CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter describes the design, settings, sample population and sampling procedure, pilot study, research instrument, data collection method and procedure, data analysis and interpretation of the results and finally, the ethical considerations for this study.

3.2 Study Design

A prospective study design was conducted in which a group of patients with primary intracerebral haemorrhage was selected and to examine factors that may affect early adaptation during the acute recovery phase. Later, the primary intracerebral haemorrhage cohort was then followed-up at three months to determine the factors associated with 3 month adaptation (functional independence). This study also determines the percentage of improvement from early to alter (3 months) post PICH in motor and cognitive domains. The follow-up after three months was applied in this study based on the findings of the pilot study (The percentage of missing samples was higher. Thus, in order to avoid missing data, a three-month follow-up was more feasible than a six-month follow-up. Later, the primary intracerebral haemorrhage cohort was then followed-up at three months to determine the factors associated with 3 month adaptation (functional independence).

3.3 Study Setting

The data collection in Phase I (acute inpatient recovery phase) was conducted at two
main hospitals in the east coast of Malaysia, namely Hospital Universiti Sains Malaysia (Hospital USM) and Hospital Sultanah Nur Zahirah Kuala Terengganu (HSNZ). Both hospitals receive admissions and provide treatment for patients with intracerebral haemorrhage. In Phase II (long-term recovery phase), the selected patients were followed-up at home.

Hospital USM is a teaching tertiary care hospital in Kubang Kerian, Kelantan, which is six kilometres away from the city of Kota Bharu. It is a referral centre for patients with ICH from other hospitals in the east coast of Malaysia, including Hospital Sultanah Zainab Kota Bharu and all the district hospitals in Kelantan, Hospital Sultanah Nur Zahirah and other nearby district hospitals in Terengganu, such as Hospital Besut and Hospital Jerteh. HUSM is equipped with 747 beds to provide specific care and treatment for neurological problems, including ICH patients. Patients who have been stabilized after primary intracerebral haemorrhage are admitted to an intensive care unit, where appropriate medical and surgical treatment and close observations are conducted for risk of early deterioration. Later, patients are transferred to a surgical ward for acute recovery and rehabilitation. After patients have been stabilized, they are referred to district hospitals for continuation of care and treatment.

Hospital Sultanah Nur Zahirah Kuala Terengganu (HSNZ) has an 821-bed capacity to provide care to the population of Terengganu. HSNZ is the referral centre for five district hospitals, including Kuala Terengganu, Setiu, Dungun, Kemaman and Jerteh as well as for private medical care in the state of Terengganu. ICH patients who require immediate surgery in relation to ICH are referred to HUSM. Patients who have been stabilized are admitted to an intensive care unit for appropriate medical-surgical treatment and close observation in order to prevent risk of early deterioration for patients with spontaneous
intracerebral haemorrhage. Patients who survive the critical phase are admitted to the general surgical ward until they are discharged.

3.4 Sample and Sampling

The samples comprised of all PICH patients admitted within the sampling frame with GCS of 9 and higher and fulfilled the inclusion criteria were recruited. PICH patients were recruited from Hospital USM and HSNZKT who have fulfilled the criteria within the sampling frame with a GCS of 9 and higher. There were 147 post-primary intracerebral haemorrhage (PICH) patients admitted to Hospital USM and HSNZKT between June 2009 and December 2010 who met the criteria for this study. However, during the follow-up at three months, 26 patients (17.6%) died due to severe neurological status, medical problems and severe complications, such as respiratory infections and bed sores. Eight patients were excluded from the study because three of them were confirmed as not having intracerebral bleeding after a CT scan analysis and another five could not be contacted or found either by telephone or based on the addresses given. Thus, a total of one hundred and thirteen (113) post-PICH patients participated in this study. Figure 3.1 shows the flow and outcomes of the patients who were recruited in the study.

3.4.1 Inclusion Criteria

The inclusion criteria were: (1) patients over eighteen years old; (2) having intracerebral haemorrhage (ICH) on the initial CT scan; (3) Glasgow Coma Scale (GCS) of 9 or more than 9, and (4) in the recovery stage. Patients with a score of 9 or greater and a hematoma volume of less than 30 ml. had a mortality rate of 17% and potentially good patient outcomes (Adnan, Stanley, Joseph & Batjer et al., 2001).
Figure 3.1: Flow of PICH patients who were included in the study and reasons for dropping out from the study
This study also determined the availability of a primary family caregiver in providing support to PICH patients. A primary caregiver for a hospitalized PICH patient is identified as a person with a responsibility to stay and help the patient at all times during hospitalization. The inclusion criteria for a family caregiver were (1) 18 years old or older; (2) a primary family member; and (3) responsible for caring and helping the patient at all times during the recovery phase. The caregiver variables that were collected for this research included age, sex and relationship with the stroke patient.

### 3.4.2 Exclusion Criteria

The exclusion criteria were: (1) patients with traumatic haemorrhage, haemorrhages secondary to a brain tumour or thrombolytic treatment, a haemorrhagic transformation of cerebral infarction, (2) patients with a vascular malformation or aneurysm, and those suspected of having secondary bleeding; (3) patients with subarachnoid haemorrhage and patients with previous ICH; and (4) patients with a Glasgow Coma Scale (GCS) score of less than 9, with bilateral fixed, dilated pupils, and impending death. Patients with a Glasgow Coma Scale (GCS) score of less than 9 were excluded based on the finding of Gupta, Jamjoom, Nikkar-Esfahani & Jamjoom (2010) that a decreased initial Glasgow Coma Scale score is one of the strongest predictors of the 30-day poor outcome and death.

### 3.4.3 Calculation of sample size

The sample size for this study was estimated at a level of significance (α) of 0.05 to the power of 0.80 (1-β) (Munro, 2001; Polit & Hungler, 1999). The sample size to determine the correlation between numerical variables with early adaptation (within two weeks) and later (at three months) adaptation was calculated using the single sample correlation by
Arun Varman Software (Arun Varman, 2008) (Table 3.1). It was based on the findings of a study by Rochette (2006), as shown below.

**Table 3.1: Calculation of Sample Size for Correlation**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Alpha</th>
<th>power</th>
<th>Correlation coefficient ($r$)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptation (QOL) – Coping strategies</td>
<td>0.05</td>
<td>0.8</td>
<td>0.30 $^a$</td>
<td>85</td>
</tr>
<tr>
<td>Adaptation - Complication (depression)</td>
<td>0.05</td>
<td>0.8</td>
<td>0.25 $^a$</td>
<td>123</td>
</tr>
<tr>
<td>Stressful – Depression</td>
<td>0.05</td>
<td>0.8</td>
<td>0.29 $^a$</td>
<td>91</td>
</tr>
<tr>
<td>Adaptation (QOL) – Controlled by self</td>
<td>0.05</td>
<td>0.8</td>
<td>0.33 $^a$</td>
<td>70</td>
</tr>
</tbody>
</table>

$^a$Rochette (2006)

The sample size to test for changes in the adaptation and depression scores over time was calculated based on a comparison of two means ($t$ test) using PS software (Dupont and Plummer, 1998) (Table 3.2).

**Table 3.2: Calculation of sample size to test for differences in adaptations to depression for acute and long-term outcomes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>alpha</th>
<th>power</th>
<th>SD of mean difference</th>
<th>Mean difference</th>
<th>n per group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptation acute and long-term outcomes (FIM score)</td>
<td>0.05</td>
<td>0.8</td>
<td>21 $^a$</td>
<td>10</td>
<td>37</td>
</tr>
<tr>
<td>Depression acute and long-term outcomes (CESDO score)</td>
<td>0.05</td>
<td>0.8</td>
<td>5 $^b$</td>
<td>3</td>
<td>24</td>
</tr>
</tbody>
</table>

$^a$ Darlington et al. (2007), $^b$Hadidi (2008)
The sample size to determine the association between (i) early adaptation, and (ii) later (3 months) adaptation was determined based on the results of a study by Bagg et al. (2009). It was calculated using the Linear Regression – Danielsoper Software. http://www.danielsoper.com/statcalc/calc05.aspx (Table 3.3).

**Table 3.3: Calculation of sample size to test the association between acute adaptation and long-term adaptation outcomes with predicted variables**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Alpha</th>
<th>power</th>
<th>Expected number of significant predictors</th>
<th>R²</th>
<th>f²ᵇ</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early adaptation</td>
<td>0.05</td>
<td>0.8</td>
<td>4</td>
<td>0.17</td>
<td>0.205</td>
<td>63</td>
</tr>
<tr>
<td>Long-term adaptation</td>
<td>0.05</td>
<td>0.8</td>
<td>14</td>
<td>0.17</td>
<td>0.205</td>
<td>102</td>
</tr>
</tbody>
</table>

ᵇBagg et al. (2002),ᵇ Anticipated Effect Size (f²)

The highest sample size obtained from the sample size calculation for this study was n = 123. In view of the fact that 10% of the participants dropped out, the estimated sample size for the present study was 123/0.9 = 136.

### 3.5 Variables and Instruments used in the Pilot Study

Seven instruments were used for the data collection in Phase I and II (Appendix A):

Phase I (at 5 days post-PICH during acute inpatient recovery): The instruments used were Demographic Data, Glasgow Coma Scale (GCS), Functional Independence Measure (FIM), National Institutes of Health Stroke Scale (NIHSS), Complication Inventory Checklist (CIC), Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS), and Stroke Knowledge Questionnaire (SKQ).
3.5.1 Translation process for the instruments

Four established questionnaires in English version were translated into Malay language and validated. The questionnaires include National Institutes of Health Stroke Scale (NIHSS), Functional Independence Measure (FIM), Patient Health Questionnaire 9-item depression scale (PHQ-9-DS) and Stroke Knowledge Questionnaire (SKQ). The Malay version of the questionnaires was developed by translating from the English to Malay version using forward and backward translation. The original questionnaires in the English language were translated to the Malay version using forward translation by two independence translator who are expert in Malay and English language. The comparison and synthesis of translated questionnaires were done. The blind backward translation of the translated questionnaires was done by two professional linguistic experts to the original English language and after that the two transacted version was compared to ensure the congruence of the Malay and English of the questionnaire (Sousa & Rojjanasrirat, 2014).

3.5.2 Validity of the instruments

The validation of the psychometric instruments involved two main parts: validity and reliability. The validity refers to the ability of an instrument to measure what it is designed to measure (Noorhayati, Aniza, Hazlina & Azman, 2015). The questionnaire for this study was validated using the face validity. Since all the instruments had already been published (except in Malaysia), the instruments were considered as appropriate for measuring each targeted construct. The face validity and construct validity were used to assess the targeted construct of the Malay version of the instruments.
3.5.3 Face Validity

Content validity of the questionnaires was then reviewed and analysed by an expert panel in area of neurology and stroke illness using face validity. Face validity is “the degree to which respondents judge that the variables of the instruments are appropriate and assessment objectives (Noorhayati, Aniza, Hazlina & Azman, 2015). The face validation required experts to review and comment on the whole questionnaire in terms of its presentation, arrangement, clarity and relatedness. Their understanding on each item was explored (Noorhayati, Aniza, Hazlina & Azman, 2015). The instruments were revised according to the suggestions from the panel review (Polit and Beck, 2006). Later, validity and reliability analyses were performed using SPSS software. The reliability of the research instruments is described in the following sections.

3.5.4 Reliability

The reliability of the National Institutes of Health Stroke Scale (NIHSS), Complication Inventory Tool (CIC), Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS) and Stroke Knowledge Questionnaire (SKQ) were tested on 30 ICH patients. Cronbach’s alphas were calculated for internal consistency using correlation coefficients.

3.5.5 Test-retest reliability

Following the reliability testing, the test-retest reliability of the instruments was evaluated and represented by the intraclass correlation coefficient (ICC) with a 95% confidence interval. The test-retest reliability Alpha was 0.55, which falls in the category of fair strength agreement.
3.6 Pilot study

A pilot study was conducted before proceeding to the main study. The pilot test was a prospective cohort study in line with the main study. It was performed as similarly as possible to the proposed study, using similar patients, settings, questionnaires and data collection procedures.

3.6.1 Pilot Study Design and Setting

The data collection for the pilot study consisted of two phases, where selected ICH patients on admission were followed-up at home at three-month post-stroke. The pilot study was conducted at HUSM and HSNZ from June to September 2009 after ethical approval was obtained from the Human Research Ethics Committee, USM and the Ethics Committee & Medical Research (Ministry of Health, Malaysia).

The purpose of the pilot study was to test the validity and reliability of the instruments, to correct and alter of the questionnaire if needed, to perform preliminary testing of the hypothesis, whether to change or retain the formulated hypothesis, to drop or develop a new hypothesis, to obtain ideas, to evaluate the usefulness for the data and to make an alteration in data collection approaches. It was performed as similar as possible to the proposed study, using similar subjects, settings, questionnaires and data collection procedures. The pilot data collection consists of two phases where selected ICH patients at admission were followed up at home at three and six-month post stroke.
3.6.2 Patient Selection

Approximately 20% (27) of sample required for full study was adequate for the aims as to test the validity and reliability of the instruments (Hertzog, 2008; Cohen 1992). Thus, a total of 30 subjects who were admitted to HUSM and diagnosed as having the intracerebral haemorrhage were approached for this pilot study. The inclusion criteria for the subjects include (1) evidence of having ICH on the initial CT scan, (2) GCS of 9 or more than 9 and in acute recovery stage (Hertzog, 2008).

3.6.3 Findings of the pilot study

This result of pilot study has provided the researcher’s experience recruiting samples, accessing the research setting, study method, data collection procedure, research instruments and analysis. The results from the pilot study showed that overall, the administration procedures were feasible. Little changes were done to improve the main study result. Modification of the instruments was made based on the researcher’s comment and suggestions, and the administration procedure was refined. The pilot study indicated the data collection for PICH should be done just before discharged and at three months. This approach was taken to avoid the probability of missing data, which were higher at six months.

As the conclusion to pilot study, the results showed that overall, the administration procedures were feasible. The pilot study indicated that the data collection for PICH patients should be done just before discharge and at three-month post PICH. This approach was taken to avoid the probability of missing data, which was higher at six months.
3.7 Study instruments

Seven instruments were used to collect the data in Phase I and II of the main pilot study. Phase I (at five-day post-PICH during the acute inpatient recovery phase): The instruments were Demographic Data, Glasgow Coma Scale (GCS), Functional Independence Measure (FIM), National Institutes of Health Stroke Scale (NIHSS), Complication Inventory Checklist (CIC), Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS), and Stroke Knowledge Questionnaire (SKQ).

3.7.1 Demographic Data

The demographic variables of the patient included age, sex, marital status, educational level, occupation and socioeconomic status. The caregiver variables collected were age, sex, marital status and relationship with stroke patients. The data of risk factors of ICH were smoking, alcohol, past health history (including hypertension, hypercholesterolemia, diabetes mellitus and heart disease) (Appendix A – Part 1.1).

3.7.2 Glasgow Coma Scale (GCS) (Teasdale & Jennett, 1974)

The Glasgow Coma Scale (GCS) (Appendix A – Part 1.1) is a standard scale that used to assess the level of consciousness (Teasdale & Jennett, 1974). It includes three items, which are eye opening, best verbal response, and best motor response. Lower scores indicate a greater degree of impairment. In this study, GCS was used as criteria for subject selection. Patients with GCS 9 or more than 9 and in recovery stages were selected as subjects in the study. Patients with a Glasgow Coma Scale (GCS) score of less than 9, with bilateral fixed, dilated pupils, and impending death were excluded (Appendix B).
The scores for GCS are listed as below:

Eye opening: Spontaneous opening = 4 score
To speech = 3 score
To pain = 2 score
None = 1 score

Best verbal response Oriented = 5 score
Confused = 4 score
Inappropriate words = 3 score
Incomprehensible sounds = 2 score
None = 1 score

Best motor response Obey commands = 6 score
Localized pain = 5 score
Non-purposeful = 4 score
Flexion to pain = 3 score
Extension to pain = 2 score
None = 1 score

The GCS is a scale that is used worldwide for determining the level of impaired consciousness, especially among those with brain injuries, and it is a valid measure of the severity of the impact from ICH stroke (Talukder, Islam, Hossain & Jahanet al., 2012). Many studies have reported that the GCS is a valid scale for determining a change in the level of awareness for a variety of neurological problems, such as subarachnoid haemorrhage (SAH) (Ogunbo, 2003) and traumatic brain injury (McLernon, 2014; Brain Trauma Foundation, 2007), drug overdose (Livingstone et al., 2000) and infections (Holdgate et al, 2006). In terms of reliability, the GCS showed a high level of agreement.
between observations and also a consistency between the scores (Kombluth J, Bhardwaj, 2011; Baker, 2008). Many studies have revealed a high interrater reliability and accuracy in the GCS scores (Teasdale, & Jennett, 1974; Baker, 2008). Studies by Heard and Bebarta in the year 2004, showed a high interrater reliability, with the kappa indicated as being in the range of 0.85 (McLernon, 2014).

3.7.3 National Institutes of Health Stroke Scale (NIHSS)(Brott et al., 1989)

The severity of neurological deficits was examined using the National Institutes of Health Stroke Scale (NIHSS) (APPENDIX A –Part 1.2). The NIHSS was originally designed as a research tool to measure the severity of strokes (Brott et al., 1989), and the examinations for this study were conducted during the hospital stay of the patients at the acute recovery phase. The NIHSS consists of fifteen (15) neurological items that include the level of consciousness, language, neglect, visual field loss, extra-ocular movement, motor strength, ataxia, dysarthria and sensory loss. The total NIHSS score ranged from 0-42, with the highest scores indicating severe neurological deficits, and the lowest score of 0 indicating the absence of neurological deficits. The original scoring levels to determine stroke severities were categorised into: Mild, ranging from 1 – 5 (>25 percentile); mild to moderate, ranging from 5-14, severe, ranging from 15 – 24 and very severe, > 25 (Brott et al., 1989 available in rehabmeasure.org). However, in this study, ataxia was excluded, thus, a total of fourteen (14) NIHSS items were used in this study. In this study, NIHSS was assessing as a baseline during early phase post PICH. The reason of excluded items 7 ataxia it is because as during acute stays of ICH patients, they usually having alteration in conscious level, having right or left hemiparesis with mild or moderate dysarthria and sensory loss, and it is difficult to obtain a score for this item. Brown (2016), stated that ataxia is scored only if present out of proportion to weakness, and ataxia cannot be tested.
on patient with presence of paresis or weakness. Even the score can be given as ataxia is absent in patient who cannot understand or paresis or paralyzed, however, this represents a redundancy in the overall score and may lead to falsely excessively high total scores (Brown, 2016). The patients usually could not follow instruction and lower ability to do movement especially among with low or moderate GCS scores. This reason supported by Goldstein et al. (1989) found that the scores of the observers with regard to limb ataxia were in poor agreement during determining the score of this item. Others study also reported that item ataxia was consistently found to be low (least) reliability indices because the scoring of these items have proven difficult in certain types of patients, especially in patients with altered conscious level and hemiparesis was stressed to the raters (Zandieh et al., 2012; Goldstein & Samsa, 1997).

Brott et al. (1989) stated that a high level of validity for the NIHSS scale (r = 0.68) was obtained when the NIHSS score was compared with the infarction volume, as measured by a CAT scan one week after the event. A study conducted by Lyden et al. (1999), which compared the score with the clinical outcome at three months, showed that there was a high validity (r=0.79), and that the correlation coefficients between the NIHSS and the Barthel Index, the Rankin Scale, and the Glasgow Outcome Scale were significant but modest in magnitude both at the baseline and two hours after a stroke (Lyden et al.1999). The original authors evaluated the reliability of the scale using the kappa statistic and found that while most items had good to excellent reliability (Cronbach alpha> 0.5), two items, dysarthria and consciousness, rated from fair to poor (Brott et al., 1989). Goldstein et al (1989) and Lyden et al. (1994), reported that of the 15 items making up the NIHSS, 13 items showed no statistical difference between assessors. The assessors had poor agreement on the score in examining facial palsy and limb ataxia (alpha < 0-3). The scores of the observers with regard to facial palsy and limb ataxia (alpha< 0.3) were in
poor agreement. The NIHSS correlated well with the clinical outcome of three months ($r = 0.79$), and the interrater reliability for the scale was high (kappa = 0.69), while the test-retest reliability was 0.66 to 0.77 (Ostwald, 2008). The reliability of the scale was tested using a correlation coefficient in the pilot study on 30 stroke patients before the main study with a Cronbach’s alpha of 0.81. A reliability coefficient of 0.81 was considered high because 0.70 is considered as an acceptable coefficient value for newly-developed instruments (Goldstein, Bartels & Davis, 1989; Lyden et al., 1999; Brott et al., 1989). Others study also reported that item ataxia was consistently found to be low (least) reliability indices because the scoring of these items have proven difficult in certain types of patients was stressed to the raters (Zandieh et al., 2012; Goldstein & Samsa, 1997).

The reliability of the Malay version of the NIHSS was tested on 30 ICH patients during the pilot study prior to data collection.

### 3.7.3.1 Reliability

The reliability of the scale was tested using the correlation coefficient in the pilot study on 30 stroke patients before the main study, and Cronbach’s alpha of 0.86 was obtained. A reliability coefficient of 0.86 was considered high because 0.70 is considered an acceptable coefficient value (Lyden et al., 1999). The reliability of the Malay version of the NIHSS was tested on 30 ICH patients prior to the data collection.

### 3.7.3.2 Test-retest Reliability

Following the reliability testing, the test-retest reliability of the NIHSS was evaluated using intra class correlation coefficient (ICC) with a 95% confidence interval. The test-retest reliability Alpha was 0.96, indicating high-strength agreement.
3.7.4 Functional Independence Measure (FIM) (Dodds, Martin, Stopor & Dego, 1993).

The patients’ early adaptation to sudden stroke-related disabilities and long-term adaptations at three months post-PICH was measured using Functional Independence Measure (FIM-ACUTE and FIM THREE MONTHS) tools (Musicco, Emberti, Nappi & Caltagirone, 2003; Ottenbacher, Gonzales, Smith, Liig, Fiedler & Granger, 2001). The Functional Independence Measure (FIM) was developed in 1983 by the National Institute on Disability and Rehabilitation Research (NIDRR) and the American Congress of Rehabilitation Medicine (ACRM) (Musicco, Emberti, Nappi & Caltagirone, 2003).

The Functional Independence Measure (FIM) consists of 18 items, which measure a patient’s degree of dependence or independence and need for care (Cournal, 2011). The FIM covers two domains during early and long-term rehabilitation, namely motor and cognitive domains. The motor function is divided into 4 sub-domains; i.e. self-care, sphincter control, transfers and locomotion, while the cognitive function is divided into 2 sub-domains, i.e. communication and social cognition (Dodds, Martin, Stopor & Dego, 1993). The scores for each item within a sub-domain were added to make up the section scores, and these scores were summed up to produce the total FIM score.

The total FIM MOTOR SCORES ranged from 91 for complete independence to 13 for complete dependence. The scoring levels could also be categorized into an independent functioning range of 65.1–91, modified dependence range of 26.1–65.0, and complete dependence on a helper range of 13.0–26.0. The total FIM COGNITIVE SCORE ranged from 35 for complete independence to 5 for complete dependence. The scoring level could also be categorized into an independent functioning range of 25.1–35.0, modified
dependence range of 10.1–25.0 and complete dependence on a helper range of 5–10
(Nilsson, Aniansson & Grimby, 2000).

The total FIM scores ranged from 126 for complete independence to 18 for complete
dependence. The scoring levels were categorized into an independent functioning range
of 90.1–126, modified dependence range of 36.1-90, and complete dependence on a
helper range of 18.0-36.

In this study, the FIM tool was used as an indicator of the patients’ adaptation to stroke-
related disabilities. The FIM tool was intended to measure what a patient was actually
able to do or to reflect the adaptation to the disability after PICH. The ratings of the
individual items focused on the amount of assistance needed by the person to complete
the activity that was being evaluated (Ottenbacher, Gonzales, Smith, Liig, Fiedler &
Granger, 2001). The patient’s ability to perform the activities was scored on a seven–level
scale representing the gradation from independent to dependent behaviour (Table 3.5).
The scoring levels were later categorized into an independent functioning range of 90.1–
126, modified dependence range of 36.1-90, and complete dependence on a helper range
of 18.0-36.
Table 3.4: Description levels of functions and their scores for the Functional Independence Measure tool

<table>
<thead>
<tr>
<th>Score</th>
<th>Independence</th>
<th>Score</th>
<th>Modified Dependence</th>
<th>Complete Dependence</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Complete Independence (Timely, Safely)</td>
<td>5</td>
<td>Supervision</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Modified Independence</td>
<td>4</td>
<td>Minimal Assistance (Patient = 75%+)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>NO HELPER</td>
<td>3</td>
<td>Moderate Assistance (Patient= 50%+)</td>
<td></td>
</tr>
</tbody>
</table>

(Dodds, Martin, Stopov&Dego, 1993)

3.7.4.1 Reliability

The FIM is valid for measuring the change in impact from a stroke. A study of stroke patients revealed that the FIM is valid for capturing minimal changes in the functional ability measure of ADL and functional abilities in the stroke population (Cournan, 2011). The FIM was considered valid because it had been tested for validity in more than 50 medical facilities across the United States and found to have faced validity (Granger, Cotter, Hamilton & Fiedler, 1993).

The reliability was tested in the pilot study with a sample of 30 in patients with intracerebral haemorrhage. The value of Cronbach’s alpha for FIM was 0.94. The interrater reliability obtained by a previous study was 0.91 (Kenney, O’ Connor &Enterlante, 2000), and the internal consistency of the total items was 0.96 (Ottenbacher, Gonzales, Smith, Liig, Fiedler & Granger, 2001).
3.7.4.2 Test-retest Reliability

The test-retest reliability of the FIM tool was evaluated and represented by the intra class correlation coefficient (ICC) with a 95 % confidence interval. The test-retest reliability Alpha was 0.90, which fell within the category of high-strength agreement.

3.7.5 Complication Inventory Checklist (CIC-ACUTE) (Langhorne et al., 2000).

The complication status of PICH patients at the acute recovery phase and at three month was identified using a Complication Inventory Checklist (Appendix A- Part 1.4 & Part 2.2). The CIC was modified based on a study by Langhorne et al. (2000). The CIC variables consisted of five categories marked by respiratory infections, urinary infections, bedsores, deep-vein thrombosis and shoulder pain. The post-stroke complications were given a score of 2 points for YES as evidence of having respiratory infections, urinary infections, bedsores, deep-vein thrombosis and shoulder pain or NO as evidence of being free from complications. The variables of stroke complications are summarized below (Table 3.5).

The instruments were revised according to the validated questionnaires suggested by a panel for this study. However, the CIC was considered as a new instrument that was purposely developed for this study, and no study had been carried out to examine the validity of the CIC. The face validity of the CIC was reviewed and analysed by an expert panel (Appendix B) for this study, and was revised according to the suggestions from the experts. No major corrections were necessary.
### Table 3.5: Definitions of post-stroke complications during hospitalization and community follow-up

<table>
<thead>
<tr>
<th>Post-stroke Complication Variables</th>
<th>During Hospitalization</th>
<th>Community Follow-Up</th>
</tr>
</thead>
</table>
| 1. Chest infection                 | Auscultatory respiratory crackles and fever or radiographic evidence, or new purulent sputum.  
- fever (T > 38 ° C)  
- leukocytosis: WBC > 10,000 cell/mm with neutrophil > 80 % | Chest infection requiring medical help and/or antibiotic treatment                      |
| 2. Urinary tract infection         | Clinical symptoms of urinary tract infection or positive urine culture  
- Fever (T > 38 ° C)  
- Urinalysis shows white blood cell count > 10 WBC                                      | Urine infections requiring medical help and/or antibiotic Treatment                   |
| 3. Pressure sore/skin break        | Any skin break or necrosis resulting from either pressure or trivial trauma (skin trauma directly resulting from falls was not included). | Any skin break or necrosis resulting from either pressure or trivial trauma (skin trauma directly resulting from falls was not included). |
| 4. Shoulder pain                   | Pain in the shoulder area requiring analgesia on 2 or more consecutive days.           | Pain in the shoulder area requiring analgesia on 2 or more consecutive days.         |


#### 3.7.5.1 Reliability

The reliability was tested in this pilot study with a sample of 30 inpatients with ICH. The value of Cronbach’s alpha for the Complication Inventory Checklist was 0.55.

#### 3.7.5.2 Test-retest Reliability

Following the reliability testing, the test-retest reliability of the Complication Inventory
Checklist (CIC-ACUTE) was evaluated and represented by the intra class correlation coefficient (ICC) with a 95% confidence interval. The test-retest reliability Alpha was 0.55, which fell within the category of fair strength agreement.

3.7.6 Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS) (Kronish et al., 2012)

In terms of the depression status, there are many questionnaires available to determine depression such as the Zung (1965) and Hamilton, (1960) scales and the Centre for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977) and the Health Questionnaire (PHQ) (Spitzer et al., 1999) (Appendix A - Part 1.5 & Part 2.3). The Patient Health Questionnaire 9-item depression scale or PHQ-9 (Spitzer, et al 1999), a self-administered depression screening and diagnostic tool, was used in this study. All the subjects were screened for depression with the PHQ-9, a 9-item scale that assesses the 9 depression symptoms for frequency of occurrence during the previous two weeks. The PHQ-9 can be used as a screening tool, with the total score ranging from 0 (no depression symptoms) to 27 (all symptoms occurring daily). A PHQ-9 score of 10 has been found to have 88% sensitivity and 88% specificity for a diagnosis of major depression. The PHQ-9 can also be used as a diagnostic assessment, with major depression diagnosed if five or more of the nine symptoms have been present at least more than half the days of the past two weeks, and one of these symptoms are either depressed mood or anhedonia.

The PHQ-9 has performed with a similarly high diagnostic accuracy for both major depression and any depression in patients with PSD, and has performed just as well with stroke survivors as it has with the general medical outpatient population in which it was developed. The performance of the PHQ-9 does not differ with age, ethnicity, or gender.
The PHQ-2 has also performed quite well as a depression-screening tool, with nearly an identical performance to the PHQ-9 in identifying subjects with any depression. However, for a diagnosis and more complete clinical evaluation of depression symptoms, those scoring three on the PHQ-2 should be administered the additional seven items to complete the PHQ-9 (Williams et al., 2005).

A structured questionnaire was designed to identify symptoms of depression and for diagnosing depression, and it was validated for use in post-stroke patients (Kronish et al., 2012). Each of the 9 items asked for each of the symptoms of depression and scored according to the 4 point- Likert scale from (0) Not at all (1) Several Days (2) More Than Half the Days to (4) Nearly Every Day. The scores measured severity of depression range from 0 (absence of depressive symptoms) to 27 (most severe depressive symptoms). The subtotal scores of severity of depression were categories using four levels (Table 3.6).

A number of studies have been published in the West on the validity and reliability of the PHQ-9 as a diagnostic measure as well as its utility in assessing depression severity and in monitoring treatment responses (Kronish et al., 2012). However, as far as is

<table>
<thead>
<tr>
<th>Table 3.6: Severity of depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild depression</td>
</tr>
<tr>
<td>Moderate depression</td>
</tr>
<tr>
<td>Moderately severe depression</td>
</tr>
<tr>
<td>Severe depression</td>
</tr>
</tbody>
</table>

(Pfeil et al., 2009)
known, no study has examined the validity of the Malay version of the PHQ-9 in Malaysia. The face validity of the Malay version of the Patient Health Questionnaire 9-item depression scale (PHQ-9-DS) was reviewed and analysed by an expert panel (Appendix A) for this study, and was revised according to their suggestions, with no major corrections.

A number of studies on the validity and reliability of PHQ-9, as a diagnostic measure as well as its utility in assessing depression severity and in monitoring treatment responses have been published in western countries (Poongothai et al 2009). However, to our knowledge, no study has examined the validity of the PHQ-9 in Malaysia using Malay language. The instruments were revised according to the expert’s suggestions.

3.7.6.1 Reliability

The reliability of the PHQ-9-DS was tested on ICH patients and their caregivers. Cronbach’s alpha was calculated for the internal consistency using correlation coefficients, and it was found that the Cronbach's alpha was 0.92.

3.7.6.2 Test-retest Reliability

The test-retest reliability of the PHQ-9-DS was evaluated and represented by the intra class correlation coefficient (ICC) with a 95% confidence interval. The test-retest reliability Alpha was 0.55, indicating fair strength agreement.

3.7.7 Stroke Patients and Caregivers’ Stroke Knowledge Questionnaire (SKQ) (Kotari, 1977).

PICH patients and their relatives were assessed on their level of knowledge regarding stroke disease at two-week post-PICH and prior to discharge. The questionnaire was
developed from an instrument used by Kotari and co-workers at the University of Cincinnati (Hoffmann et al., 2007; Cross & Walker, 2008; Lindsay et al., 2008; Weltermann et al., 2000). The Stroke Knowledge Questionnaire assessment was composed of 7 items: their understanding of the symptoms of stroke, the risk factors, the body part affected by the stroke, and the actions required in case of a recurrent stroke, the follow-up and communication with the doctor, the way of controlling/managing depression, how to manage the disease in general, and how to manage symptoms of post-stroke complications (Appendix 1.6).

The variables for stroke in the Stroke Knowledge Questionnaire were summarized in Appendix 1.7. The YES KNOWLEDGE (or excellent strong knowledge) was classified as follows: if they (1) know at least 3 stroke symptoms (good symptom knowledge), (2) know at least 3 stroke risk factors (good risk factors knowledge), and (3) know that immediate hospital admission or call to the hospital emergency department in case of a stroke is required (good action knowledge), (4) know the importance of follow-up, (5) know of at least 3 ways to prevent and manage post-stroke depression, (6) know of at least 2 ways to manage the general illness during post-stroke and (7) know of at least 3 ways to manage symptoms of post-stroke complications. An answer guide was prepared to aid during the data collection (Table 3.7).

The stroke patients and caregiver were scored as having (NO knowledge) if they did not (1) know at least 3 stroke symptoms (good symptom knowledge), (2) knew at least 3 stroke risk factors (good risk factors knowledge), and (3) knew that immediate hospital admission or call to the hospital emergency department in case of stroke (good action knowledge), (4) knew the importance of follow up, (5) knew at least 3 ways how to prevent and manage depression post stroke, (6) knew at least 2 ways how to manage the general illness post stroke and (7) knew at least 3 ways how to manage symptom of post stroke complications.
The total score of stroke knowledge of stroke and their caregiver are 30 and then classified under four categories; which were ‘No stroke knowledge’ ranging from 0-1 = 0-14.2 percentile), ‘Low knowledge’ (2-3 = 28.5-42.8 percentile), ‘Average knowledge’ (4-5 = 57.1-74.1 percentile) and ‘High knowledge’ (6-7 = 85-100 percentile).

The instruments were revised according to the expert’s suggestions. Reliability of the Stroke Knowledge Questionnaire was tested on 30 ICH patients and their caregivers. Cronbach’s alphas were calculated for internal consistency using correlation coefficients and found that the Cronbach’s Alpha was .801.

### 3.7.7.1 Reliability

The reliability of the Stroke Knowledge Questionnaire was tested on ICH patients and their caregivers. Cronbach’s alpha was calculated for the internal consistency using correlation coefficients, and it was found that the Cronbach's alpha was 0.93. The inter-items correlation is presented in Table 3.10. The results showed that there was a high correlation between the items in the Stroke Knowledge Questionnaire.

### 3.7.7.2 Test-retest reliability

Following the reliability testing, the test-retest reliability of the Stroke Knowledge Questionnaire (SKQ) was evaluated and represented by the intra class correlation coefficient (ICC) with a 95% confidence interval. The test-retest reliability for Alpha was 0.55, which placed it in the category of fair strength agreement.
3.8 Data Collection Procedure

The selection of samples for this study was according to the sampling criteria in the two phases; Phase I and Phase II. In Phase I, the data collection on the post-PICH patients was done within two weeks of admission at the acute inpatient recovery phase. The variables gathered included patient demographics, clinical characteristics, length of hospitalization, ICH treatments, neurological status, post-stroke complications (acute), post-stroke depression (acute), patients and caregivers’ stroke knowledge and acute functional status (FIM ACUTE) (Figure 3.2). The data collection in Phase II was performed at three-month’s post-PICH at the patients’ homes. The researcher went to the patients’ houses at the given addresses. The data collection procedure was done according to the same procedure as in Phase I. The variables collected included post-stroke complications (long-term), post-stroke depression (long-term) and adaptation outcomes to long-term stroke-related disabilities (Figure 3.2).
Phase I: Acute recovery phase post-stroke
(i) Demographic data
(ii) Clinical characteristics
(iii) Neurological Status (NIHSS)
(iv) Post-stroke Complications (CIC-ACUTE)
(v) Post-Stroke depression (PHQ-9-DS)
(vii) Patients and caregivers’ stroke knowledge (SKQ)
(viii) Early adaptation (FIM)

Medical folder review
(i) Collect demographic data and clinical characteristics from medical records of patients
(ii) Assess evidence of neurological deficits
(iii) Assess post-stroke complication
(iv) Assess depression status
(v) Assess level of stroke knowledge
(vi) Assess functional activities

Phase II: Follow-up at three months post-stroke at home
(i) Adaptation Outcome (FIM)
(ii) Post-Stroke complication (CIC AT THREE MONTHS)
(iii) Post-stroke depression (AT THREE MONTHS)

Questionnaire and physical examination
(i) Assess post-stroke complication
(ii) Assess depression status
(iii) Assess functional activities

Selecting patients
(i) Moderate and mildly severe – GCS > 9 and above (GCS)
(ii) Admitted in acute recovery phase

A Glasgow Coma Scale (GCS) score of < 9, with bilateral fixed, dilated pupils, and died.

Obtaining written consent for participation from each patient or family member

Figure 3.2: Data Collection Flowchart
3.8.1 Selecting patients according to the inclusion criteria

The selection of samples was based on the categories of severity of PICH that were determined using the GCS during the acute inpatient recovery phase. The patients who were diagnosed with PICH were reviewed in relation to the status of their illness according to the Glasgow Coma Scale documentation in their records and were chosen as the sample for this study if their GCS score was at least 9 and above.

A visit was then made to those patients who met the inclusion criteria in order to explain the purpose of the study and their possible contributions. Furthermore, the ethical considerations involved were explained to the patients, such as the fact that their involvement in this study was on a purely voluntary basis, and that they had the right to withdraw at any time without their present and future healthcare services being affected in any way. The patients were encouraged to ask questions and raise any queries at any time before or during the interview or assessment. Arrangements were made to conduct the assessment in a quiet area to ensure privacy. The written consents of the patients or their caregivers were obtained prior to the data collection. The data collection was conducted through the use of questionnaires or a checklist, and was supplemented with physical assessments for the clinical data (Appendix A). Face-to-face interviews were used during the data collection to obtain accurate data from the patients and their caregivers. These were supplemented by observations and physical assessments of the patients, including neurological assessments and observations of functional abilities and possible post-stroke complications, such as chest infections, urinary tract infections, bedsores, deep-vein thrombosis and shoulder pain. The assessment was performed by the researcher in the examination room to ensure privacy. The findings from the assessment were verified against the written assessments in the patients’ medical records.
3.8.1.1 Demographic Data

The patient’s demographic variables included age, sex, marital status, educational level, occupation and socioeconomic status. The risk factors of ICH are smoking, alcohol, status of previous health history (including hypertension, hypercholesterolemia, diabetes mellitus and heart disease).

3.8.1.2 Assessment of severity of neurological deficits

The severity of the neurological deficits was assessed. Interviews, observations and examinations were conducted according to the assessment criteria of the NIHSS, which consisted of 14 neurological items, including levels of consciousness, language, neglect, visual-field loss, extra ocular movement, motor strength, dysarthria, and sensory loss.

The examination and scoring were performed by checking the consciousness level, which included the level of responsiveness, the responses to two questions, and the ability to follow the commands given. After that, the patient was checked for the position of the eyes and the movement for gaze by looking at the position of the eyes at rest, and the spontaneous eye movements to the left and right. The patient was then asked to look to the left or right. Only horizontal eye movements were tested. In order to check the visual field, the patient was asked to count the fingers in all the four quadrants. The checking of facial movement was done by looking at the patient’s face and noting any spontaneous facial movement and response to commands by asking the patient to smile, to puff out his or her cheeks, to pucker and to close his or her eyes forcefully.

Following that, the PICH patient was assessed in terms of the motor functions of the arm (left and right) by asking the patient to extend his/her arm in front of the body at 90
degrees (if sitting) or 45 degrees (if supine). To assess the motor functions of both legs, the patient was asked to hold the outstretched leg 30 degrees above the bed for five seconds. After completing the motor function assessment, the patient's sensory functions in the proximal parts of all four limbs were examined with a pin, and they were asked to describe how they felt about the stimulus. Their language function was tested by showing the patient standard groups of objects and making them read a series of sentences. Later, the patient was asked to read and pronounce a standard list of words from a sheet of paper to determine the problem of dysarthria. The last NIHSS assessment involved examining the patient's ability to recognize simultaneous cutaneous sensory and visual stimuli from the right and left sides. (The details of the NIHSS examination and the scores are given in Appendix C).

3.8.1.3 Assessment of status of post-stroke complications

The patient was then assessed on the status of acute stroke complications using the Complication Inventory Checklist (CIC-ACUTE), which consisted of 4 categories of evidence of respiratory infections, urinary infections, bedsores, and shoulder pain. Lastly, it was also observed whether the patients were experiencing pain in the shoulder area requiring analgesia on two or more consecutive days.

During the follow-up with the patients at home, it was determined whether complications occurred at three-month post-PICH using the Complication Inventory Checklist Post-Discharge (CICPD). The patients were checked for evidence of chest infections. They were considered as having a chest infection if they had symptoms of it, had a positive chest assessment and required medical help and/or antibiotic treatment. The PICH patients were also checked for problems with urine elimination or infection, and if they required medical help and/or antibiotic treatment during their rehabilitation at home.
After that, it was determined whether the patients had any skin breaks or necrosis resulting from either pressure or trivial trauma (skin trauma as a direct result of falls was not included). It was also determined whether they had any episodes of blood clots in the leg requiring medical treatment, and lastly whether they experienced any pain in the shoulder area requiring analgesia on two or more consecutive days.

3.8.1.4 Depression Status

The PHQ 9-item Depression Scale (PHQ 9-item DS) (Kronish et al., 2012) questionnaire was used to evaluate the presence of depressive symptoms during the first 2 weeks after PICH and at the follow-up after three months. The assessment was done by the researcher herself on both phases on the patients with some information obtained from patients’ caregivers. The assessment was done using in person interview, observations and examinations in relation to have a clear evidence of depression according to criteria of the PHQ 9-itemDS.

3.8.1.5 Stroke Knowledge

The Stroke Knowledge Questionnaire (SKQ) (Kotari, 1977), was used to determine the level of knowledge of the patient and their family caregivers regarding stroke and the management of PICH by asking open-ended questions regarding stroke symptoms, risk factors, and the body parts that are affected by a stroke. In the close-ended questions, they were asked about the appropriate action in the event that stroke symptoms occurred. The patients and their caregivers were also questioned as to whether they were aware of the importance of following up and communicating with the doctor, and the ways to prevent depression and post-stroke complications.
3.8.1.6 Early Adaptation (Functional Status at the Acute Phase) and Later Adaptation Outcomes (Functional Status at Three Months)

The early adaptation and later adaptation outcomes of the disabilities resulting from stroke-related disabilities post-PICH were determined using the Functional Independence Measure (FIM acute) tool (Dodds, Martin, Stopor & Dego, 1993). The FIM acute domains were assessments of the motor and cognitive functions, with the motor function variables, including self-care, sphincter control, transfers and locomotion, while the cognitive function variables included communication and social cognition. Using FIM, the patients were reassessed in terms of their level of independence in performing functional activities.

The early functional adaptation (acute phase) was assessed during acute inpatient recovery phase within day 2 to 14 after admission or prior discharge, and the later (3 month) functional adaptation outcome was determined during a follow-up at the patients’ homes in the community areas (at three months post-PICH). The patient’s ability to perform functional activities in the physical and cognitive domains was assessed using FIM.

3.9 Data Analyses and interpretation of results

All the data were entered and analysed using the Statistical Package for Social Science (SPSS) version 19.0 for Windows. The data were checked and cleaned, while the distributions and frequencies were examined.
Descriptive statistics were used to explore the mean, standard deviation (SD) or median and interquartile range (IQR) for the numerical variables. The categorical variables were presented in the form of frequencies and percentages.

In order to confirm that the patients showed functional improvements after the rehabilitation treatment, the FIM scores obtained at the early adaptation were compared with the long-term adaptation post-PICH. A paired t-test was applied to test the significant differences between the total FIM, the cognitive FIM, and the motor FIM scores between the acute and long-term stages.

The correlation between age, severity of PICH (GCS), severity of neurological deficits (NIHSS), acute post-stroke depression, and stroke knowledge, with total early adaptation was performed using Pearson’s correlation analysis.

Univariate analysis between selected variables with early adaptations and long-term adaptations were tested using Simple Linear Regression.

In the multivariate analysis, a multiple linear regression analysis was used to measure multiple associations between early adaptation and a group of 15 potential predictor variables. Multiple linear regressions were also used to determine the factors that affect the long-term adaptation process (Table 3.8). The level of significance was set at 0.05. Beta coefficients with 95% confidence intervals were obtained for those factors that were significant in the final model.
3.10 Ethical Considerations

The data was collected after approval was obtained from the Human Research and Ethical Committee, USM and from the Ministry of Health (Appendix). Written informed consent either from the patients or the patients’ family caregiver was obtained prior to the commencement of the interviews. The consent form included statements about the researcher, purpose of the study, assurance of the patients’ anonymity, voluntary nature of the participation in the study, freedom to withdraw from the study at any time, anticipated usefulness of the results, and the name and address of the researcher and other contact persons (Appendix A).

There might have been some questions that were sensitive or could lead to emotional discomfort during the assessment procedure. Therefore, before the assessment started, it was explained to the patients that they had the right to refuse to answer any questions, which made them feel uncomfortable. The patients were also informed that they had the right to ask questions at any time before or during the interview or assessment. If the patients showed any emotional feelings during the assessment, the assessment was discontinued, and they were comforted and allowed to express their feelings. Those patients who showed signs of depression were referred to the nurse in the ward or at the community area or were referred to the hospital.

Confidentiality and anonymity were strictly assured. The patients’ personal particulars such as their name, registration number, address and telephone number were kept in file notes for each individual participant; a code number was used instead of the sample’s name and it was restricted to the researcher’s assessment only. The questionnaires were coded according to the sequence of the samples. A code number was put in every questionnaire and was deleted thereafter.
3.11 Summary

To summarize, this study involved patients with primary ICH who were in the acute inpatient recovery phase at HUSM, Kelantan and HSNZ, Terengganu. The patients were followed up at three months at home during the rehabilitation phase. It was designed to investigate the relationship between changes in the neurological status, post-stroke complications, depression status of post-primary intracerebral haemorrhage patients, and the degree of adaptation to stroke-related disabilities in the acute inpatient recovery phase (Early Adaptation and at three months (Long-term Adaptation Outcomes)). Adaptation is measured according to the physical and cognitive domains of the level of independence or ability to participate in functional activities.

Seven instruments were used to collect the data in phase I, namely (i) Demographic Data, (ii) Glasgow Coma Scale (GCS), (iii) National Institutes of Health Stroke Scale (NIHSS), (iv) Complication Inventory Checklist (CIC-ACUTE), (v) Functional Independence Measure, (vi) Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS), and (vii) Stroke Knowledge Questionnaire (SKQ). In phase II, four instruments were used, namely (i) Complication Inventory Checklist (CIC-AT THREE MONTHS), (ii) Functional Independence Measure, (iii) and Patient Health Questionnaire 9-item Depression Scale (PHQ-9-DS).