CHAPTER 3 METHODOLOGY

3.0 Introduction

This chapter provides the description and the rationale behind the selection of the study design, setting, sampling, instruments, educational intervention and the method of data collection. Measures taken to minimize the potential bias are also highlighted to ensure that the study was carried out in an ethical and rigorous manner.

3.1 Study design

This is a longitudinal study conducted using a quasi-experimental, non-equivalent pre-test-and post-test control group design. A quasi-experiment is an empirical study used to estimate the causal impact of an intervention on its target population. A quasi-experimental research design was chosen based on the non-random distribution of subjects to either the experimental or the control group. The participants were divided into two groups according to patient dialysis schedules. All patients who attended dialysis sessions on Mondays, Wednesdays and Fridays (MWF) were assigned to the experimental group, while patients who came for dialysis sessions on Tuesdays, Thursdays and Saturdays (TTS) were designated as the control group. This was to ensure that only subjects from the experimental group received the educational intervention and that the control group participants were not privy to details of the intervention to avoid diffusion of information. A longitudinal study involves repeated observations of the same variables over a period of time.

Baseline data on outcome measures - IDWG, MPBP and RFA - were collected over duration of three months for both groups before the educational intervention. The experimental group received an education intervention on the importance of fluid control, the amount of fluid intake and complications that may occur due to excessive fluid in the body. The outcome measures were assessed after one-month, three-months and six-months post-intervention.

3.2 Study setting

The study area was in the Klang Valley. A total of nine public hospitals and two teaching hospitals providing dialysis services for the renal failure patients were invited to take part in the study. The nine public hospitals were Kuala Lumpur Hospital, Ampang Hospital, Selayang Hospital, Sungai Buloh Hospital, Tengku Ampuan Rahimah Hospital, Banting Hospital, Kajang Hospital, Serdang Hospital and Putrajaya Hospital while the two teaching hospitals were University Malaya Medical Center and Universiti Kebangsaan Malaysia Medical Center. Of these, only four public hospitals and one teaching hospital consented to participate in this study. The four public hospitals were Kuala Lumpur Hospital (HKL), Serdang Hospital (HS), Ampang Hospital (HA), and Putrajaya Hospital (HP) and University Malaya Medical Center (UMMC).

3.2.1 Study hospital

Kuala Lumpur Hospital (HKL), which is located in the center of Kuala Lumpur, is currently the largest hospital under the Ministry of Health (MOH), and it is considered one of the biggest hospitals in Asia. It is a government funded hospital as well as a tertiary referral hospital with 86 wards and 2,500 beds. Back in the 1980s, HKL was the first hospital to provide haemodialysis treatment to patients with kidney failure patients in Malaysia.

Serdang Hospital (HS) is a government-funded multi-specialty hospital with 620 beds and is located in the district of Sepang which is in the state of Selangor, which commenced operations on December 15, 2005. Serdang Hospital is one of the pioneering electronic-system hospitals whose management heavily relies on information technology and uses the 'Total Hospital Information System'. Serdang Hospital also provides daycare services to hemodialysis and continuous ambulatory peritoneal dialysis patients.

Ampang Hospital (HA) is a 147-bedded hospital which is located in the heart of Kuala Lumpur city. The hospital provides a full range of state-of-the-art diagnostic and treatment facilities to its patients and includes specialized outpatient as well as inpatient services. The Hemodialysis Centre provides outpatient treatment catering mostly to the lower and middle-income groups.

Hospital Putrajaya (HP) is a 272-bedded hospital located in the new government administrative area of Putrajaya in the district of Sepang, Selangor. The hospital provides secondary care services with an emphasis on daycare management. The nephrology unit of this hospital provides dialysis treatment and outpatient services for renal failure patients. Hospital Putrajaya operates and is managed based on the Total

Hospital Information System (T.H.I.S) concept. It is poised to be the leading hospital of its class and to be the model hospital for the future generation of hospitals of this type.

University Malaya Medical Center was previously known as University Hospital Kuala Lumpur. It is under the Ministry of Education and functions as the teaching hospital for the oldest university in Malaysia. It was established back in 1968 and it is the oldest hospital in the country. University Malaya Medical Center provides services to over 900 inpatients and a maximum of 1500 outpatients daily. The Dialysis Unit is affiliated with the hospital and consists of haemodialysis, peritoneal dialysis and renal transplant sections. There are twenty-four haemodialysis machines in an open daycare area, with 6 other haemodialysis machines in another room, a single room for infectious cases, as well as an additional room for continuous ambulatory peritoneal dialysis (CAPD) and a facility for renal transplants. All visits in this unit are managed on an outpatient basis. On average, there are about 80 to 90 patients who undergo haemodialysis treatment per day at the dialysis unit between 7am to 9pm. Even though there are differences in the physical setting in these hospitals, the procedures involving patient admission and the process of receiving patients for their haemodialysis treatment are similar.

Nurses typically assess all patients who come to the dialysis unit before starting them on their haemodialysis treatment. All nurses carry out pre-dialysis assessments on the haemodialysis patients by conducting general health and wellness assessments, as well as the assessment of any intradialytic and interdialytic problems. Weight and blood pressure is taken before and after the dialysis treatment. Ambulatory patients use a standing weighing scale for weight taking while patients who require assistance use the sitting weighing scale for weight measurement. Assessment of weight before dialysis is essential to allow the nurses to determine the amount of fluid that needs to be deducted

from ‘dry weight’ during dialysis. Increased interdialytic weight is used to assess the fluid accumulated or weight gain between dialysis treatments. A general rule of thumb is that for every kilogram of weight increase from dry weight, one liter of fluid needs to be removed during dialysis. Patients’ post-dialysis weight is measured to determine the amount of fluid removed during dialysis and to ensure the dry weight is achieved at the end of the dialysis session.

An automated blood pressure set is used to measure the pre- and post-dialysis blood pressure. The pre-dialysis blood pressure is recorded as a baseline measurement and compared to post-dialysis blood pressure. It has been reported that blood pressure may rise in patients who have an overloaded circulating volume or high interdialytic weight gain, or a weight gain of more than 2.0 kilograms (Thomas, 2002).

3.3 Population and Sample

3.3.1 Target population

There were about 1,900 patients receiving acute and chronic haemodialysis treatment at all five study hospitals. At the time of the study, there were about 500 patients from Kuala Lumpur Hospital, and Serdang Hospital, and 300 patients from Putrajaya Hospital, Ampang Hospital and University Malaya Medical Center receiving haemodialysis treatment. The target population included adult patients receiving long-term haemodialysis treatment with three dialysis sessions weekly at any of the study hospitals. The total number of chronic dialysis patients from the five study hospitals was 329. A total of 74 were from Serdang Hospital, 48 from Ampang Hospital, 48 from University Malaya Medical Center, 120 from Kuala Lumpur Hospital and 39 from Putrajaya Hospital (Refer to Table 3.1).

3.3.2 Sample criteria

All adult patients on chronic haemodialysis for more than six months were sampled from dialysis units of participating hospitals. The specific time frame of six months was chosen for the purpose of stabilizing dry weight and blood pressure.

Inclusion criteria:

- Patients must be literate either in English or Malay language.
- Patients must be independent and care for their own dialysis needs.
- Patients must be a regular unit attendee i.e. three times a week for haemodialysis.
- An absence of any active malignant, infectious, or psychiatric disease.
- No medical problems that require hospitalization.

Exclusion criteria:

- Patients who need assistance with their daily activities and treatment therapy.
- Hospitalization due to severe illness in the past three months.
- Pregnancy.
- Patients with bilateral arterio-venous fistula.

3.3.3 Sample size

Convenience sampling was used due to the limited availability of target population and subject sampled according to inclusion criteria set earlier.

Roasoft sample size calculator (2004) was used to calculate the sample size for the survey. The calculation was based on an estimated total population size of 330, with a 5% margin of error, confident interval of 95%, and 50% response distribution, for which the minimum recommended sample size was 178. There were a total of 329 chronic haemodialysis patients at the five study hospitals, and after a selection based on the inclusion criteria, 291 subjects were recruited for the survey. However, 29 patients dropped out during the intervention phase due to unforeseen circumstances: deaths (n= 24), patient transfers (n= 2), and patients being switched to other treatment options (n= 3). Finally, 262 participants were recruited for the study, which included 145 subjects in the experimental group and 117 subjects in the control group.

In order to detect the differences in patient compliance between the two groups and the effect of the educational intervention, the Cohen (1988) Power Table was used for effect size, and ‘d’ was used to calculate the sample size.

Cohen (1988) proposed a medium effect size as desirable as it approximates the average size of the observed effects in various fields. Cohen (1988) also argued that a medium effect size could represent an effect that would likely be “visible to the naked eye of a careful observer”.

Sample size calculation using d = 0.4

According to Cohen (1988), to achieve a power of 0.80 with a medium effect of 0.40 at a 5% level of significance, the sample size required for each group is 99. Allowing for an attrition rate of 20%, the estimated sample would be 120 for each group, or a total of 240 patients for the entire study.

Two groups of patients attended haemodialysis treatments three times a week. The first group which came in for treatment on Mondays, Wednesdays and Fridays was referred to as the MWF group. The second group of patients which came in on Tuesdays, Thursdays and Saturdays was named the TTS group. The MWF group (n = 145) was the experimental group while the TTS group (n = 117) was the control group. The total sample size is summarized in Table 3.1

Table 3.1: Frequency distribution of total sample recruited

	HOSPITALS	Acute and chronic patients: n	No. of chronic HD patients: (Target)	Recruited n=291 (Survey) :	Recruited: n=262 (education intervention)
1.	Serdang	500	74	69	Dropped out : 29
2	Ampang	300	48	41	Death :24
3	UMMC	300	48	43	Transfer to other dialysis center : 2
4	Kuala Lumpur	500	120	109	Renal transplanted :2 Peritoneal dialysis :1
5	Putrajaya	300	39	29	
	Total patients:	1900	329	291 Experimental:154 Control:137	262 Experimental:145 Control:117

3.4 Instruments

3.4.1. Questionnaire

The questionnaires used in this study consisted of a set of close-ended questions with dichotomous responses of either a 'Yes' or a 'No'. This questionnaire was translated into two major languages which was English and Malay Language. The researcher did the Malay Language translation and which was checked by a lecturer from the Department of Malaysian Languages and Applied Linguistics, Faculty of Languages & Linguistics, University Malaya. Patients from the pilot study verified the clarity of the questionnaire and its translated versions.

Patient knowledge on fluid and salt control was assessed using a questionnaire (Appendix A). The questionnaire consisted of two parts. Part A focused on fluid overload experiences and sources of information on fluid and salt control while Part B assessed patient knowledge on fluid and salt control which contained eight general knowledge questions on dialysis, fluid and salt intake, as well as tips on fluid and salt control.

There were eight questions related to knowledge, which included the purpose of the treatment (Q1), the importance of fluid control (Q2), the amount of fluid intake and salt per day (Q3 & 4), the weight gain between dialysis intervals (Q5), the awareness on the dangers of fluid overload (Q6), the type of food to consume (Q7) and methods to control fluid intake (Q8). There were two response options (Yes or No) for all the 8 questions. Respondents needed to answer 'Yes' (correct answer) for the positive questions (Q1, Q4-Q6 & Q8) and 'No' (correct answer) for the negative questions (Q2-Q3 & Q7). Every correct answer was given 1 mark, with a total of 8 marks (score

ranges from 0-8) for the knowledge component. The level of knowledge was further categorized and compared to the midpoint scores (4 marks) of the total marks. Participants were considered to have good knowledge with knowledge scores of five and above (5-8 points), while knowledge scores of four and below (0-4) categorized as poor knowledge.

3.4.2 Questionnaire Validity and Reliability

Validity refers to the accuracy of a measurement tool, and its ability to measure what is supposed to be measured. There was no study reported measurement of knowledge on fluid and salt intake locally to our best knowledge, therefore there was no published questionnaire found. The questionnaire was designed based on a teaching plan, literature, Clinical Practice Guidelines (MOH, 2004) and professional consultations with the purpose of assessing the level of patient knowledge on fluid and salt control. The questionnaire was presented and the content validated by an expert panel. The panel consisted of five experts, namely a nephrologist (n = 1), renal clinical nurse specialists (n = 2) and dieticians (n = 2). After the validation, the questionnaire was pilot tested with ten stable hemodialysis patients from a private setting. Based on the remarks from the expert panel and feedback from the pilot test, the questionnaire was modified accordingly. The researcher and a trained renal nurse offered clarification and explanation of the questionnaire during the data collection process.

Reliability estimates the consistency of a measurement tool, to ensure that the instrument measures the variable the same way each time it is used under the same conditions with the same subjects. The same set of questionnaires were used twice to assess knowledge at the pre- and post–intervention phase in the same group of participants. Test-retest assessment was used to determine the reliability of the instrument under similar conditions at least twice. The questionnaire was piloted using 40 participants from Kuala Lumpur Hospital and University Malaya Medical Center. The interval of repeated administration of the instrument was three weeks. Knowledge scores from the two repeated tests were compared using Pearson correlation coefficient. A positive relationship was noted for the total knowledge scores from Time 1 and 3 weeks later at Time 2 ($r = 0.70$, $p<0.001$). Correlations between the eight items ranged from 0.24-0.77 with significant levels of $p<0.05$. The correlation coefficient between the two scores at different intervals was high ($r = 0.70$), which indicated good test-retest reliability.

Cronbach's alpha was used to assess the internal consistency reliability of the items. Ideally the alpha should be positive and greater than 0.70 in order to provide good support for internal consistency reliability. Cronbach's alpha reliability test was conducted on twenty items in the questionnaire and for forty subjects from the pilot study, and the results showed $\alpha = 0.82$.

3.4.3 Patient Data Collection Sheet

The Patient Data Collection Sheet was developed based on routine particulars from patient folders and haemodialysis treatment records. The researcher completed the details in the Patient Data Collection Sheet (Appendix B) which contained information such as the patient's socio demographic status and medical data.

Section 1: Social-demographic data and medical data

The questionnaire contains six items on patient demographic background variables: age, gender, ethnicity, educational level, employment and marital status. The disease related variables included the duration of dialysis, type of concurrent disease, anti-hypertensive therapy and the number of anti-hypertensive medication.

Section II: Pre-intervention data (Baseline data)

The pre-intervention data included previous post-dialysis weight, pre-dialysis weight, weight gain, and adherence to weight restrictions, previous post-dialysis blood pressure and pre-dialysis blood pressure. The three-month baseline data was collected before the initiation of the educational intervention. There were a total of 40-dialysis sessions from August to October 2010. Its purpose was to obtain baseline data to determine fluid compliance status pre- and post-intervention particularly for the experimental group.

Section III Post - intervention data

The post-intervention data collected was the same as the baseline data, but was collected at three different intervals, namely at 1-month, 3-month and 6-month. The data collection started only after the completion of the educational intervention. For example, assuming the educational intervention was completed in March 2011, the 1-month interval was scheduled in April 2011, the 3-month interval in June 2011 and the

6-month interval in September 2011. There were a total of thirteen measurements collected at each interval.

3.5 Data collection method

The study was conducted in two phases - Phase 1 and Phase 2.

3.5.1 Phase 1: Survey and retrieve information from patients' record

There were a total of five study settings. The data collection process did not start simultaneously because of the differences in the time taken to obtain approval to conduct the study by the various hospitals. The data collection for the survey started in December 2009 and ended in October 2010. The researcher took about one month to complete the survey in each hospital. The survey commenced in University Malaya Medical Center (3rd to 24th December 2009), followed by Kuala Lumpur Hospital (1st to 30th March 2010), Putrajaya Hospital (5th to 23rd April 2010), Ampang Hospital (6th to 24th September 2010) and lastly by Serdang Hospital (4th to 26th October 2010).

The survey included all chronic haemodialysis patients who fulfilled the inclusion criteria of this study (N = 291). The purpose of this survey was to explore patient knowledge on fluid and salt control, and the source of information they received. The survey was conducted using a structured questionnaire interview method. The survey was an interviewer administered questionnaire as the majority of patients had an arterio-venous fistula (AVF) on their dominant hand, which made it inconvenient for them to hold a pen to answer the questionnaire during dialysis. Each interview session took about 5 to 10 minutes to complete but this varied among participants.

All chronic patients had an individual haemodialysis record. Patient hemodialysis records were reviewed by the researcher. The most recent records for the past three months (August – October 2010) were documented as the baseline data. The baseline data included previous post-dialysis weight, pre-dialysis weight, interdialytic weight gain, adherence to weight gain, previous post-dialysis blood pressure, and predialysis blood pressure.

3.5.2 Phase 2: Educational intervention

The educational intervention included an individual teaching, a Patient Information Booklet and weekly reinforcement. The duration of the educational intervention was three months. It started in January 2010 and ended in February 2011 for all five hospitals. The teaching intervention started with University Malaya Medical Center (January to March 2010), Kuala Lumpur Hospital (April –June 2010), Putrajaya Hospital (June to August 2010), Ampang Hospital (October to December 2010) and Serdang Hospital (December 2010 to February 2011).

Two control measures taken during the interventional phase included control of patient sodium levels and having no additional educational activities in both the study groups to ensure the effectiveness of the intervention.

The entire cohort used preset sodium of 140 mmol/L in the dialysate. The experimental group was informed that the amount of salt allowed was between 2 to 4 grams (½ to 1 teaspoon) per daily intake, based on the practice guidelines. The sodium level in the dialysate serves as a control variable to minimize the impact of thirst and drinking behavior among the haemodialysis patients. As suggested by Shaldon (2000), dietary sodium chloride restriction may be the most effective way to control hypertension

among end stage renal disease patients. In addition, Mailloux (2000) also proposed that salt restriction of 750 to 1000 mg/day might help decrease thirst and control interdialytic weight gain.

The researcher explained the purpose of the study and the teaching intervention to the ward sister/ ward manager. They were requested not to provide any information to patients during the two phases until the post-intervention data collection was completed.

3.5.2.1 Teaching plan and guides

The education intervention was introduced to participants in the experimental group for three months. A structured teaching plan was developed based on the literature review (Pryer, 2005), professional consultations and the Renal Replacement Therapy Clinical Practice Guidelines (Ministry of Health, 2004). The educational intervention focused on the needs of haemodialysis treatment, the importance of fluid control, fluid intake, tips on fluid control and salt intake as well as tips on salt and weight gain control. Patients enrolled in private chronic dialysis program at the University Malaya Specialist Clinic (UMSC) were pre-tested with the educational intervention. The teaching plan was well understood by the patients, and no major changes were made after that pre-test.

The education interventions were conducted at the hospital dialysis centers during haemodialysis treatments. The researcher delivered the teaching to the participants in the experimental group while they were receiving their haemodialysis treatment. The teaching was done face-to-face for each patient using a pre-prepared file with slides in both English and the Malay language (Appendix C).

The slides covered the following content:

Slide 1: Kidney function and haemodialysis treatment

Slide 2: Fluid control

Slide 3: Fluid intake

Slide 4: Sodium intake

Slide 5: Foods to avoid

Slide 6: Weight control

Each teaching session lasted about 20-30 minutes. The patient was allowed to ask any questions during the teaching session. Patient understanding was continuously assessed via questions and feedback throughout the teaching session.

Individual teaching was only carried out once during the study, and was followed by weekly reinforcement. Patients with renal failure may process information differently at various points in time along their disease trajectory. Renal failure patients usually have depressed mentation and require much repetition of information .They may have altered perceptual states and need frequent clarification and reassurance, and thus need additional repetition and positive reinforcement. Hence, weekly reinforcement was recommended to enhance learning (Charold & Lancaster, 1995).

The follow-up sessions took about 10-15 minutes weekly for three months. The follow up of educational intervention was carried out after the haemodialysis treatment. Encouragement and motivation was given to participants who adhered to fluid intake recommendations and those who kept within the recommended interdialytic weight (IDWG $\leq$ 2kg) during the follow up session. Patients who had an interdialytic weight gain of more than 2.0 kg received positive reinforcement or a gentle reminder on the importance of fluid intake and weight control again. An allowance was made for up to 1kg of interdialytic weight gain (IDWG) between weekdays, and 1.5 to 2.0kg for

weekends as recommended by the KDOQI (2006). Interdialytic weight gain of 2.0kg and below was categorized as fluid compliance in this study.

The control group did not receive any educational intervention but continued with the usual haemodialysis activities and routine care at the dialysis unit, which included patient education by the nurses only when problems occurred with no written materials provided.

3.5.2.2 Patient information booklet

All participants from the experimental group were given a Patient Information Booklet after the first individual teaching session (Appendix D). The purpose of the information booklet was to help the participants retain their knowledge on fluid and salt control. The content of the booklet was exactly the same as the teaching plan, but with an addition of the patient's record of their fluid intake and urine output. Participants were told to record the amount of fluid consumed and urine output for 12 weeks until the end of the intervention. In order to standardize the amount of fluid taken, each of the participants received a small cup for fluid measurement. The researcher or a trained renal nurse checked the book weekly and ensured that the intake of fluid was according to interdialytic weight gain (IDWG). Interdialytic weight gain does not exceed 2 kg if the patient consumes fluid as recommended (500mls per day).

3.5.3 Data collection process

The researcher wanted to deliver the education intervention personally to all participants. However, there were some inevitable factors such as the disease condition of the patients, where the teaching had to be put on hold. Whenever such a situation occurred, the intervention was conducted at the next dialysis session when the

participant felt better. Participants were also sometimes too tired or not feeling too well during the dialysis session and in some instances, the participants arrived at the hospital late in the evening when the researcher was not around to conduct the intervention. In such situations, where the researcher was not around, the teaching was conducted by a trained dialysis nurse. The nurse was taught by the research to interview using the structured questionnaire and to give the intervention on fluid control following the teaching guide. After providing the training, the researcher tagged along with the nurse and evaluated her interviewing and teaching skills. The nurse worked independently once the researcher was certain that she was competent to carry out those skills well. The selected nurse was part of the staff working at the dialysis unit where the participants received their treatment.

The intervention was delivered based on a teaching plan and guide to ensure that all educational interventions were as standardized as possible and that all participants received the same unbiased information (Appendix C). The teaching was delivered at a suitable time and at an appropriate place. The researcher conducted the intervention after participants started their dialysis. As haemodialysis treatment often takes up to four hours, participants usually eat or rest during this period. There is thus ample time to administer the intervention.

The Patient Data Collection Sheet was used to collect socio-demographic data, which included several variables such as patient age, gender, duration of time on haemodialysis treatment, education level, occupational status, marital status, types of concurrent disease and anti-hypertensive therapy prescribed. The fluid compliance indicators were interdialytic weight gain (IDWG), mean predialysis blood pressure

(MPBP) and the rate of fluid adherence (RFA). All these indicators were assessed at the pre-intervention, and at 1-month, 3 month and 6-month post-intervention.

Predialysis weight was obtained each time the patients comes for dialysis. A calibrated weighing machine was used to check patient weight during the pre- and post-dialysis period each time they presented at the dialysis unit. The nurse recorded the predialysis weight and checked the previous post-dialysis weight to calculate the interdialytic weight gain, which is then recorded in the patients' dialysis record. Interdialytic weight gain is measured by subtracting the post dialysis weight from the next session's predialysis weight. For example, if the patient's predialysis weight is 60 kg and at post dialysis 57 kg, the interdialytic weight gain is 3kg, and the dialysis machine would be set to extract 3000 mls of fluid from the patient.

Patient blood pressure was measured using an automated blood pressure machine (Dinamap) both before and after haemodialysis. The mean predialysis blood pressure (MPBP) served as one of the indicator for fluid compliance. A mean predialysis blood pressure of 100mmHg and below was considered fluid compliance.

Rate of Fluid Adherence (RFA) was used to determine patient fluid compliance status and to evaluate the effectiveness of the education intervention on fluid compliance. Rate of Fluid Adherence is calculated based on the number of dialysis sessions that adhere to IDWG $\leq$ 2kg, divided by the total number of dialysis sessions in a given period of time. The total number of dialysis episodes was forty dialysis sessions at baseline and thirteen dialysis sessions at 1-, 3- and 6-month respectively. Participants were allowed three non-compliant dialysis sessions, with non-compliance defined and measured by interdialytic weight gain exceeding the recommended guidelines. The Rate of Fluid Adherence should be 75% and above based on 12 dialysis sessions in one

month (9/12 x100% =75%). The RFA of 75% and above implies a positive change from non-compliance to fluid compliance, and demonstrates that the educational intervention actually improves fluid compliance among haemodialysis patients. An RFA score of below 75% is considered poor fluid compliance.

3.5.4 Post-intervention data collection

The same questionnaire set was used to reassess participants' knowledge at 3-month post- intervention. The 3-month interval chosen was to avoid the "immediate effect" factor. Fluid compliance on IDWG, MPBP and RFA was assessed at three different intervals: 1-month, 3-month and 6-month.

The post-intervention data was completed in September 2011. The researcher took some time to complete data collection due to the five different study locations, and to complete retrieval of information from haemodialysis patient records. Furthermore, there were also many other unforeseen circumstances, such as drop-out cases due to death, patients being transferred to other settings, and change of treatment options. The data collection process is summarized in the Flow Chart of Data Collection Process (Figure 3.1).

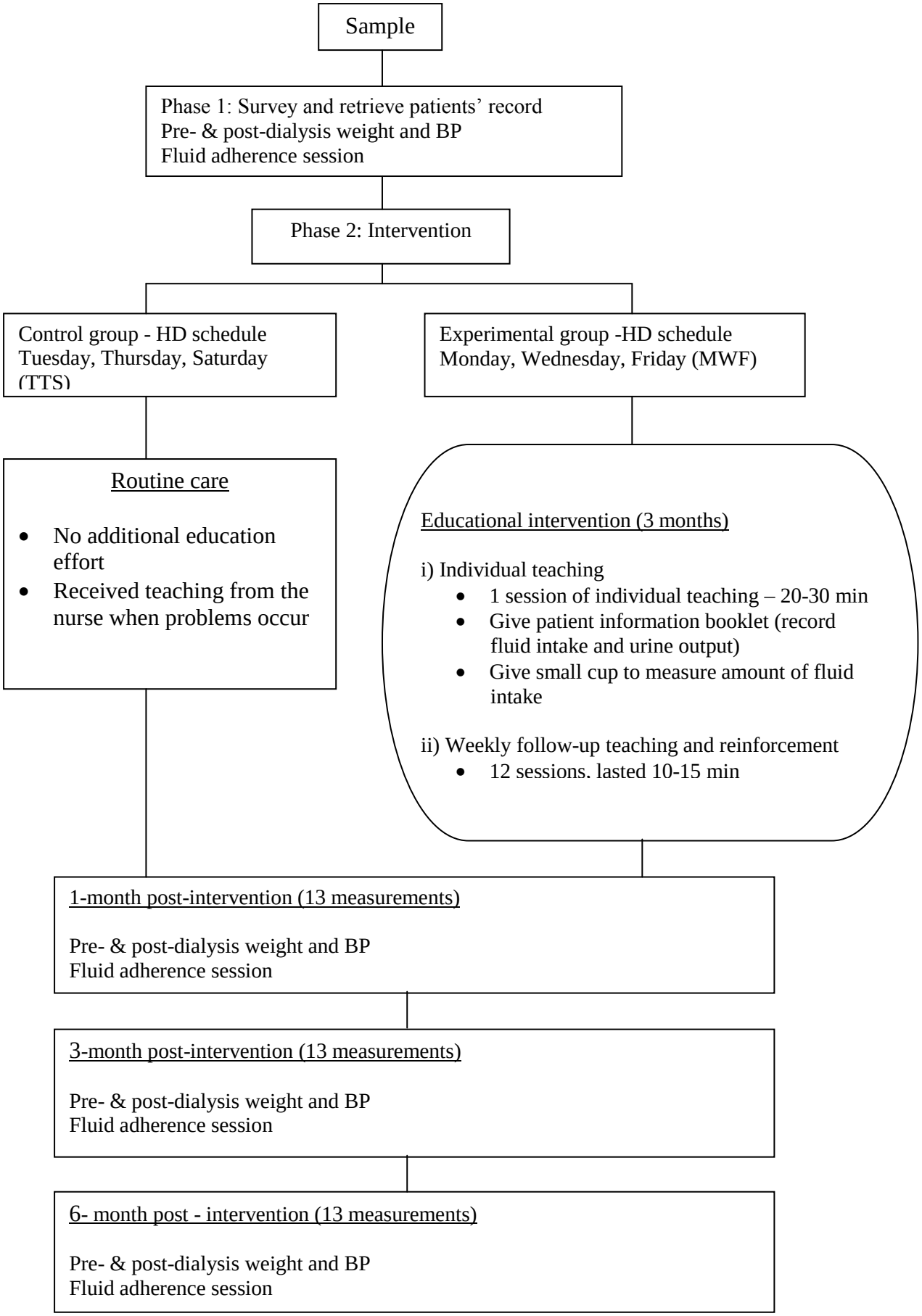

Figure 3.1 Flow Chart of Data Collection Process.

3.6 Analysis of data

The data was analyzed using SPSS version 16.0. Descriptive statistics was used in the analysis of patient characteristics, level of knowledge and fluid compliance status. An independent t-test was used to compare mean total knowledge scores and fluid compliance between experimental and control groups.

A paired t-test was used to compare mean total knowledge scores before and after the intervention within the experimental and control groups.

Calculation using the effect size calculator (Morris and DeShon, 2002) was applied to determine the effect of the intervention on both the experimental and control groups. Cohen's d which was 0.70 was considered a large effect size.

The effectiveness of the intervention was analyzed using odds ratio analysis. A univariate analysis and multivariate analysis was performed to determine the association and prediction between the level of knowledge and fluid compliance indicators with socio-demographic factors and clinical factors. If the factors had a *p* value <0.20, it was included in the multivariate analysis. In all the analyses, a *p*-value of less than 0.05 was considered statistically significant.

The McNemar test was conducted for a paired comparison of proportion within the experimental and control group at the pre- and post-intervention phase. A chi-square test was used to determine association between the factors and knowledge improvement. The test was appropriate because both independent and dependent variables were categorical variables. Multivariate logistic regressions were used to

identify predictors, which influenced knowledge improvement among the patients in the experimental group. Goodness of fit was assessed using the Hosmer-Lemeshow test.

A mixed between-within subject ANOVA (combination of between-subjects ANOVA and repeated measures ANOVA) was conducted to assess fluid compliance differences between the experimental and the control groups at the four time periods (pre-intervention, one-month, three-month and six-month). Wilks' lambda was used to determine the interaction and main effect, while Partial Eta Squared was used to assess the effect size. Based on guidelines by Cohen (1988)), 0.01 is a small effect, 0.06 a moderate effect and 0.14 a large effect.

3.7 Ethical considerations

This study was conducted in four public hospitals and one university hospital located in the Klang Valley. For the four public hospitals, approvals were obtained from the National Clinical Research Center (NMRR), Director of the Hospital and Head of Department at the respective hospitals. Ethical clearance was given by the University Malaya Medical Center (UMMC) ethic committee to carry out the study at the dialysis unit in UMMC (refer Appendix E).

Participation was voluntary and patients were asked to sign a written consent if they agreed to participate in the study (refer to Appendix F). All patients who took part received an explanation as per the explanatory statement (refer to Appendix G). The researcher ensured that the educational sessions were carried out in private and all records remained confidential and only for academic purposes.

The researcher explained the purpose of the study to all dialysis nursing staff and on their responsibilities during the study period. The study period was different for the five different hospitals, but the researcher ensured that the intervention was complete at one hospital before commencing at another hospital.

3.8 Pilot study

The pilot study was conducted from August to September 2009. It was conducted at Kuala Lumpur Hospital and UMMC. Forty patients were involved in the pilot study, with 30 patients from HKL and 10 from UMMC. Participants were interviewed using the questionnaire. No major changes were made after the pilot study. During the interview, all questionnaires were read out in a similar manner to participants. The educational session was given once, mainly to test for understanding and content clarification, and to evaluate patients on their knowledge and compliance. The level of knowledge was quite low, which was less than 60% with compliance levels of approximately 45%.

3.9 Summary

This chapter gives a detailed description of the research design, setting, and the study sample. A concise explanation on how the study was conducted is reported along with measures to improve and maximize the validity of the study. The procedure used to analyze the data was also presented. Results from the analysis of the data collected will be presented in the following chapter.