructed to rate the list of dimensions but this time on a seven point scale (from 1-not at all important to 7-extremely important).
Round 2 Analyses	Median score and semi-interquartile range analysis will be done on all remaining dimensions. A summary report of responses will be generated and emailed out to participants.
Round 3	Third survey will be include all the original dimensions with the exception of dimensions that were judged to be not important by the experts from the first and second questionnaire. Participants will be instructed to rate the list of dimensions on a seven point scale The experts will be asked to select the five domains they deem the most relevant to quality of life and then rank them with 5 being the most important.
Round 3 Analyses	Median score, semi-interquartile range, and weighted means analysis will be done on remaining dimensions. A summary report of responses will be generated and emailed out to participants.

Appendix 9. Summary Report of Survey #2

AWARE
STUDY

Western
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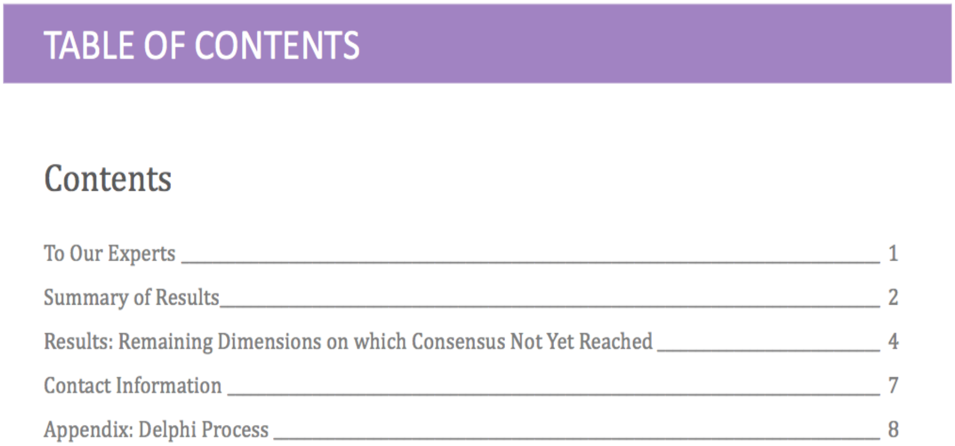
Rotman Institute
of Philosophy

CONSENSUS SURVEY ROUND #2
RESULTS

2016

The report summarizes the results from the round #2 of the Delphi consensus survey for the Aware Study



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To Our Experts

THANK YOU

The second survey of the Aware Study had an excellent response rate (97%) and moved us a step closer to consensus. We appreciate that respondents took time out of their busy schedules to complete the survey within a short timeframe. We thank all experts again for participating and lending their expertise to the complicated task at hand.

In total, 34 respondents completed the second survey. In the second survey consensus was reached on an additional 17 of 28 dimensions: 9 dimensions were considered very important and 8 were considered not important for ascertaining quality of life in minimally conscious and covertly aware vegetative state patients.

For the third and final survey, experts are asked to review the results from the second round and re-rate the remaining 11 dimensions where consensus has not yet been reached. Additionally, a new, final question for this survey asks experts to select and rank order five dimensions they feel are essential for inclusion in a quality of life instrument for patients who are behaviourally nonresponsive. This round has two purposes: (1) to reach consensus on the remaining dimensions, and (2) for experts to select dimensions they believe are the most important to include on a quality of life instrument, where only *a limited number* of questions can be asked and answered using a brain-computer interface.

SUMMARY OF RESULTS

Summary of Results

A median score and semi-interquartile range (SIR) were calculated for each dimension to determine consensus. The SIR is a measure of variation in responses that can be interpreted as half the distance needed to cover half the responses. There were three possible outcomes for each dimension: consensus that the dimension is important, consensus that the dimension is not important, or no consensus reached on the dimension. The following is an updated list of dimensions where consensus has already been reached with the bolded dimensions being the results from the second round.

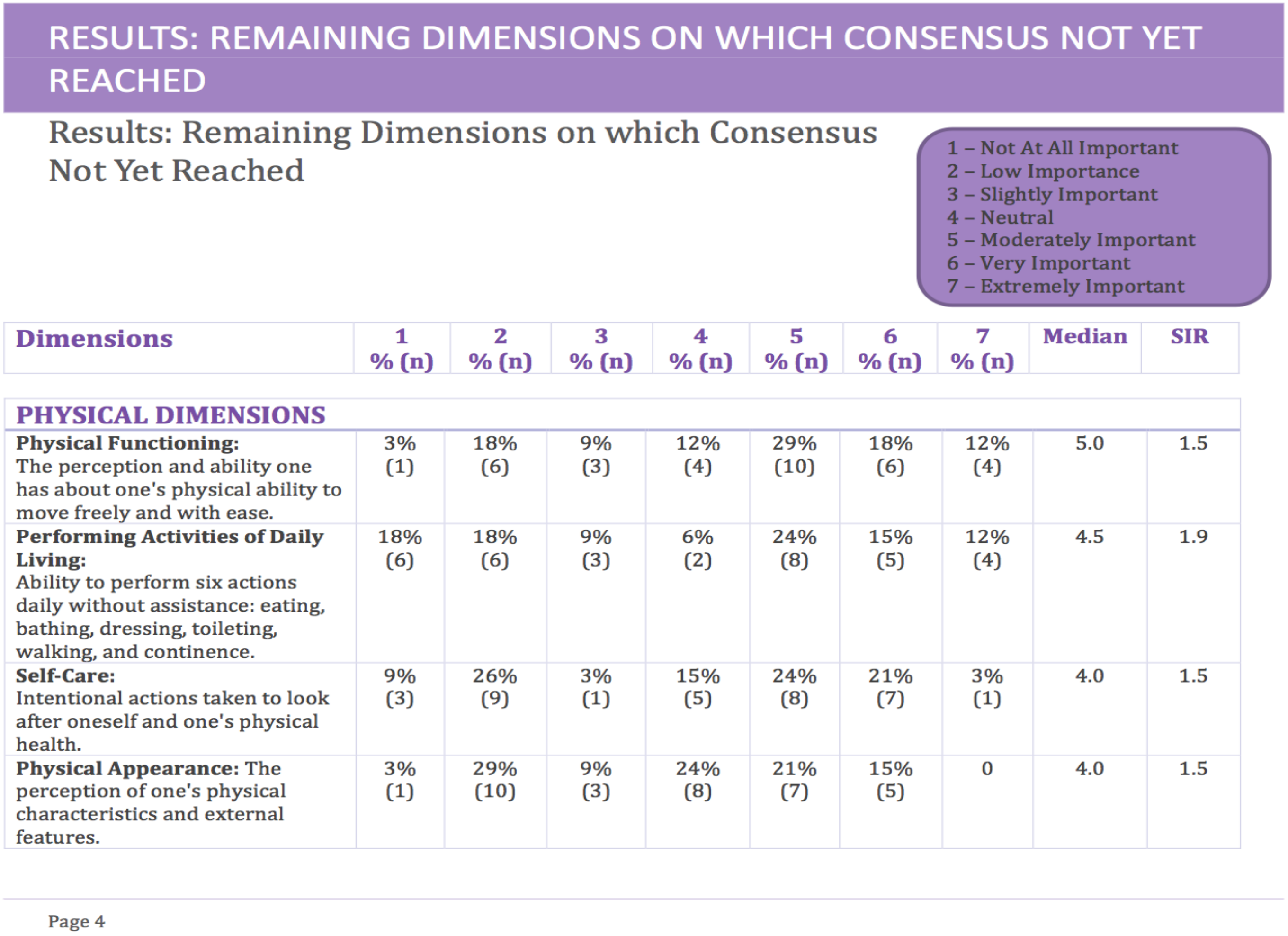
Dimensions where consensus was reached on importance

- **Issues Sleeping**
- **Physical Senses**
- **Self-Acceptance**
- **Self-Esteem**
- **Ability to Cop**
- **Appreciation of Life**
- **Social Support**
- **Autonomy and Independence**
- **Feeling Respected**
- Somatic Complaints
- Communication Capacity
- Bodily Pain & Discomfort
- Experiencing Anxiety
- Experiencing Depression
- Experiencing Negative Emotions
- Experiencing Positive Emotions
- Experiencing Loneliness
- Personal Relationships
- Relationship with Family
- Satisfaction with Medical Treatment/Services
- Effects of Medication
- Overall Quality of Life

SUMMARY OF RESULTS

Dimensions where consensus was reached on lack of importance

- **Vitality**
- **Cognitive Functioning**
- **Perception of One's Health**
- **Positive Future Outlook**
- **Social Functioning**
- **Limitations in Life Roles**
- **Safety and Security**
- **Satisfaction with Living Conditions**
- Sexual Activity
- Satisfaction with Financial Resources
- Satisfaction with Employment



RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Results: Remaining Dimensions on which Consensus Not Yet Reached

1 – Not At All Important
2 – Low Importance
3 – Slightly Important
4 – Neutral
5 – Moderately Important
6 – Very Important
7 – Extremely Important

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	5 % (n)	6 % (n)	7 % (n)	Median	SIR
PHYSICAL DIMENSIONS									
Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.	3% (1)	18% (6)	9% (3)	12% (4)	29% (10)	18% (6)	12% (4)	5.0	1.5
Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.	18% (6)	18% (6)	9% (3)	6% (2)	24% (8)	15% (5)	12% (4)	4.5	1.9
Self-Care: Intentional actions taken to look after oneself and one's physical health.	9% (3)	26% (9)	3% (1)	15% (5)	24% (8)	21% (7)	3% (1)	4.0	1.5
Physical Appearance: The perception of one's physical characteristics and external features.	3% (1)	29% (10)	9% (3)	24% (8)	21% (7)	15% (5)	0	4.0	1.5

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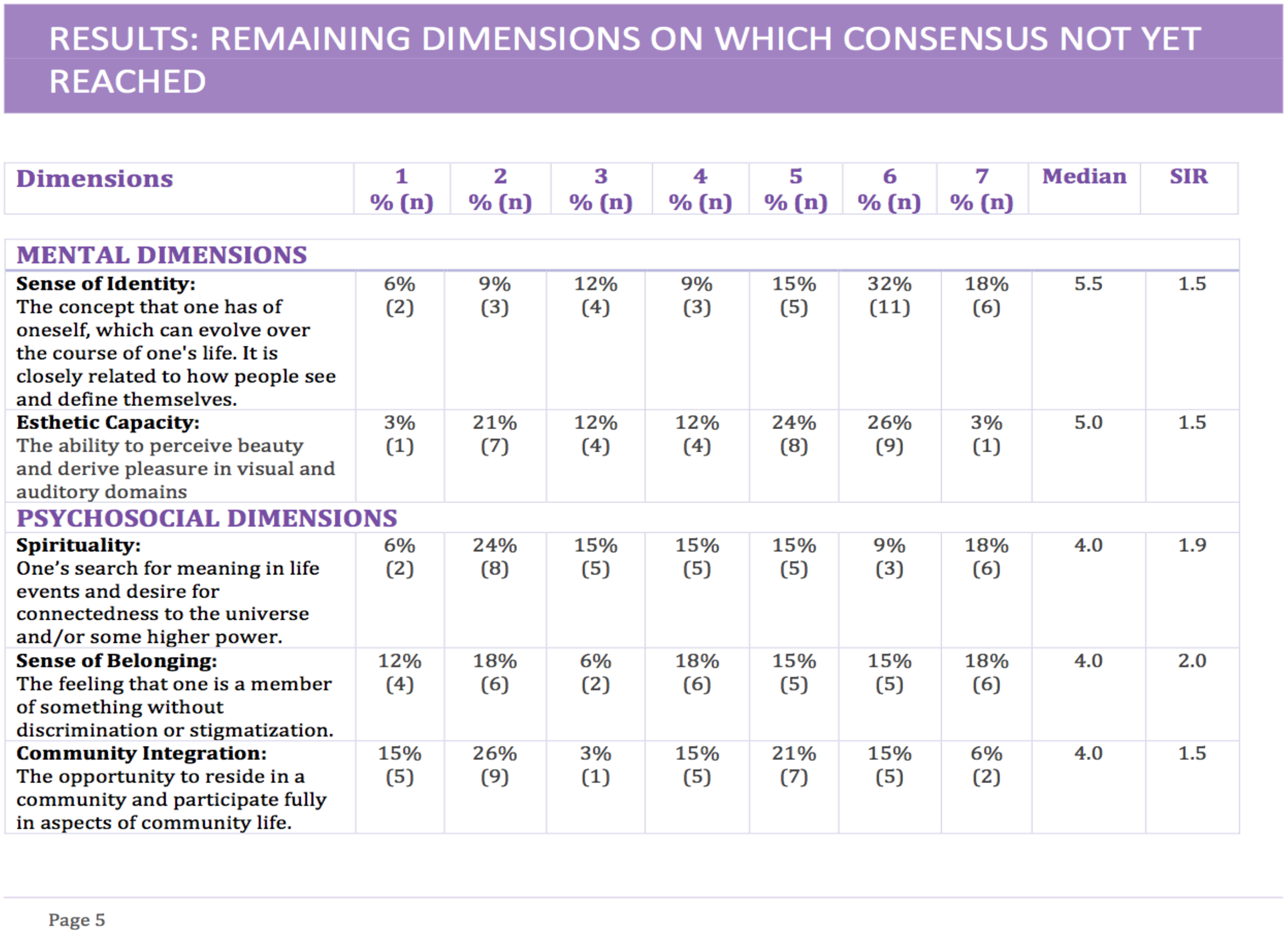

RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	**1** **% (n)**	**2** **% (n)**	**3** **% (n)**	**4** **% (n)**	**5** **% (n)**	**6** **% (n)**	**7** **% (n)**	**Median**	**SIR**
MENTAL DIMENSIONS									
Sense of Identity: The concept that one has of oneself, which can evolve over the course of one's life. It is closely related to how people see and define themselves.	6% (2)	9% (3)	12% (4)	9% (3)	15% (5)	32% (11)	18% (6)	5.5	1.5
Esthetic Capacity: The ability to perceive beauty and derive pleasure in visual and auditory domains	3% (1)	21% (7)	12% (4)	12% (4)	24% (8)	26% (9)	3% (1)	5.0	1.5
PSYCHOSOCIAL DIMENSIONS									
Spirituality: One's search for meaning in life events and desire for connectedness to the universe and/or some higher power.	6% (2)	24% (8)	15% (5)	15% (5)	15% (5)	9% (3)	18% (6)	4.0	1.9
Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.	12% (4)	18% (6)	6% (2)	18% (6)	15% (5)	15% (5)	18% (6)	4.0	2.0
Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.	15% (5)	26% (9)	3% (1)	15% (5)	21% (7)	15% (5)	6% (2)	4.0	1.5

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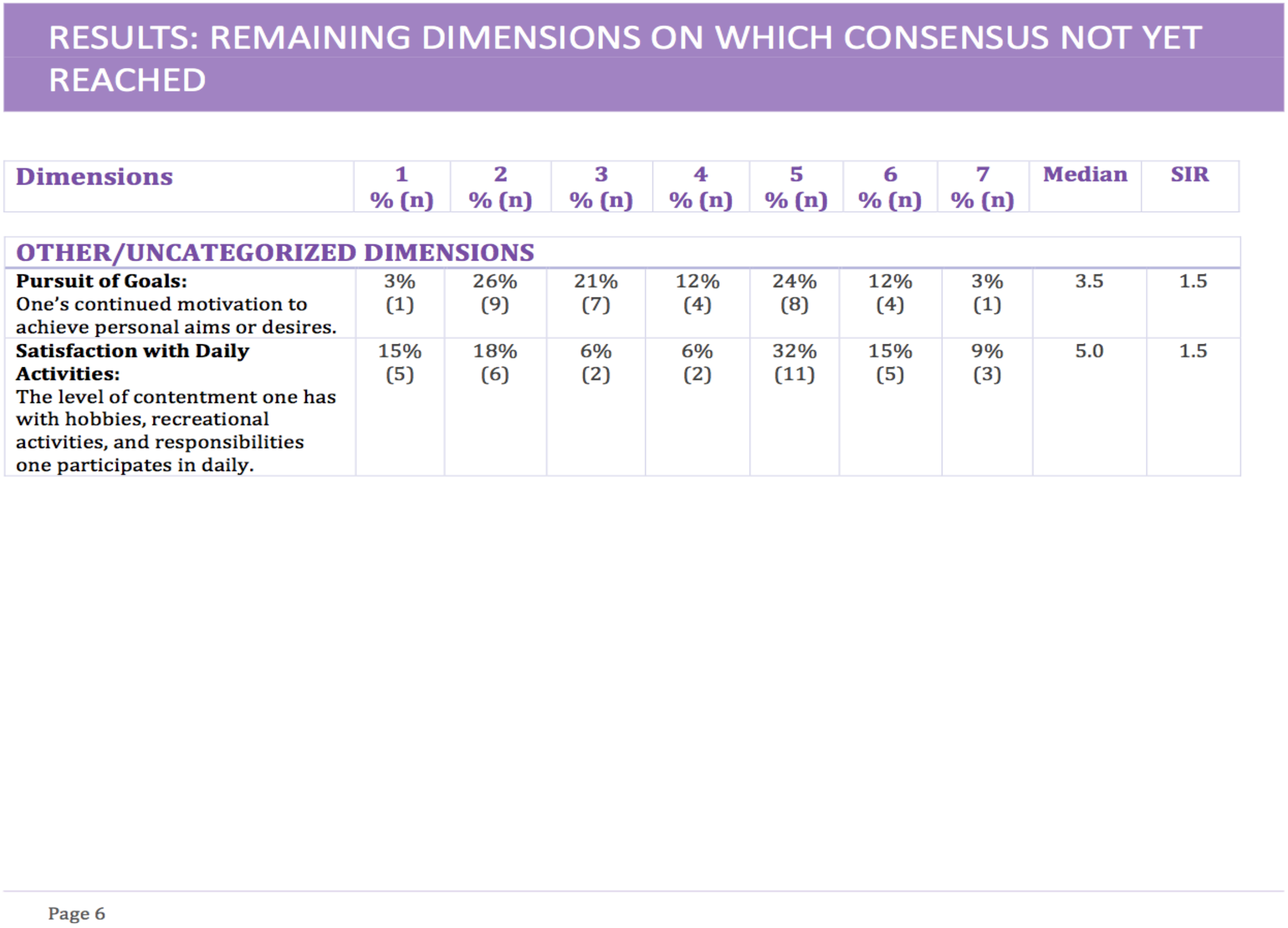

RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	**1** **% (n)**	**2** **% (n)**	**3** **% (n)**	**4** **% (n)**	**5** **% (n)**	**6** **% (n)**	**7** **% (n)**	**Median**	**SIR**
OTHER/UNCATEGORIZED DIMENSIONS									
Pursuit of Goals: One's continued motivation to achieve personal aims or desires.	3% (1)	26% (9)	21% (7)	12% (4)	24% (8)	12% (4)	3% (1)	3.5	1.5
Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.	15% (5)	18% (6)	6% (2)	6% (2)	32% (11)	15% (5)	9% (3)	5.0	1.5

CONTACT INFORMATION

Contact Information

If you require any further information regarding this research project or your participation in the [redacted]

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[redacted]

APPENDIX: DELPHI PROCESS

Appendix: Delphi Process

Stage	***Description***
Initial Contact	Experts will be emailed a formal introduction to the study, timeline of the project, relevant research material and information on what is expected from them.
Round 1	First survey will include the list of dimensions of quality of life that have been systematically selected from existing measures in use. The experts will be asked to rate each domain on a scale from 1 (not important) to 4 (very important).
Round 1 Analyses	Median score analysis will be done on all dimensions. A summary report of responses will be generated and emailed out to participants.
Round 2	Second survey will include the dimensions for which consensus was not reached and the newly added dimensions from experts. Participants will be instructed to rate the list of dimensions but this time on a seven point scale (from 1-not at all important to 7-extremely important).
Round 2 Analyses	Median score and semi-interquartile range analysis will be done on all remaining dimensions. A summary report of responses will be generated and emailed out to participants.
Round 3	Third survey will include all the original dimensions with the exception of dimensions that were judged to be not important by the experts from the first and second questionnaire. Participants will be instructed to rate the list of dimensions on a 7-point scale. The experts will be asked to select the five domains they deem the most relevant to quality of life and then rank them with 1 being the most important.
Round 3 Analyses	Median score, semi-interquartile range, and weighted means analysis will be done on remaining dimensions. A summary report of responses will be generated and emailed out to participants.

Appendix 10. Summary Report of Survey #3

CONSENSUS SURVEY ROUND #3 RESULTS

2017

The report summarizes the results from the 3rd and final round of the Delphi consensus survey for the Aware Study

TABLE OF CONTENTS

Contents

TO OUR EXPERTS

To Our Experts

THANK YOU

The third survey of the Aware Study had an excellent response rate (94%) and we appreciate that respondents took time out of their busy schedules to complete the survey within a short timeframe. We thank all experts again for participating and lending their expertise to the important task at hand.

In total, 33 respondents completed the third survey. In this round, consensus was reached on one additional dimension, and a list of 10 dimensions was generated that were most important for evaluating quality of life in minimally conscious and covertly aware vegetative state patients. Furthermore, a closer look was taken to see which dimensions patient advocates, compared with the other panelists (referred to as 'professionals' for the analysis), ranked the highest. Our results indicated that both patient advocates and professionals rated the three dimensions as being highly important for inclusion on a future quality of life instrument: Bodily Pain & Discomfort, Communication Capacity, and Personal Relationships/Relationship with Family. Interestingly, patient advocates indicated that the dimension Feeling Respected is of the utmost importance when considering quality of life of minimally conscious and covertly aware vegetative state patients.

This report concludes this stage of the Aware Study and we are pleased with the success of the project. We received positive feedback from many of you over the course of the study. The project would not have been possible without your time and valuable insight. We look forward to sharing the final publication once it is accepted by a peer-reviewed scientific journal. Additionally, we may contact you sometime in the future regarding opportunities to participate in further work related to this project.

SUMMARY OF RESULTS

Summary of Results

A median score and semi-interquartile range (SIR) were calculated for each dimension to determine consensus. The SIR is a measure of variation in responses that can be interpreted as half the distance needed to cover half the responses. There were three possible outcomes for each dimension: consensus that the dimension is important, consensus that the dimension is not important, or no consensus reached on the dimension. Below is an updated list of dimensions where consensus has been reached over the course of the study with the bolded dimensions being the results from the third round.

Dimensions where consensus was reached on importance

- Issues Sleeping
- Physical Senses
- Self-Acceptance
- Self-Esteem
- Ability to Cope
- Appreciation of Life
- Social Support
- Autonomy and Independence
- Feeling Respected
- Somatic Complaints
- Communication Capacity
- Bodily Pain & Discomfort
- Experiencing Anxiety
- Experiencing Depression
- Experiencing Negative Emotions
- Experiencing Positive Emotions
- Experiencing Loneliness
- Personal Relationships
- Relationship with Family
- Satisfaction with Medical Treatment/Services
- Effects of Medication
- Overall Quality of Life

SUMMARY OF RESULTS

Dimensions where consensus was reached on lack of importance

- **Sense of Identity**
- Vitality
- Cognitive Functioning
- Perception of One's Health
- Positive Future Outlook
- Social Functioning
- Limitations in Life Roles
- Safety and Security
- Satisfaction with Living Conditions
- Sexual Activity
- Satisfaction with Financial Resources
- Satisfaction with Employment

In addition to calculating a median score and SIR for each dimension, for the third round a mean rank score was calculated to determine which dimensions were mentioned most often in the list of the five most important dimensions selected by experts. If an expert ranked a dimension as being the most important (number 1), it was coded as 5, if a dimension was ranked number 2, it was coded as 4, if a dimension was ranked number 3, it was coded as 3, if a dimension was ranked number 4, it was coded as 2, and if a dimension was ranked number 5, it was coded as 1. Therefore, a higher mean rank score indicates greater importance being placed on the dimension by experts.

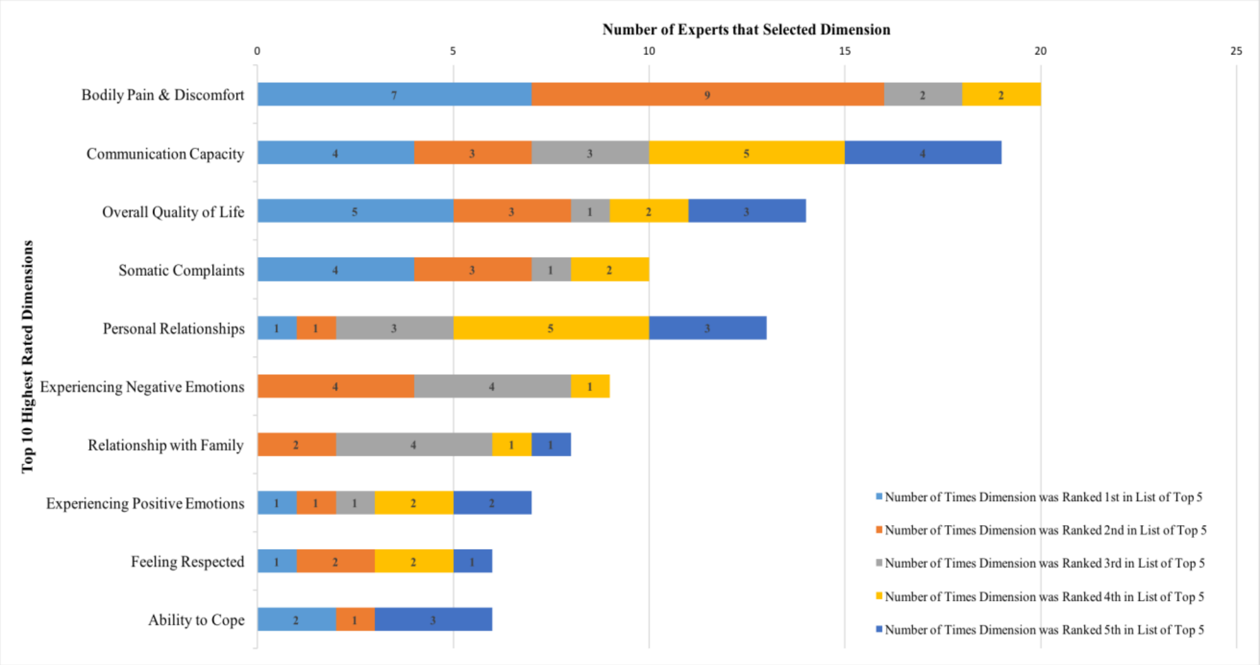
A subgroup analysis was done to compare the selections and rankings between the patient advocates and the remainder of the panel (referred to as 'professionals' for this analysis). The panel of experts was split in such a way because we believe the patient advocate group differs the most from the other groups in their daily interaction with patients. The analysis will determine if patient advocates rate particular dimensions in terms of importance for quality of life evaluation more or less than professionals.

SUMMARY OF RESULTS

The frequency with which dimensions were selected in the final question, mean rank scores of the top 10 most highly rated dimensions, and the subgroup analysis results are outlined below.

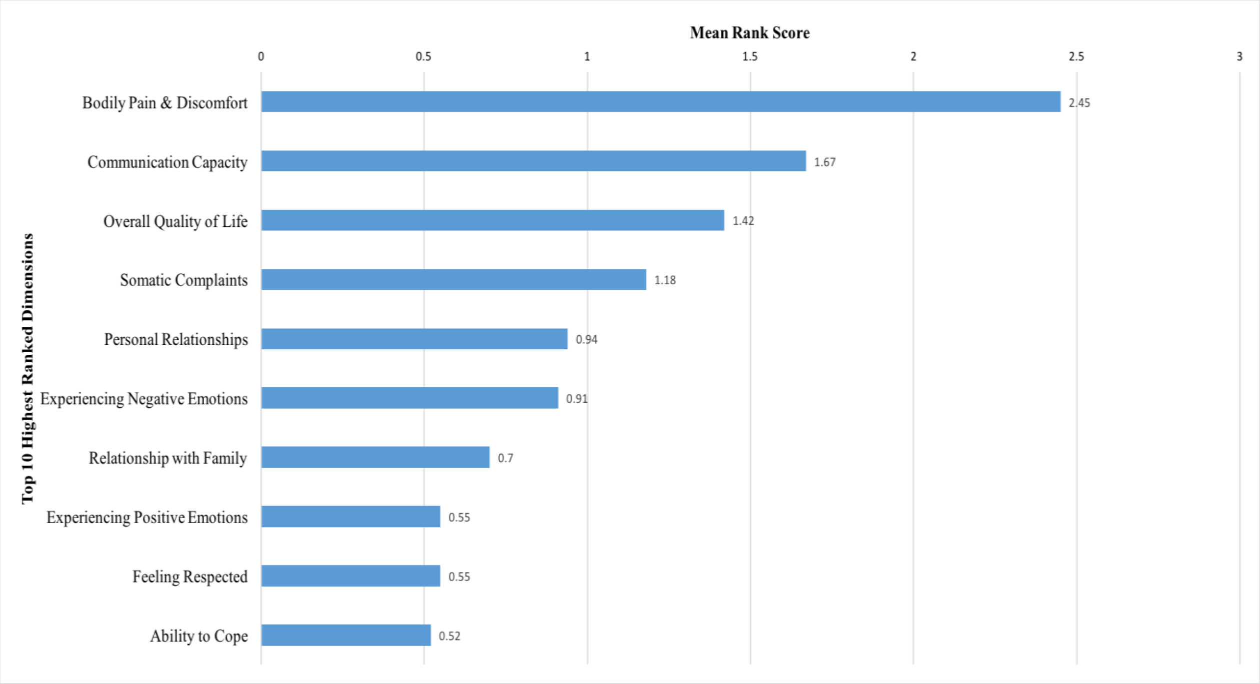
SUMMARY OF RESULTS

Top 10 Highest Rated Dimensions: Frequency of Selection and Ranked Position



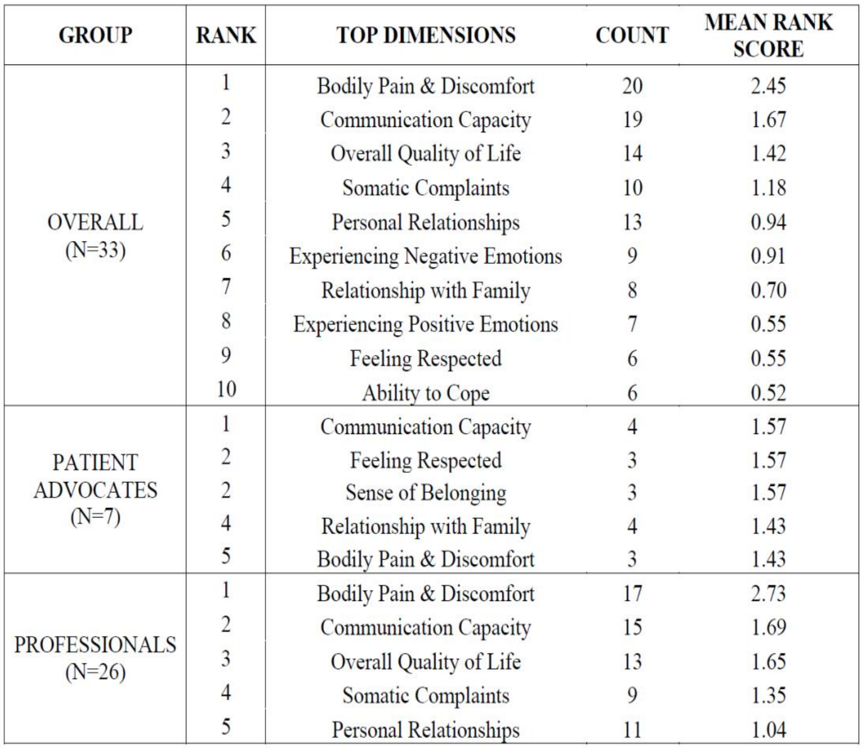
SUMMARY OF RESULTS

Top 10 Highest Rated Dimensions: Mean Rank Scores

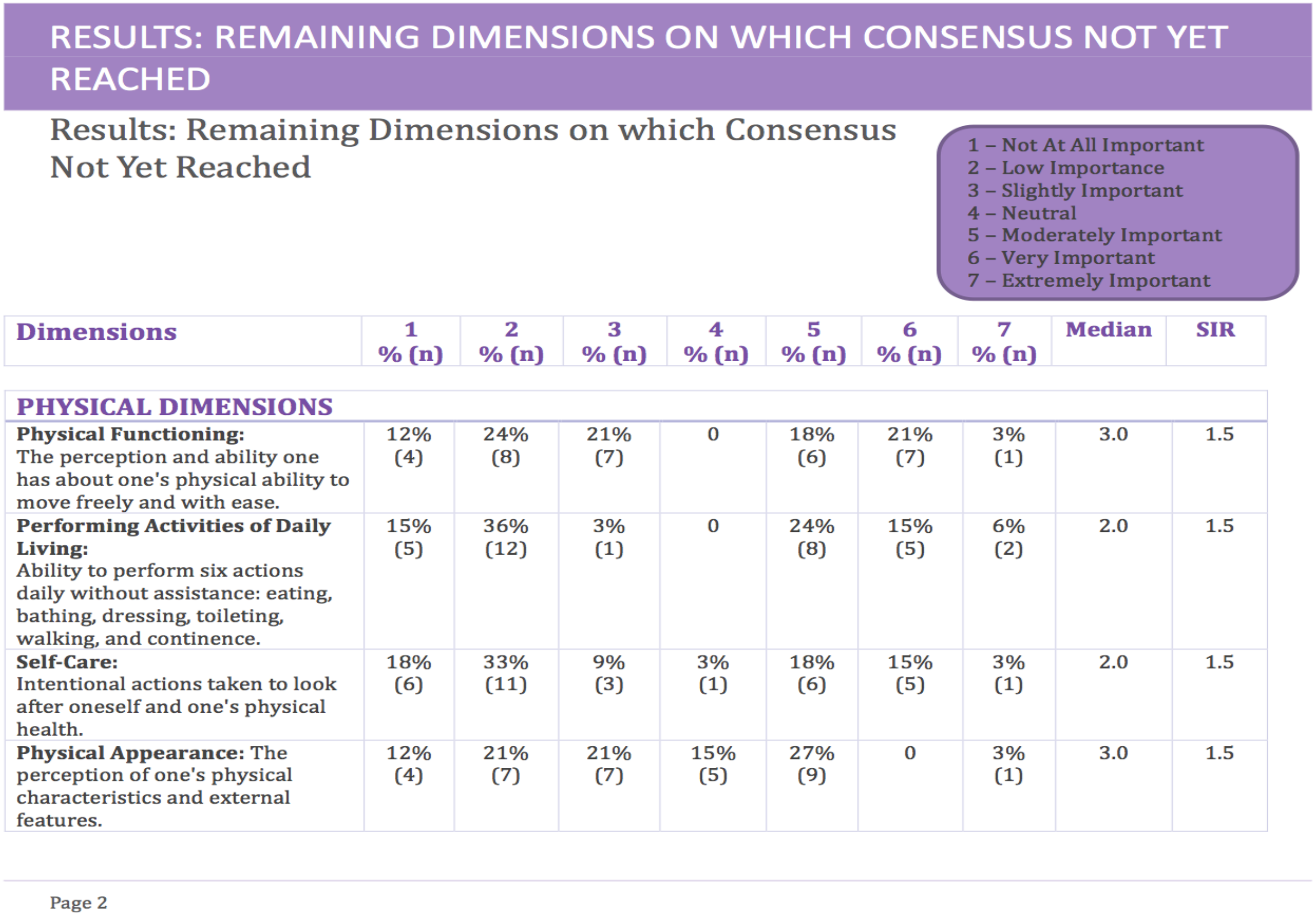


SUMMARY OF RESULTS

Subgroup Analysis of Dimension Rankings Between Patient Advocates and Professionals



GROUP	RANK	TOP DIMENSIONS	COUNT	MEAN RANK SCORE
OVERALL (N=33)	1	Bodily Pain & Discomfort	20	2.45
	2	Communication Capacity	19	1.67
	3	Overall Quality of Life	14	1.42
	4	Somatic Complaints	10	1.18
	5	Personal Relationships	13	0.94
	6	Experiencing Negative Emotions	9	0.91
	7	Relationship with Family	8	0.70
	8	Experiencing Positive Emotions	7	0.55
	9	Feeling Respected	6	0.55
	10	Ability to Cope	6	0.52
PATIENT ADVOCATES (N=7)	1	Communication Capacity	4	1.57
	2	Feeling Respected	3	1.57
	2	Sense of Belonging	3	1.57
	4	Relationship with Family	4	1.43
	5	Bodily Pain & Discomfort	3	1.43
PROFESSIONALS (N=26)	1	Bodily Pain & Discomfort	17	2.73
	2	Communication Capacity	15	1.69
	3	Overall Quality of Life	13	1.65
	4	Somatic Complaints	9	1.35
	5	Personal Relationships	11	1.04



RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Results: Remaining Dimensions on which Consensus Not Yet Reached

1 – Not At All Important
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3 – Slightly Important
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Dimensions	**1 % (n)**	**2 % (n)**	**3 % (n)**	**4 % (n)**	**5 % (n)**	**6 % (n)**	**7 % (n)**	**Median**	**SIR**
PHYSICAL DIMENSIONS									
Physical Functioning: The perception and ability one has about one's physical ability to move freely and with ease.	12% (4)	24% (8)	21% (7)	0	18% (6)	21% (7)	3% (1)	3.0	1.5
Performing Activities of Daily Living: Ability to perform six actions daily without assistance: eating, bathing, dressing, toileting, walking, and continence.	15% (5)	36% (12)	3% (1)	0	24% (8)	15% (5)	6% (2)	2.0	1.5
Self-Care: Intentional actions taken to look after oneself and one's physical health.	18% (6)	33% (11)	9% (3)	3% (1)	18% (6)	15% (5)	3% (1)	2.0	1.5
Physical Appearance: The perception of one's physical characteristics and external features.	12% (4)	21% (7)	21% (7)	15% (5)	27% (9)	0	3% (1)	3.0	1.5

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RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	5 % (n)	6 % (n)	7 % (n)	Median	SIR
MENTAL DIMENSIONS									
Esthetic Capacity: The ability to perceive beauty and derive pleasure in visual and auditory domains	6% (2)	18% (6)	6% (2)	9% (3)	27% (9)	27% (9)	6% (2)	5.0	1.5
PSYCHOSOCIAL DIMENSIONS									
Spirituality: One's search for meaning in life events and desire for connectedness to the universe and/or some higher power.	3% (1)	24% (8)	12% (4)	21% (7)	9% (3)	18% (6)	12% (4)	4.0	2.0
Sense of Belonging: The feeling that one is a member of something without discrimination or stigmatization.	3% (1)	21% (7)	12% (4)	15% (5)	12% (4)	21% (7)	15% (5)	4.0	1.5
Community Integration: The opportunity to reside in a community and participate fully in aspects of community life.	6% (2)	21% (7)	15% (5)	12% (4)	27% (9)	12% (4)	6% (2)	4.0	1.5

RESULTS: REMAINING DIMENSIONS ON WHICH CONSENSUS NOT YET REACHED

Dimensions	1 % (n)	2 % (n)	3 % (n)	4 % (n)	5 % (n)	6 % (n)	7 % (n)	Median	SIR
OTHER/UNCATEGORIZED DIMENSIONS									
Pursuit of Goals: One's continued motivation to achieve personal aims or desires.	6% (2)	24% (8)	9% (3)	3% (1)	30% (10)	12% (4)	15% (5)	5.0	2.0
Satisfaction with Daily Activities: The level of contentment one has with hobbies, recreational activities, and responsibilities one participates in daily.	6% (2)	21% (7)	9% (3)	6% (2)	38% (13)	9% (3)	9% (3)	5.0	1.5

CONTACT INFORMATION

Contact Information

If you require any further information regarding this research project or your participation in the [redacted]

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Curriculum Vitae

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Post-secondary Education and Degrees:	Simon Fraser University Burnaby, British Columbia, Canada 2008-2013 B.Sc. Health Sciences
	Western University London, Ontario, Canada 2014-2017 M.Sc. Epidemiology & Biostatistics
Honours and Awards:	Western Graduate Research Scholarship 2014-2016
Related Work Experience	Research Assistant Western University London, Ontario, Canada 2014-2017