Malaysian Journal of Medicine and Health Sciences (eISSN 2636-9346)

ORIGINAL ARTICLE

A Nationwide Assessment of Psychosocial Adjustment and Its Associated Factors in People With Spinal Cord Injury and Disorders (PA-SCID): The Study Protocol

Danial Asyraf Saharuddin[1], Julia Patrick Engkasan[2], Aaron Fernandez[3], Chew Boon How[1]

[1] Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia
[2] Department of Rehabilitation Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia
[3] Department of Psychiatry, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia

ABSTRACT

Introduction: This article aims to describe the study protocol of a nationwide survey on psychosocial adjustment of people with spinal cord injury or disorders (SCID) and its associated factors. SCID is a complex clinical condition and debilitating public health issues to families and societies. Psychosocial adjustment is represented in this study as health-related quality of life, perceived social support, coping, independence, and spiritual well-being. This study aims to determine the psychosocial adjustment of people with SCID in Malaysia. **Methods:** This is a study protocol for a nationwide cross-sectional postal and online survey of people with SCID. Cross-cultural adaptation and hypothesis-validity testing will be conducted for independence and spiritual well-being measures. A total of 786 eligible participants will be recruited from eight public hospitals in the Peninsular, Sabah, and Sarawak. The questionnaires include the World Health Organization Quality of Life-Brief (WHOQOL-BREF), Spinal Cord Independence Measure – Self-report (SCIM-SR), Brief Coping Orientation to Problems Experienced (Brief COPE), Medical Outcome Survey – Social Support (MOS-SSS) and Functional Assessment of Chronic Illness Therapy – Spiritual Well-being Short Version (FACIT-Sp-12). HRQoL measured by WHOQOL-BREF is the main primary outcome of this study. Independent association between the sociodemographic and clinical characteristics with the outcome variables will be determined separately using multiple linear regression. **Discussion:** The findings of the study will be informative regarding the causes of SCID and factors associated with psychosocial adjustment in Malaysia. It will benefit future medical and public health initiatives to improve on the existing rehabilitation programs and social services to people with SCID.

Keywords: Spinal Cord Injury, Quality of Life, Functional Status, Independence, Coping

Corresponding Author:
Chew Boon How, PhD
Email: chewboonhow@upm.edu.my
Tel: +603 97692520

INTRODUCTION

Spinal cord injury or disorders (SCID) is a complex clinical condition and poses a great challenge to the public health in terms of prevention and improving post-illness life integration of the people with SCID. It results from either trauma, diseases, or degenerative conditions. It is one of the significant causes of permanent disability in the world. Each year, around 400,000 people suffer from SCID, and a considerable proportion of it is due to traumatic cause and of a preventable nature, for example, motor vehicle accidents, falls, or violence (1). It is estimated that for the South East Asia region, traumatic SCID incidence rates are at around 236-464 per million population in which falls and land transport-related injuries predominate at 48% and 46%, respectively, and slightly more than half of these resulted in paraplegia (2). As opposed to traumatic SCID, there is no reported data on the incidence rate for non-traumatic SCID for the South East Asia region. In Australia, it is estimated that the incidence rate for non-traumatic SCID was 26 cases per million population according to a review done between 2002-2006 (3). The incidence rate of SCID in proportion to the general population may seem to be low, but because of the nature of the morbidity for being costly and burdensome to the person and family members, SCID deserves more attention from the healthcare providers.

Apart from life-changing experiences of traumatic falls or sports injury, SCID patients also face challenges in many aspects of life post-illness, including increased risk of secondary health complications such as pressure ulcers, bladder and bowel complications, and musculoskeletal pain (4). These health complications may deleteriously affect the psychosocial functioning of persons with SCID (5). For example, people with SCID may have a diminished sense of self-esteem and experience dissatisfaction with life due to the repeated disruptions to daily life for example, whenever they need repeated specialized care such as wound dressing for the management of pressure ulcers.(6). The loss of physical functioning and inability to perform self-care may directly affect the process of psychosocial adjustment, requiring much social and community support to regain effective coping, independence, sufficient quality of life, and well-being SCID (6).

There have not been many psychosocial adjustment studies on people with SCID in South East Asia, especially in developing countries like Malaysia (7,8). According to a study in Taiwan, more than half of SCID patients achieved moderate life adjustment following the injury, and the vocational and social factors are the essential contributors (9). It was further noted that younger people and those who had the injury at a younger age had a much higher level of adjustment when compared to their older counterparts (9).

Engaging in spiritual activities were also noted to help people with SCID to cope better with their illness, and it was found to be one of the contributors for better well-being (10). The sense of having a connection with a higher power (or God) helps SCID patients to adjust better with the disability (11). Apart from spiritual connection, having a strong interpersonal relationship (such as with extended family members and social friendship) is shown to be associated with better psychosocial adjustment (12,13). On the contrary, some characteristics are associated with poorer adjustment. For instance, people with SCID with social issues such as alcohol and drug abuse tend to be less successful than those without the history of alcohol and drug abuse (12). Accordingly, we aim to assess the psychosocial adjustment in people with SCID in Malaysia. Psychosocial adjustment is conceptualized and represented as health-related quality of life, perceived social support, coping, independence, and spiritual well-being in facing the condition. Studying these internal and external psychosocial environments of persons with SCID would help us understand the spectrum of their daily challenges, the necessary supports, and possible interventions appropriate to empower self-care and improve their quality of life. These aspects of the people with SCID had been shown to be important and beneficial in improving the life of SCID patients when modified through an intervention such as an enhanced or improved rehabilitation services that provide due attention to them (9). We hypothesize that the local SCID population will have a moderate quality of life, a fair functioning in activities in daily living (ADL), and a strong perception about the social support they receive. We also hypothesize they will have a high level of spiritual well-being and use various methods of coping mechanisms in overcoming difficulties in life post-illness.

UNDERPINNING THEORY AND CONCEPT

Psychosocial adjustment is a process in which a person with a disability is making a transition from a state of disablement to a state of enablement (10). The end of the process is usually indicated by the achievement of an adaptive adjustment characterized by the maximum congruence between an individual's subjective experience and its surroundings (10). It is a dynamic process that involves psychological, social, environmental, and personal factors that interact and influence the process of adjustment. Many have proposed the meanings and what constitutes the psychosocial adjustment process, and it was noted that these models shared some similar components (11). These components are a) the background and triggering events (in this context, the causes of SCID), b) presently influencing processes and life context, and c) a set of outcome indicators that mainly focuses on quality of life. The quality of life comprises the intrapersonal, interpersonal, and extra-personal life domains, also known as environment or community-based domains, which involve activities that are performed within a community such as at work or a learning institution.

Antecedent events are one of the factors that may influence the process of psychosocial adjustment. Antecedent events refer to events that linked to the onset of disability, which in our context are referring to causes and co-morbidities at the time of SCID. Other factors that have influenced the process of psychosocial adjustment are variables associated with the SCID, such as the type of SCID, severity of the symptoms or secondary complications, and functional limitation imposed due to the condition (12). In addition, sociodemographic profiles such as age, gender, education, religion, and socioeconomic status also could influence the process and categorized as contextual variables to the psychosocial adjustment to SCID (12). Adaptation-associated outcome indicators are characterised by assessing a broad scope of adaptation outcomes such as quality of life measures, perceived life satisfaction, and disability-specific indices of psychosocial adjustment to disabilities or illnesses (14) (Fig. 1). Londono and McMillan (2015) described the adaptation-associated outcome as "consequences," which grouped into two broad categories: (1) good outcomes and (2) poor outcomes. The good outcomes are the outcome of positive internal attributes as a result of the successful psychosocial adjustment process and vice versa for poor outcomes. Some examples of positive outcomes include better functioning in daily life, improved quality of life, the feeling of connectedness, and an attempt to seek supports, including spiritual support. Examples of

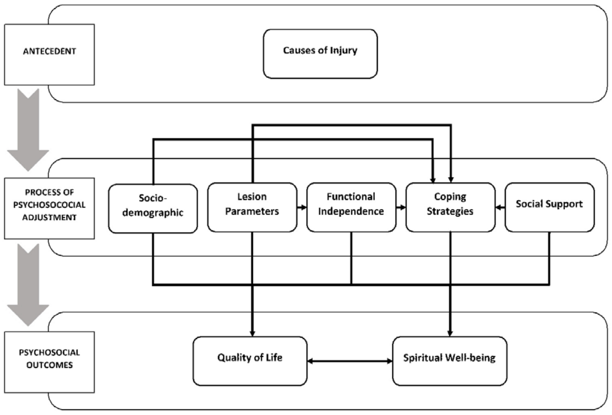

Figure 1: Underpinning Theory and Concept

negative outcomes include a feeling of frustration and hopelessness, depression, uncertainty, and as well as social avoidance. For this study, the measurement of psychosocial adjustment will be based on the assessment of the following aspects: quality of life, functional independence, perceived social support, and coping strategies. It is in accordance with the proposed method of studying psychosocial adjustment by focusing on the functional outcome domains of the adjustment process (15).

OBJECTIVES

General Objective

The general objective of the study is to describe the sociodemographic and clinical profiles of people with SCID in Malaysia and to determine their state of psychosocial adjustment following the diagnosis of SCID.

Specific Objectives

We further intend to assess the several components that made up the concept of psychosocial adjustment and to determine their association with sociodemographic and SCID characteristics.

- To determine the general health-related quality of life of people with SCID and its association with sociodemographic and SCID lesion characteristics, and independence, coping, social support, and spiritual well-being.
- To determine the functional status of a person with SCID and its association with sociodemographic and SCID lesion characteristics, and quality of life, coping, social support, and spiritual well-being.
- To examine the association of different coping styles and its association with sociodemographic and SCID lesion characteristics, and independence, quality of life, social support, and spiritual well-being.
- To determine the spiritual well-being of a person with SCID in Malaysia and its association with sociodemographic and SCID lesion characteristics and quality of life, independence, coping, and social support.
- To adapt and validate the 10-items Spinal Cord Independence Measure for self-report (SCIM-SR) and the 12-item Functional Assessment of Chronic Illness Therapy – Spiritual well-being (FACIT-Sp-12) questionnaires.

MATERIALS AND METHODS

Study Design

This research project consists of two parts (Fig. 2). The first being the cross-cultural adaptation and validation of the 10-items Spinal Cord Independence Measure for self-report (SCIM-SR) and the 12-item Functional Assessment of Chronic Illness Therapy – Spiritual well-being (FACIT-Sp-12) questionnaires. The second is a nationwide survey of people with SCID of their psychosocial adjustment (Fig. 3).

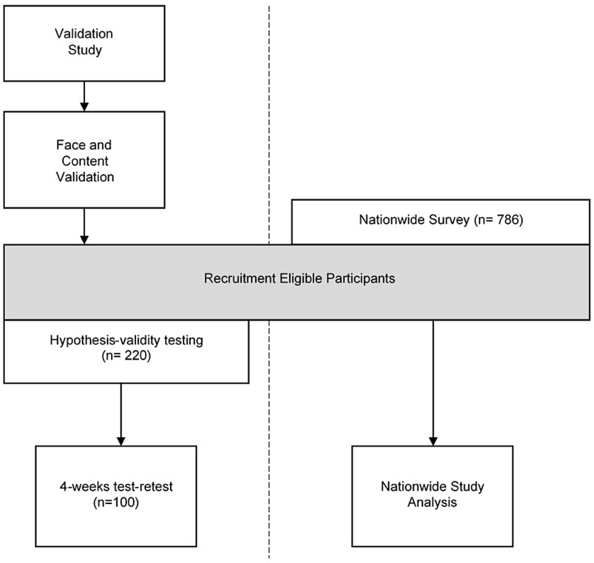

Figure 2: Study Flowchart

Ethical consideration

This study has received ethics approval from the Ethic Committee For Research Involving Human Subject, Universiti Putra Malaysia (JKEUPM-2019-513), the Medical Research and Ethics Committee (MREC) Ministry of Health Malaysia NIH (67)KKM/NIHSEC/ P19-2333(5) on 11 November 2019 and University of Malaya Medical Centre UMMC ID NO: 2019620-7541 on 26 July 2019 to conduct the study at respective centres. All collected data will be kept strictly confidential, and no unique identifier(s) will be present on the questionnaire package. Results and data presented will not identify individual respondents. Participation in this study will not bring any serious risk or harm to the people with SCID.

Sampling Method

Eight participating hospitals are selected for being the referral and established centres for SCID in the country and willing to participate in this study. Sampling frame for this study will be obtained from these hospitals

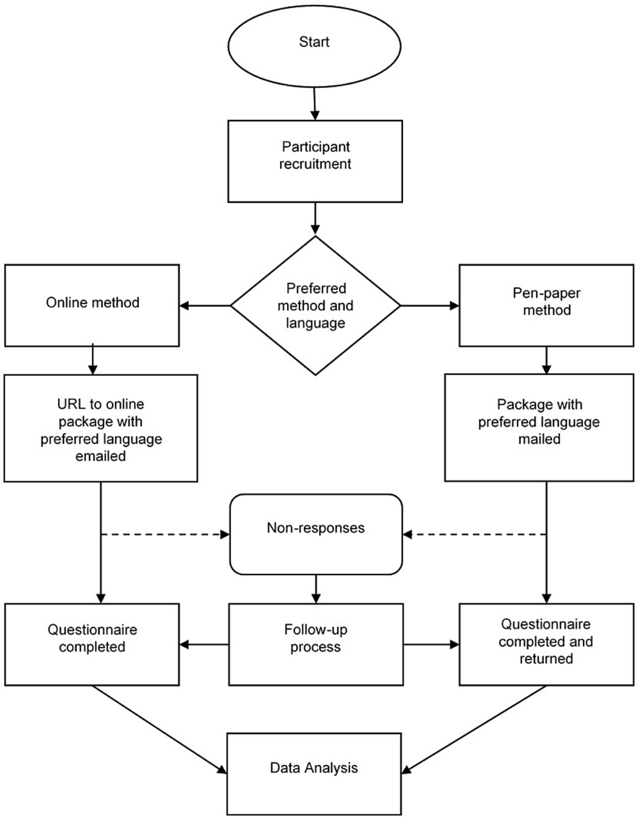

Figure 3: Nationwide Study Flowchart

and it comprises all eligible patients according to the eligibility criteria. A universal sampling for participant selection is used in order to achieve the required sample size of the people with SCID as well as in overcoming the possibility of a high proportion of refusal rate or incomplete questionnaires (see further).

Sample size estimation

The required sample size to estimate 5% (lowest proportion) returned to paid work in the first year since injury among the people with SCID with the power 0.80 and α 0.05 at two tails is 786. Also based on our primary objective of quality of life, assuming that 15 predictors account for 10% of the variance of quality of life in a random model multiple linear regression at two tails, the ρ2 is 0.10, and the required sample size is 213 subjects to achieve the same power and α levels used for the sample size estimation for the lowest proportion of returning to a paid work. Thus, we use the larger required sample size of 786 and inflate it with 50% non-response and non-completion rates (16,17); the required number of participants to be approached is 1179.We estimated there are about 1400-1800 number of patients who are currently being followed-up at the eight participating centres. . Therefore, it is feasible to achieve the required number of eligible respondents through both the online and in print questionnaires survey strategies. This sample size estimation is also more than sufficient for the validity testing of SCIM-SR and FACIT-Sp-12, which is 220 participants for the two questionnaires with a total of 22 items at a ratio of 1:10 (18). A minimum of 50 participants will be needed for the four-week intra-rater test-retest reliability test (19). Assuming a 50% participation rate, the study will re-invite at least 100 participants at random from the list of those who answered the Malay online-based questionnaire in the nationwide survey (Fig. 2).

Setting

The participating public hospitals are from five regions in the country: central, north, and south of Peninsular Malaysia and Sabah and Sarawak. They are selected for being the referral centres for SCID. Following are the list of the hospitals according to their respective regions:

1. Central
   i. University of Malaya Medical Centre, Klang Valley
   ii. Sungai Buloh Hospital, Sungai Buloh
   iii. Cheras Rehabilitation Hospital, Cheras
   iv. Raja Permaisuri Bainun Hospital, Ipoh

2. Northern region
   v. Penang General Hospital

3. Southern region
   vi. Sultan Ismail Hospital, Johor Bahru

4. Sabah
   vii. Queen Elizabeth Hospital, Kota Kinabalu

5. Sarawak
   viii. Sarawak General Hospital, Kuching

Each participating study sites are well-equipped with facilities for SCID rehabilitation services and by multidisciplinary teams, including rehabilitation physicians, physiotherapists, occupational therapist, and nurses. They provide personalized rehabilitation programs that are tailored to an individual requirement and are continually adjusted according to SCID patient's progress.

Participants

The people with SCID in this study are patients who are registered and receiving spinal rehabilitation care at eight public hospitals in Malaysia (see further). The inclusion criteria include adults aged 18 years old and above, able to speak and understand either English or Malay, sustained either traumatic or non-traumatic spinal cord injury and who were diagnosed more than one year ago and ever followed-up at least once at the clinic in the past year at the department of rehabilitation in the participating hospitals. The exclusion criteria are SCID related to congenital aetiologies and neurodegenerative disease. The reason is that the present study aims to examine the psychosocial adjustment of people with SCID who had a near healthy lifestyle before the illness. Another exclusion criterion is documented psychiatric illness, including post-traumatic stress disorder, impaired cognitive function, as this may impair accurate self-perception of the psychosocial conditions.

The same inclusion and exclusion criteria will be applied when recruiting patients for the psychometric testing of the two questionnaires. For the 4-week test-retest reliability testing, we will re-invite those who answered the Malay questionnaire and via the online method (see further).

Outcome Measures

Demographic variables

The questionnaire consists of personal information, injury characteristics, and health-related problems. Personal information includes age, gender, ethnicity (according to the paternal side), marital status, education (primary education, secondary education, vocational training or tertiary education), engaged in gainful employment, current household income (low, medium or high according to the Malaysian definition of total household income), current living arrangement (alone, with family or in an institution), number of people living under the same roof, place of residency and if receiving any disability benefits. As for the injury characteristics, it includes the etiology of the injury and the date of injury, current medical illness including SCID-specific sequelae such as pressure ulcers, spasticity, and bowel and bladder problems as well as general medical illness such as heart disease and diabetes, and whether treatments were sought for this illness.

Quality of life

The World Health Organization's quality of life BREF assessment (WHOQOL-BREF) will be used to measure the quality of life (QOL) of respondents in this study. It was developed by the WHO Quality of Life group with a collaboration of 15 centers around the world (20). It is one of the most used quality-of-life tool to assess an individual's perception of their well-being. Studies using WHOQOL-BREF among SCID patients have shown that it has several advantages over other QOL assessment tools as the domains that constitute WHOQOL-BREF are more sensitive at capturing themes that represent QOL notions for persons with SCID (21). WHOQOL-BREF is a self-administered questionnaire that comprises 26 items with four primary domains: (1) Physical capacity, (2) Psychological well-being, (3) Social relationships, and (4) Environment. In addition to four domains, WHOQOL-BREF includes two standalone questions; one is about the overall perception of QOL, and the second is the perception of general health. These two questions may be analysed separately from the four domains. It has been shown to have moderate to excellent reliability and an acceptable internal consistency value for all the items ranging from 0.75-0.87 (21).

Each item in the domains is rated based on a Likert-scale, ranging from 1 to 5: not at all (1), a little (2), moderately (3), mostly (4), and completely (5). The mean score of items within each domain is then used to calculate the domain score in which the higher the score denotes a higher quality of life perception in that particular domain (20).

Medical Outcome Scale – Social Support Survey (MOS-SSS)

The quality of social support will be assessed with the Medical Outcome Scale – Social Support Survey (MOS-SSS) questionnaire, which was designed to be concise and easy to administer. It is a comprehensive assessment of the functional and quality social support received by a person with a chronic illness. The MOS-SSS is a 19-items self-rated questionnaire that covers a full dimension of social support, including emotional support, informational support, tangible support, positive social interaction, and affection support (22). The subscales contain 3-8 items each. MOS-SSS is reported to have good internal consistency and test-retest stability with Cronbach's alpha of 0.91 – 0.97 (22).

For all items, a 5-points Likert-scale is given as responses, coded as none of the time (1), a little of the time (2), some of the time (3), most of the time (4) and all of the time (5). A score of each subscale is obtainable by averaging the scores in each subscale. The total score of all the subscales is a range from 19-95, but it can be transformed to a 100-points scale using the formula: Transformed score = [(observed score – minimum possible score)/ (maximum possible score – minimum possible score)] x 100. The higher the score indicates better social support (23).

Coping styles

The Brief Coping Orientation to Problems Experienced (Brief COPE) is a multi-dimensional self-rated questionnaire, an abbreviated version of the COPE Inventory. This will be used to measure the different coping styles used by the participants. It has 28 items exploring different coping styles (known as scales) (24). The Brief COPE assessed the following 14 coping strategies: (i) Active coping, (ii) Planning, (iii) Positive reframing, (iv) Acceptance, (v) Humour, (vi) Religion, (vii) Using emotional support, (viii) Using instrumental support, (ix) Self-distraction, (x) Denial, (xi) Venting, (xii) Substance use, (xiii) Behavioural disengagement and (xiv) Self-blame. Brief COPE has been shown to have an acceptable internal consistency coefficient of 0.5 – 0.9 (25).

The 14 scales of coping styles have two items each. The items are rated on four responses and scored in ascending manner: I have not been doing it at all (1), I have been doing this for a little bit (2), I have been doing this a medium amount (3), and I have been doing this a lot (4). The score is calculated by summing up both items within each scale, and the minimum and maximum score for each coping style are 2 to 8, respectively. The higher the score indicates, the more frequent use of that particular coping style (24).

Functional independence

This is measured using the Spinal Cord Independence Measure for self-report (SCIM-SR). It is a self-report version of the clinician-administered Spinal Cord Independence Measure (SCIM-III). The primary function of SCIM-SR is to capture the ability to complete various activities of daily living (ADL) in community settings. SCIM-SR has an overall internal consistency of α=0.79 (26).

A total of ten items comprise three subscales weighted as follows: self-care (scored 0-20), sphincter management (scored 0-30), and mobility (scored 0-16). A total score ranging from 0-66, and the higher the score indicates, the lesser assistance needed or, the more independent the patient is.

Spiritual well-being

The spiritual well-being subscale (FACIT-Sp-12) from the Functional Assessment of Chronic Illness Therapy – Spiritual well-being (FACIT-Sp) will be used to assess the spiritual well-being (27). It is a self-administered instrument that comprises 12 items that evaluate three main domains of spirituality: (1) Peace, (2) Meaning, and (3) Faith. It was previously validated in cancer and palliative care patients and the internal consistency of this instrument (Cronbach's alpha), ranging from 0.81 – 0.88 (27).

The FACIT-Sp-12 uses a 5-point Likert scale in which respondents will choose the best answer that represents their spiritual perception. The scoring system is as follows: not at all (0), a little bit (1), somewhat (2), quite a bit (3), and very much (4). Therefore, each item will have a minimum and maximum score of 0 and 4, respectively. The total score of FACIT-Sp-12 is calculated by combining scores from all items. A subscale score can be obtained using the formula: Subscale score = [sum of item scores x number of items in subscale]/ [number of items answered]. The higher the total score (range from 0-48), means better the spiritual well-being (28).

DATA COLLECTION

The data collection process will be carried out by approaching the potential participants in-person during their scheduled visit to the rehabilitation clinics and contacting those in the clinics' patient registry through telephone. It begins with explaining the purpose of the survey and why they are selected for the study, and the language and types of the questionnaire (online or paper form) they prefer (see Fig. 3). These preferences, hospital registration number, contact number, and residential address of the consented participants will be recorded by clinic staff on a standardized form at the respective rehabilitation clinics. Questionnaire packages are prepared in two languages, namely English and Malay. The method for data collection using online-based questionnaires will be conducted through a URL that will be emailed or sent personally to the participant. Each URL is specifically assigned to one ID for tracking purposes. We will use Research Electronic Data Capture (REDCap) as our platform to create the online questionnaire. It is a free web-based software to non-profit organizations that join the REDCap consortium. A copy of the participant information sheet (PIS) will be given together with the Uniform Resource Locator (URL) link in the email or as a mobile message sent to the participant.

Alternatively, if the participant wishes to use the printed questionnaire, we will post them a cover letter explaining the purpose of the study, a copy of the consent form, and a copy of the questionnaire (in the language preferred). Once the participants have completed the questionnaire, they will notify the study investigator for a courier service to pick-up the completed questionnaire without a cost. The investigator's contact details are provided in the patient information sheet in the questionnaire package. In order to increase the response rate, we adopting the Dillman method of follow-up with the respondents by sending out series of reminders to non-respondents, which will be planned in three stages (29):

1. Two weeks after the initial mailing or message – a follow-up email or message or/and call;
2. Four weeks after the initial mailing or message – a follow-up email or message or/and call, and a new covering letter and questionnaire if needed; and
3. Six weeks after the initial mailing or message – a follow-up email or message or/and call, and third covering letter and questionnaire if needed

Psychometric investigation

Cross-cultural adaptation and hypothesis-validity testing SCIM-SR and FACIT-Sp-12 have been translated in the conventional manner into Malay but not yet validated in the local settings (28,30). In reference to previous guidelines on the cross-cultural adaptation and validation, the process will be conducted in three stages: (1) face and content, (2) cognitive debriefing, and (3) psychometric and 4-week intra-rater test-retest reliability testing (31,32). The face and content validity had been conducted for SCIM-SR and FACIT-Sp-12 questionnaires by the research team members consisting of experts in the field of psychology and spinal cord rehabilitation together with two persons with SCID. These experts are multi-lingual. Cognitive debriefing with another ten people with SCID has also been conducted at a rehabilitation outpatient clinic in Universiti Malaya Medical Centre (UMMC), Kuala Lumpur. Feedback and changes have also been made to the questionnaires accordingly before it was finalized and to be used in the nationwide survey. In the final step of the validation study, the psychometric and 4-week test-retest reliability testing of the two questionnaires will be done concurrently with the nationwide survey (see Fig. 2 and Fig. 3). FACIT-Sp-12 and SCIM-SR will measure the constructs of spiritual well-being and functional independence in patients with relatively stable SCID, therefore a 4-week period interval were choosen for the test-retest reliability (33,34). A shorter test-retest reliability period would produce a higher and better ICC but it will not be a fair estimate to be taken for the tool property in patients with stable conditions.

DATA ANALYSIS

All data will be entered into a computer that is protected. On completion of the study, data on the computer will be copied to CDs, and data on the computer will be erased. CDs and any hardcopy data will be safeguarded in a locked cabinet in the principal investigator's office and maintained for a minimum of seven years after the completion of the study. The CDs and data will be destroyed after the period of storage.

Nationwide survey

Data will be cleaned and checked for the missing datum. Extreme and suspicious values will be verified with the respondents and assessed in a sensitivity analysis as well as omitted as missing values. Once the missing data determined to be missing at random, multiple imputations with ten runs may be conducted to replace the missing data. A descriptive analysis will be used to summarize the sociodemographic data and clinical variable, and to describe the scoring results of each instrument. We will dichotomize the place of the resident into urban and rural according to the Population and Housing Census (2010), and the duration of SCID into ≤ one year and > one year. Comparisons of mean levels for each primary and secondary outcome will be performed separately using the Student's t-test and Chi-square test for proportionate samples. The equivalent non-parametric tests will be used for data with non-normal distribution.

Quality of life (measured by WHOQOL-BREF), coping styles (Brief COPE), functional status (SCIM-SR), and spiritual well-being (FACIT-Sp-12) are the main dependent variables. WHOQOL-BREF and MOS-SSS will be analysed and reported as interval variables descriptively according to the data distribution. WHOQOL-BREF, Brief COPE, SCIM-SR, and FACIT-Sp-12 will be analysed according to the subscales as interval variables. Some of these interval variables (in the example of Brief COPE 14 domains) may be further dichotomized into categorical forms to provide meaningful comparisons. For example, we will categorize the 14 coping styles in Brief COPE into three major groups a) Emotion-focused strategies, b) Problem-focused strategies, and c) Dysfunctional coping strategies (35). With these larger subgroups of coping styles, we may further determine the independent effects of the demographic and clinical variables. In another example, the WHOQOL-BREF has two standalone questions that capture the perception of the respondents on their overall QOL and general health. We will dichotomize the 5-point-response into "poor QOL" versus "good QOL" and "dissatisfied with their own health" versus "satisfied with their own health", respectively. These categorical forms of QOL will be used as the dependent variables, and the independent effects of the demographic variables, for example, such as gender, household income groups, place of residence, duration of injury, and level of injury will be determined.

The associated and independent factors from the demographic and clinical variables on each of the primary and secondary dependent variables will be estimated in separate models. Any of this factor with a P-value <0.20 from univariable linear regression analyses will be included in the multiple linear regression analysis (36). Multicollinearity between any independent variables will be checked according to the tolerance < 0.4 (Variance inflation factors, VIF ≥ 2.5). In the presence of multicollinearity, the more critical or essential variable from clinical perspectives will be selected for use in the final regression analysis. All models, Q-Q plots for normality, the residual plots for linearity and homogeneity assumptions and model fitting will be checked. Data analyses will be performed with Statistical Package for Social Sciences (SPSS) version 25.0 (IBM, Chicago, IL).

Cross-cultural adaptation and validation of the questionnaires

The internal consistency reliability will be estimated using Cronbach's alpha (0.75 or higher considered good) for SCIM-SR and FACIT-Sp-12. Exploratory factor analysis (EFA) using principal component analysis (PCA) will be used to examine the structural validity of SCIM-SR and FACIT-Sp-12. The Kaiser-Mayer-Olkin test of sampling adequacy, Bartlett's test of sphericity, and the scree plot will be performed. The convergence criteria will be set at eigenvalue above 1. We will also examine psychometric properties of the WHOQOL-BREF among the SCID respondents in this study including the internal consistency of the items and other aspects of the structural validity.

Hypothesis-testing validity of SCIM-SR will be done with WHOQOL-BREF, Brief COPE (active coping, planning, positive reframing, acceptance, and the use of instrumental support), MOS-SSS, and FACIT-Sp-12. We hypothesize that SCIM-SR will be associated with these other related domains by at least a coefficient of 0.10 (37–40). Similarly, the hypothesis-testing validity of FACIT-Sp-12 will be assessed against WHOQOL-BREF, Brief COPE (religion, self-destruction, substance abuse, behavioral disengagement, and self-blame) and MOS-SSS. We hypothesize that FACIT-Sp-12 will be associated with these domains by at least a coefficient of 0.30 (41,42).

A four-week intra-rater test-retest reliability testing will be carried out for the SCIM-SR and FACIT-Sp-12 primarily through online method. A follow-up invitation email will be sent out one week after the initial invitation in the event of non-response to the first email. The intra-rater test-retest reliability will be estimated using the intra-class correlation coefficients (ICC). The interpretation of ICC values are in accordance to Portney and Walkins (2000) in which the ICC values of less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 to 0.9 are indication of good reliability and more than 0.9 indicate very good reliability (43).

RESULTS

The purpose of this paper is to report on the PA-SCID study protocol comprising the study's theoretical design, data collection design and analysis plan. The results will be reported once we have completed the data collection and analysed the data.

DISCUSSION

Adapting to SCID may be a daunting experience, especially if it involves significant alteration to the day-to-day functioning and requires a tremendous amount of support from other people. Locally, empirical studies on SCID in Malaysia, the adjustment process and its associated factors are is still lacking. This study will provide substantial insight into the psychosocial adjustments, sociodemographic, and clinical determinants in people with SCID in Malaysia. The exploration of the psychosocial adjustment of individual with SCID in the context of quality of life, functional independence, perceived social support, and coping strategies are very important to the individual, the caregiver and people surrounding them (44). The identified needs of people with SCID will serve to inform stakeholders to improve relevant healthcare services. To our best knowledge, this is the first nationwide study in Malaysia to address these issues in people with SCID.
The study uses a locally validated instruments (45–47) except for the SCIM-SR and FACIT-Sp-12 questionnaires for secondary objectives which will be subjected to rigorous cross-cultural adaptation process and validity testing .

There are a few limitations associated with this study — the first being the inability to get locally validated instruments in Chinese. This may limit the participation of the study by Chinese who are not familiar in the other languages. Similarly, inviting only active patients as respondents from public hospitals and not from private healthcare institutions and SCID-related non-governmental organizations (NGOs) may have selection bias. However, we believe the eight rehabilitation centres are the main centres where almost all people with SCID would have been cared for at some points during their recovery period, and therefore the external validity of this study could be expected to be high. The relatively large sample size for this study would provide precise estimates.

We design the survey questionnaires online and in print versions in order to reach broader eligible participants. Preceding the survey, we will approach them by contacting them through a telephone call to brief on the survey and to record their preference of the survey approaches either through an online or printed paper questionnaire. These sampling strategies hope to achieve a higher response rate, better efficiency, and cost-effectiveness. We are aware of the different modes of questionnaire administration could influence the quality of information collected (48), this study is designed to increase the survey response rates, the accuracy of responses, less bias (socially desirable answers), and completeness of the information through prior survey personal telephone conversation to brief on the study, record their preferences, encouraging self-administration and reinviting the same online respondents to the test-retest reliability testing.

CONCLUSION

This study is designed with the best possible methods that are feasible to produce highest quality data on the sociodemographic and clinical profiles of people with SCID in Malaysia and their psychosocial adjustment following the diagnosis of SCID. The quality of life, functional status, coping styles, social support received, and spiritual well-being of people with SCID need to be determined and explored for better understanding of their determinants on the psychosocial adjustment. The results of this study will be informative regarding the leading causes of SCID and the factors associated with psychosocial adjustment, and may benefit future medical and public health initiatives to improvise the existing rehabilitation programs and social services for people with SCID (49,50).

AKNOWLEDGEMENTS

This study has received a research grant from Universiti Putra Malaysia's Putra-IPS UPM/800/2/2/4-Geran Putra. The study protocol has undergone the standard procedure of internal evaluation by the funding body as part of the application process for the grant. All the site-investigators from eight study sites are contributing to the patient recruitment process and data collection of this study. We thank the Research Management Unit of University Malaya for granting us access to use the web-based software REDCap for our online questionnaire and database storage.

REFERENCES

1. Spinal cord injury [Internet]. [cited 2018 Nov 1]. Available from: http://www.who.int/news-room/fact-sheets/detail/spinal-cord-injury

2. Lee BB, Cripps RA, Fitzharris M, Wing PC. The global map for traumatic spinal cord injury epidemiology: Update 2011, global incidence rate. Spinal Cord [Internet]. 2014;52(2):110–6. Available from: http://dx.doi.org/10.1038/sc.2012.158
3. New PW, Cripps RA, Bonne Lee B. Global maps of non-traumatic spinal cord injury epidemiology: towards a living data repository. Spinal Cord [Internet]. 2014 Feb 15;52(2):97–109. Available from: http://www.nature.com/articles/sc2012165
4. Adriaansen J, Ruijs L, Koppenhagen C, Asbeck F, Snoek G, Kuppevelt D, et al. Secondary health conditions and quality of life in persons living with spinal cord injury for at least ten years. J Rehabil Med [Internet]. 2016;48(10):853–60. Available from: http://www.medicaljournals.se/jrm/content/abstract/10.2340/16501977-2166
5. Kennedy P, Lude P, Taylor N. Quality of life, social participation, appraisals and coping post spinal cord injury: A review of four community samples. Spinal Cord. 2006;44(2):95–105.
6. Lourenco L, Blanes L, Salomй GM, Ferreira LM. Quality of life and self-esteem in patients with paraplegia and pressure ulcers: A controlled cross-sectional study. J Wound Care [Internet]. 2014 Jun 2;23(6):331–7. Available from: http://www.magonlinelibrary.com/doi/10.12968/jowc.2014.23.6.331
7. Peter C, Mьller R, Cieza A, Geyh S. Psychological resources in spinal cord injury: a systematic literature review. Spinal Cord [Internet]. 2012 Mar 29;50(3):188–201. Available from: http://www.nature.com/articles/sc2011125
8. van Leeuwen CMC, Kraaijeveld S, Lindeman E, Post MWMM. Associations between psychological factors and quality of life ratings in persons with spinal cord injury: a systematic review. Spinal Cord [Internet]. 2012 Mar 1;50(3):174–87. Available from: http://dx.doi.org/10.1038/sc.2011.120
9. Wu MY, Chan F. Psychosocial adjustment patterns of persons with spinal cord injury in Taiwan. Disabil Rehabil [Internet]. 2007;29(24):1847–57. Available from: http://www.tandfonline.com/doi/full/10.1080/09638280601143703
10. Jones K, Simpson GK, Briggs L, Dorsett P. Does spirituality facilitate adjustment and resilience among individuals and families after SCI? Disabil Rehabil. 2016;38(10):921–35.
11. Hajiaghababaei M, Saberi H, Rahnama P, Montazeri A. Spiritual well-being and quality of life in patients with spinal cord injury: A study from Iran. J Spinal Cord Med [Internet]. 2018 Nov 2;41(6):653–8. Available from: https://doi.org/10.1080/10790268.2018.1466479
12. Judd FK, Webber JE, Brown DJ, Norman TR, Burrows GD. PSYCHOLOGICAL ADJUSTMENT FOLLOWING TRAUMATIC SPINAL-CORD INJURY - A STUDY USING THE PSYCHOSOCIAL ADJUSTMENT OT ILLNESS SCALE. Paraplegia. 1991;29(3):173–9.
13. Post MWM, Van Leeuwen CMC. Psychosocial issues in spinal cord injury: A review. Spinal Cord [Internet]. 2012;50(5):382–9. Available from: http://dx.doi.org/10.1038/sc.2011.182
14. Martz E, Livneh H, Priebe M, Wuermser LA, Ottomanelli L. Predictors of psychosocial adaptation among people with spinal cord injury or disorder. Arch Phys Med Rehabil. 2005;86(6):1182–92.
15. Livneh H. Psychosocial Adaptation to Chronic Illness and Disability. Rehabil Couns Bull [Internet]. 2001 Apr 13;44(3):151–60. Available from: http://journals.sagepub.com/doi/10.1177/003435520104400305
16. Chew B-H, Yasin MM, Cheong A-T, Rashid M-RA, Hamzah Z, Ismail M, et al. A nationwide postal survey on the perception of Malaysian public healthcare providers on family medicine specialists' (PERMFAMS) clinical performance, professional attitudes and research visibility. Springerplus [Internet]. 2015 Dec 6 [cited 2019 May 9];4(1):213. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25992310
17. Azman AB, Sararaks S, Rugayah B, Low LL, Azian AA, Geeta S, et al. Quality of life of the Malaysian general population: results from a postal survey using the SF-36. Med J Malaysia [Internet]. 2003 Dec [cited 2019 May 9];58(5):694–711. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15190656
18. Peat J. Health Science Research - Chapter: Calculating the Sample Size. 2002.
19. Terwee CB, Bot SDM, de Boer MR, van der Windt DAWM, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34–42.
20. World Health Organization. WHOQOL-BREF: INTRODUCTION, ADMINISTRATION, SCORING AND GENERIC VERSION OF THE ASSESSMENT [Internet]. 1996 [cited 2018 Dec 30]. Available from: https://www.who.int/mental_health/media/en/76.pdf?ua=1
21. Lin MR, Hwang HF, Chen CY, Chiu WT. Comparisons of the brief form of the world health organization quality of life and short form-36 for persons with spinal cord injuries. Am J Phys Med Rehabil. 2007;86(2):104–13.
22. Sherbourne CD, Stewart AL. The MOS social support survey. Soc Sci Med [Internet]. 1991;32(6):705–14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/2035047
23. RAND Health Care. Social Support Survey Instrument Scoring Instructions l RAND [Internet]. [cited 2019 May 3]. Available from: https://www.rand.org/health-care/surveys_tools/mos/social-support/scoring.html
24. University of Miami P. Brief COPE [Internet]. [cited 2018 Dec 30]. Available from: http://local.psy.

miami.edu/faculty/ccarver/sclBrCOPE.html

25. Carver CS. You want to measure coping but your protocol' too long: Consider the brief cope. Int J Behav Med [Internet]. 1997 Mar;4(1):92–100. Available from: http://ezproxy.library.capella.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=106023739&site=ehost-live&scope=site
26. Michailidou C, Marston L, De Souza LH. Translation into Greek and initial validity and reliability testing of a modified version of the SCIM III, in both English and Greek, for self-use. Disabil Rehabil [Internet]. 2016;38(2):180–8. Available from: http://dx.doi.org/10.3109/09638288.2015.1035454
27. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-being Scale (FACIT-Sp). Ann Behav Med [Internet]. 2002 Feb;24(1):49–58. Available from: https://academic.oup.com/abm/article/24/1/49-58/4631552
28. Questionnaires - FACIT.org [Internet]. [cited 2019 Apr 15]. Available from: http://www.facit.org/facitorg/questionnaires
29. Dillman DA. Call-Backs and Mail-Backs in Sample Surveys. In: Encyclopedia of Biostatistics [Internet]. John Wiley & Sons, Ltd; 2005 [cited 2020 Jun 22]. Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/0470011815.b2a16011
30. Gross-Hemmi MH, Post MWM, Ehrmann C, Fekete C, Hasnan N, Middleton JW, et al. Study Protocol of the International Spinal Cord Injury (InSCI) Community Survey. Am J Phys Med Rehabil [Internet]. 2017 Feb;96(2):S23–34. Available from: http://insights.ovid.com/crossref?an=00002060-201702001-00005
31. WHO | Process of translation and adaptation of instruments. WHO. 2010;
32. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures. Spine (Phila Pa 1976) [Internet]. 2000 Dec;25(24):3186–91. Available from: http://journals.lww.com/00007632-200012150-00014
33. Unalan H, Misirlioglu TO, Erhan B, Akyuz M, Gunduz B, Irgi E, et al. Validity and reliability study of the Turkish version of Spinal Cord Independence Measure-III. Spinal Cord. 2015;53(6):455–60.
34. Fradelos E, Tzavella F, Koukia E, Tsaras K, Papathanasiou I, Aroni A, et al. The Translation, Validation and Cultural Adaptation of Functional Assessment of Chronic Illness Therapy - Spiritual Well-being 12 (facit-sp12) Scale in Greek Language. Mater Socio Medica. 2016;28(3):229.
35. Cooper C, Katona C, Orrell M, Livingston G. Coping strategies and anxiety in caregivers of people with Alzheimer's disease: The LASER-AD study. J Affect Disord. 2006;90(1):15–20.
36. Katz MH. Setting up a multivariable analysis. In: Multivariable Analysis [Internet]. Cambridge: Cambridge University Press; 2011 [cited 2020 Jul 2]. p. 93–117. Available from: https://www.cambridge.org/core/product/identifier/CBO9780511974175A040/type/book_part
37. Saurí J, Umaca MC, Chamarro A, Soler MD, Gilabert A, Elfstrum ML. Adaptation and validation of the spanish version of the Spinal Cord Lesion-related Coping Strategies Questionnaire (SCL CSQ-S). Spinal Cord [Internet]. 2014 Nov 29;52(11):842–9. Available from: http://www.nature.com/articles/sc201444
38. Saffari M, Pakpour AH, Yaghobidoot M, Al Zaben F, Koenige HG. Cross-cultural adaptation of the spinal cord lesion-related coping strategies questionnaire for use in Iran. Injury [Internet]. 2015 Aug;46(8):1539–44. Available from: http://dx.doi.org/10.1016/j.injury.2015.04.035
39. Kennedy P, Lude P, Elfstrum ML, Smithson E. Cognitive appraisals, coping and quality of life outcomes: a multi-centre study of spinal cord injury rehabilitation. Spinal Cord [Internet]. 2010 Oct 9;48(10):762–9. Available from: http://www.nature.com/articles/sc201020
40. May L, Warren S. Measuring quality of life of persons with spinal cord injury: external and structural validity. Spinal Cord [Internet]. 2002 Jul 21;40(7):341–50. Available from: http://www.nature.com/articles/3101311
41. Holt CL, Wang MQ, Caplan L, Schulz E, Blake V, Southward VL. Role of religious involvement and spirituality in functioning among African Americans with cancer: Testing a mediational model. J Behav Med. 2011;34(6):437–48.
42. Jafari N, Farajzadegan Z, Zamani A, Bahrami F, Emami H, Loghmani A. Spiritual well-being and quality of life in Iranian women with breast cancer undergoing radiation therapy. Support Care Cancer [Internet]. 2013 May 10;21(5):1219–25. Available from: http://link.springer.com/10.1007/s00520-012-1650-1
43. Portney LG, Watkins MP. Statistical Measures of Reliability. In: Portney LG, Watkins MP, editors. Foundations of Clinical Research: Pearson New International Edition: Applications to Practice [Internet]. 3rd ed. Pearson; 2014 [cited 2020 Jul 2]. p. 595–628. Available from: https://www.pearson.com/uk/educators/higher-education-educators/product/Portney-Foundations-of-Clinical-Research-Pearson-New-International-Edition-PDF-e-Book-Applications-to-Practice-3rd-Edition/9781292033686.html?tab=formats
44. Franek G, Malicka E, Nowak-Kapusta Z, Cieślik A. Quality of Life after Spinal Cord Injury. J Neurol Neurosurg Nurs [Internet]. 2018 Jun;7(2):64–9. Available from: http://www.jnnn.pl/index.php/neurological-and-neurosurgical/article/view/198/190

45. Hasanah CI, Naing L, Rahman AR. World Health Organization Quality of Life Assessment: brief version in Bahasa Malaysia. Med J Malaysia [Internet]. 2003 Mar;58(1):79–88. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14556329
46. Saddki N, Sulaiman Z, Abdullah S, Zakaria N, Mohamad N, Ab Razak A, et al. Psychometric properties of the Malay version of the Medical Outcomes Study Social Support Survey (MOS-SSS) in a sample of patients with HIV. J HIV/AIDS Soc Serv [Internet]. 2017;16(1):60–74. Available from: http://dx.doi.org/10.1080/15381501.2015.1107801
47. Yusoff MSB. A multicenter study on validity of the 30-items Brief COPE in identifying coping strategies among medical students. Int Med J. 2010;17(4):249–53.
48. Bowling A. Mode of questionnaire administration can have serious effects on data quality. J Public Health (Bangkok). 2005;27(3):281–91.
49. Verwer JH, Van Leeuwen CMC, Bolier L, Post MWM. Feasibility of an online well-being intervention for people with spinal cord injury: A pilot study. Spinal Cord [Internet]. 2016;54(6):473–7. Available from: http://dx.doi.org/10.1038/sc.2015.165
50. Migliorini C, Sinclair A, Brown D, Tonge B, New P. A randomised control trial of an Internet-based cognitive behaviour treatment for mood disorder in adults with chronic spinal cord injury. Spinal Cord [Internet]. 2016;54(9):695–701. Available from: http://dx.doi.org/10.1038/sc.2015.221