Abstract of thesis entitled

“An evidence based educational programme to enhance fluid compliance for hemodialysis patient.”

Submitted by

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for the degree of Master of Nursing

The University of Hong Kong

in July 2014

Abstract

Hemodialysis (HD) is a common mode of renal replacement therapy in End stage renal failure patients, which replaces some of the functions of a healthy kidney, for example removal of wastes products and extra fluid. The poor compliance of fluid restriction is commonly and significantly found in HD patients. Patients with excessive inter-dialytic weight gain (IDWG) may increase the risks of experiencing life threatening adverse symptoms and complication, such as acute myocardial injury, and also mortality rate. At present, there is no well-established guidelines and intervention on educating patients the knowledge of fluid restriction in local settings. Therefore, developing an education based educational programme is necessary to
enhance fluid intake compliance in HD patients.

This dissertation is a translational nursing research, which aims at establishing evidence-based practice guidelines on the patient education for fluid restriction in HD patients. The objectives includes searching existing literature on the effectiveness of education in relation to fluid restriction, performing a critical appraisal on the literature, developing guidelines for patient education, assessing the implementation potential, and developing its implementation and evaluation plans.

Through reviewing and appraising the selected six studies, an educational intervention was related to reduction in IDWG. An implementation and evaluation plan has also been developed. A pilot study plan is recommended to investigate the feasibility of the implementation of innovation.

The proposed guidelines will be disseminated in the target HD center in local setting. The aim of the guidelines is to enhance the framework for nurses to strengthen fluid intake knowledge for HD patients. At the same time, it also aimed at minimizing IDWG by an evidence-based practice.

A systemic search was performed with two electronic databases, PubMed (1950-2010) and Cochrane Library (earliest to August 2010), on 9th August 2013. Six relevant articles, all are randomised controlled trials (RCTs), were retrieved. After the critical appraisal on the reviewed studies was performed, the grading of the level of evidence for each study was performed according to the Scottish Intercollegiate Guidelines Network (SIGN) framework. The levels of evidence of studies were graded from 1++ to 1. With the date synthesized from the reviewed studies, education was considered as an effective intervention for reducing IDWG. Moreover, different formats and approaches were suggested.
The implementation potential of the innovation was then assessed regarding the target setting and audience, transferability of the findings, and feasibility and cost-benefit ratio. After that, the guidelines were suggested to be feasible in the target setting. By supporting with evidence, the clinical practice guidelines on the patient education in fluid restriction were developed. Recommendations on the length, format, approaches and other strategies of patient education were included in the proposed guidelines.

The implementation plan was discussed in terms of the communication and pilot testing plans. The communication plan was focus on gaining approval and maintaining communication from stakeholder and potential users, including senior persons in both clinical and management level, Renal Medical Team doctors and ward nurses. A pilot test was then carried out to assess the feasibility of the new guidelines. Evaluation of patient outcomes, health care provider outcomes and systemic outcomes were included in the evaluation plan.

The fluid compliance could be enhanced by reducing IDWG with implementing the evidence-based clinical guidelines on patient education on fluid restriction.
“An Evidence-based practice educational programme to enhance fluid compliance for hemodialysis patients.”

By

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BNurs (HKU)

A thesis submitted in partial fulfillment of the requirements for the Degree of Master of Nursing at the University of Hong Kong

July 2014
Declaration

I declare that this thesis represents my own works, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed: ______________________

Ho Nga In
Acknowledgements

Special thanks should be given to my supervisor, Dr. Denise Chow, from the School of Nursing at the University of Hong Kong, for her support and guidance in this entire process.

I also sincerely thank the Nurse Consultant and Advanced Practice Nurses in my workplace, who have provided me with continuous support and encouragement throughout these years.
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## Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>APN</td>
<td>Advanced Practice Nurses</td>
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<tr>
<td>COS</td>
<td>Chief of Service</td>
</tr>
<tr>
<td>DOM</td>
<td>Department Operation Manager</td>
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<tr>
<td>EBP</td>
<td>Evidenced-based practices</td>
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<tr>
<td>ESRF</td>
<td>End stage renal failure</td>
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<td>HD</td>
<td>Hemodialysis</td>
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<td>HDF</td>
<td>Hemo-filtration</td>
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<td>IDH</td>
<td>Intra-dialytic hypotension</td>
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<td>IDWG</td>
<td>Inter-dialytic weight gain</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<td>RN</td>
<td>Registered Nurse</td>
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<tr>
<td>RRT</td>
<td>Renal replacement therapy</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>NC</td>
<td>Nurse Consultant</td>
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<td>NHHD</td>
<td>Nocturnal home hemodialysis</td>
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<td>NO</td>
<td>Nursing Officers</td>
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<tr>
<td>NS</td>
<td>Nurse Specialist</td>
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<tr>
<td>PD</td>
<td>Peritoneal Dialysis</td>
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<td>WM</td>
<td>Ward Manager</td>
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Chapter 1 Introduction

In this chapter, the background knowledge, significance and affirming needs of education on controlling inter-dialytic weight gain (IDWG) will be introduced. Then, the research questions and objectives will be discussed.

1.1 Background

End stage renal failure (ESRF) is an irreversible progressive condition, which requires life-long renal replacement therapy (RRT) for life maintenance. Hemodialysis (HD) is a common mode of treatment for ESRF, which replaces some of the functions of a healthy kidney, for example removal of wastes products and extra fluid.

Assessing IDWG offers a brief estimation of the fluid status of patients for setting HD regimen for every single treatment in clinical practices. IDWG is the weight gains between dialysis sessions, is caused by dietary and fluid intake. Patients with excessive IDWG are considered to be overweight and represent poor fluid intake compliance (Abuelo 1998, Davenport 2009, Rosenbaum & Smire, 1986, Welch et al. 2006). Most commonly, average IDWG greater than 2.5 kg (Feinstein, 1986, Christensen et al., 1997), or more than 5.7% of the dry weight (Leggat, 1998) indicate problematic adherence.

Rigorous HD is required to remove excess fluid and wastes from the body of the overweight patients. Fluid overloaded, is a common complication among ESRF patients, which caused by excessive sodium and fluid intake. Patients may complicate with hypertension, peripheral edema, pulmonary edema and breathlessness (Durose et al. 2004, Sciarini & Dungan, 1996). However, based on evidence and clinical experiences, there are increased risks of experiencing life threatening adverse symptoms and complication during intensive HD treatment with high ultrafiltration
rate, for example intra-dialytic hypotension (IDH), which may cause acute myocardial injury and suggested to be the major contributor to more than 50 percent of the overall cardiovascular mortality of ESRF patients (Henderson, 2012). Complications could adversely affect the prescribed dose and regimen of HD. Adequate HD treatment is further compromised with early termination to avoid continuous suffering.

Most of the experienced problems and the major barrier of achieving adequate HD treatment are related to the non-adherence with treatment (National Kidney Foundation, 2006). Reduction in IDWG is considered as beneficial, it represents reduction of complications by cardiovascular stress (DiClemente et al., 1982) and maximization the HD treatment adequacy. It is generally agreed that educating patient on fluid restriction through monitoring IDWG could achieve adequate HD treatment with minimal discomfort.

1.2 Affirmation of the needs

In order to improve patients’ survival and outcome, certain nursing intervention should be implemented. According to the Guidelines of HD Adequacy (National Kidney Foundation, 2006), efforts should be made to minimize the occurrence of adverse symptoms. Apart from modifying hemodialysis prescription, optimizing patient behavior is considered as an alternative strategy to achieve adequacy, comfort and benefit of patients. Moreover, various nursing paper discussed the need of educational program with regards to changing HD patients’ dietary and fluid intake behavior (Lee & Molassiotis, 2002, Sharp et al., 2005).

Current dietary and fluid control education

In current clinical setting, regular blood checking and providing dietary advices in form of leaflets are the measures on monitoring patients’ dietary and fluid restriction.
A leaflet with information on dietary and fluid control is given to newly diagnosed patients after HD treatment started, nurses briefly explain the concept and remind the importance of controlling intake. There is no standardized protocol and timeframe suggested to carry out the education. The explanation is relatively short and usually lasts only 10-15mins. Reinforcement is given if there is abnormal blood serum level or severe IDWG noted. Such brief educational intervention is common in most of the renal setting in Hong Kong, where nurses work under high workload environment. However, building up compliance is a long process and requires implementing appropriate education that is suitable for patients with different characteristics. Moreover, the effectiveness of current measures could not be guaranteed. In order to help patients to make change on dietary and fluid habit, education should be introduced to patients at the beginning of treatment. However, without concept of the treatment and the rationale of behavioral change, patients who just entering a recovering stage from illness may not be ready to receive information. Moreover, most of the patients are in old ages with limited educational level, the current written information may not be the feasible teaching material. For employed patients who work outside, their diet mostly consisted of unhealthy fast food due to time constraints, renal nurses are responsible to suggest and discuss specific strategies to assist patients achieving better dietary and fluid control. Hence, the current education should be modified and may consider of incorporating different format such as individual counseling, group sharing and videotaped education. Moreover, strategies should be introduced to ensure the effectiveness of the education, such as setting goals and arranging regular evaluation. Although there are guidelines and evidences on importance of monitoring IDWG by controlling dietary and fluid intake on preventing complication, there is lack of well-
established evidence-based guidelines or education programme in current healthcare setting. Hence, an evidence based patient educational program should be established to enhance fluid compliance.

1.3 Objectives and Significance

Significance

According to the Hong Kong Renal Registry Report 2012, there was a steadily increasing trend in the number of patients with newly diagnosis of ESRF since 1996 in Hong Kong. In 2011, 1,115 patients newly accepted RRT programmes, the incidence rate with 157 patients per million population (pmp) was reported. The point prevalence was 8,197, with a prevalence rate of 1,152.5 pmp on December 31, 2012. There were 1,246 patients were on HD in all hospitals under Hospital Authority, private or critical centers and patients’ home, which comprised 25.9% of all dialysis patients, with the point prevalence of 175.2 pmp. Under limitation of resources, financial reasons and easy access to HD centers, Peritoneal Dialysis (PD) first policy was set up in Hong Kong (HKRR, 2012).

However, HD continues to be the most common mode of RRT globally. According to the evidenced data from Annual Data Report in United States (U.S. Renal Data System, 2013), at least 80 percent of patients were on HD in over 76 percent of reporting countries. In United States, 395,656 patients were on HD in 2011, with incidence rate of 103,744, which comprised around 92% of all dialysis patients (U.S. Renal Data System, 2013).

On the particular concern are the incidence and population with complications caused by poor fluid intake adherence and excess IDWG of patients. According to research studies findings, 33–50% of HD patients were reported to be non-adherent with fluid restriction regimen (Baines & Jindal, 2000, Bame et al., 1993, Kaveh & Kimmel,
Another focus is the association of morbidity and mortality with IDWG. There were numerous observational studies showed significant correlation of IDWG, IDH and cardiovascular mortality (Shoji et al., 2004, Saran et al., 2006, Kalanter et al., 2009 & Flythe et al., 2011). A significant correlation of IDWG with 30 percent of increase in IDH and 9 percent increase in mortality (Saran et al., 2006).

The impact of excess IDWG, not only affect the quality of life but also the quantity of life in HD patients, which relate to morbidity and hospitalization (U.S. Renal Data System, 2013). The adjusted hospitalization rate caused by cardiovascular problems per patient year among HD patients was 0.51 in 2010–2011, which comprised 27.1 percent of all-cause hospitalization. In HD patients, the adjusted rates of cardiovascular hospitalization peaked in 2004, with 601 per 1,000 patient years, a fall with 13.5 percent was reported then, but still remain a relative high proportion among the all ESRF population.

On the other hand, the excess IDWG also affects the treatment outcome. The number of patients reported to have discontinued premature hemodialysis because of complications occurring during the treatment reflects the inadequacy of treatment quality. According to a large observational study (Rocco & Burkart, 1993), 55 percent of the premature terminations were due to medical reasons. Within this category, 70 percent were caused by cramps, 48 percent were a consequence of feeling sick, and 15 percent were secondary to symptomatic hypotension.

Hence, actions should be taken to improve patient survival and quality of life with adequate treatment outcome through monitoring IDWG.
Research Questions

How does an evidence based educational programme compare to the standard care programme on reducing the IDWG for hemodialysis patients?

Hypothesis

Implementing educational programme on dietary and fluid restriction can reduce the IDWG.

Study Objectives

(1) To review the evidence of effectiveness of education on dietary and fluid restriction in reducing IDWG.

(2) To appraise critically, summarize and synthesize findings from the selected articles.

(3) To establish recommendation for evidence-based educational programme on fluid restriction in HD patients.

(4) To assess the potential of implementing the proposed educational guidelines in current health care setting.

(5) To establish an implementation and evaluation plan for the proposed guidelines.
Chapter 2 Critical Appraisal

2.1 Search and Appraisal Strategies

Keywords for searching

The keywords used were divided into three categories, the population, intervention and outcomes. The keywords within each category were searched with applying function of “OR” of the searching engine, while “AND” were applied to link the three categories. The searching keywords were listed in Appendix 1.

Inclusion and Exclusion Criteria

The studies were searched with limiting to randomized controlled trials (RCT). ESRF patients treated with HD are included in the review. Patients with mental, psychiatric or cognitive disorders were excluded. This is because those groups of patients may need special and more intensive education to acquire knowledge, where outcome may not be direct and feasible to apply into target group.

Data extraction

The following variables and information were extracted from the selected articles:

(1) Population
(2) Intervention
(3) Outcome measures
(4) Result findings
Appraisal strategy

Since all selected articles are RCTs, appraisal of articles quality and grading of the level of evidence was performed by using Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist.

2.2 Results

Electronic database search

An electronic database search was performed on 9th August 2013. The search was performed with two electronic databases, PubMed (1950-2010) and Cochrane Library (earliest to August 2010).

The search yielded a total of 52 RCT. The potentially relevant articles were screened with abstracts and titles. 10 articles were identified to be eligible studies. Eventually, 9 articles were identified, and 3 duplicates were excluded. 6 relevant articles were finally selected and retrieved. The history of the electronic database search is summarized in Appendix 2.

Reference list search

The reference lists of selected article were another source of searching relevant articles that might not be available in the previous two databases. Potential articles could be retrieved through assessing the title, abstract and full text. However, no new article was found.
2.3 Data Summary

Study Characteristics

The variables extracted from the 6 selected articles were summarized into Table of Evidences, which was presented in Appendix 3.

The six articles were controlled trial studies with introducing both intervention group and a control group. Allocation of participants was purely randomized. The level of evidence ranged from 1++ to 1-. The publication years ranged from 2003 to 2012. Two studies were conducted in Iran (Aliasgharpour et al., 2012 & Baraz et al., 2010), the others were conducted in Taiwan, Middle East, United Kingdom, & South Louisiana (Tsay, 2003, Moattari et al., 2012, Sharp et al., 2005 & Molaison et al., 2003). A total of 547 participants were recruited in the six studies, sample size ranged from 50 to 316.

Patient characteristics

The participants in all studies were patients with ESRF and on HD in outpatient HD center. All studies mentioned the distribution of gender, where the proportions of male participants were ranged from 41.9 to 67.8 percent. Only adult patients were included in all studies, the mean age of the participants was reported from 34.8 to 57.8 years. Educational background of participant was reported in all studies, which was classified into different level, from none to university level. The mean length of participants on HD treatment ranged from 3 to 156 months in all studies.

Intervention and Control

Education was introduced to the intervention group, when no education was
introduced in control group. There were different components incorporated into the education. The individual counseling (Moattari et al., 2012, Molaison et al., 2003 and Tsay, 2003) and group interactive sessions (Aliasgharpour et al., 2012, Baraz et al., 2010, Moattari et al., 2012, Molaison et al., 2003 Sharp et al., 2005 & Tsay, 2003) were the two main components included in selected studies. Oral and video approaches were also compared in one of the study (Baraz et al., 2010).

For the studies included group interactive sessions, 2 of 6 studies mentioned the number of patients to be included, which ranged from 2 to 8 patients within each group (Sharp et al., 2005 & Aliasgharpour et al., 2012).

Only one study mentioned initiation of education. Early initiation was reported with effective reduce in IDWG (Sharp et al., 2005). The total length of education intervention was reported in 5 studies (Aliasgharpour et al., 2012, Baraz et al., 2010, Moattari et al., 2012, Sharp et al., 2005 & Tsay, 2003), ranged from 1 to 12 hours.

Apart from the main components, some supplementary strategies were included in selected studies. Apart from face-to-face education mentioned in all studies, 4 of the studies provided participants with booklet or handout on dietary and fluid restriction information (Aliasgharpour et al., 2012, Baraz et al., 2010, Molaison et al., 2003 & Sharp et al., 2005). Another study also incorporated bulletin board displays (Molaison et al., 2003). Participants were encouraged to have goal setting (Moattari et al., 2012, Sharp et al., 2005 & Tsay, 2003) and self-monitoring (Sharp et al., 2005 & Tsay, 2003) in particular studies. Evaluation was done by providing feedback (Aliasgharpour et al., 2012, Moattari et al., 2012, Tsay, 2003 & Molaison et al., 2003) and reviewing laboratory results (Moattari et al., 2012 & Molaison et al., 2003). Muscle relaxation workshop was incorporated in 4 studies for stress management.
(Aliasgharpour et al., 2012, Moattari et al., 2012, Sharp et al., 2005 & Tsay, 2003).

**Measure outcomes**

IDWG was compared in all studies, which is the difference of post HD weight and the pre HD weight of the next dialysis session; other physiological outcomes were investigated, such as blood pressure and blood serum laboratory results. 3 studies also included psychological outcomes, such as self-efficacy score and quality score (Moattari et al., 2012, Sharp et al., 2005 & Molaison et al., 2003).

**Summary of quality assessment**

The methodology SIGN checklists of individual study were shown in Appendix 4 and the critical appraisals of the checklists are summarized in Appendix 5. In all reviewed articles, the population, intervention and outcome measures were clearly reported and specified. Focused questions were clearly located in all studies. All reviewed articles were RCTs studies, the effectiveness of the interventions were tested appropriately. The levels of evidence of studies were graded from 1++ to 1-.

Randomizations were mentioned in all studies; however only 2 studies clearly and adequately described randomization method (Baraz et al., 2010, Sharp et al., 2005). In all studies, the intervention and control groups were clearly reported with insignificant differences before trial (p>0.05), and the interventions were the only differences between two groups. Only 2 studies were clearly applying concealment (Baraz et al., 2010, Sharp et al., 2005). Reliable outcome measures were introduced in all studies.

Blinding method was mentioned in 2 articles (Moattari et al., 2012, Tsay, 2003). Blinding of participants seemed to be limited, as the intervention required their active
involvement. To minimize bias, single blinding was incorporated on persons such as
the nurses and laboratory staffs who were responsible for data collection. Although
there was no blinding applied in two of the studies, the open non-blind study designed
with measuring objective numbers (Sharp et al., 2005) and strict instruction was
suggested and given on measuring outcomes (Molaison et al., 2003) to minimize risks
of bias.

3 studies provided clear description on the sample size calculation. 2 of the 3 studies
obtained sufficient statistical power of 80 percent (Moattari et al., 2012 & Tsay,
2003), and a pilot investigation study used power of 70 percent (Sharp et al., 2005).
The treatment and control groups were considered to be similar before starting the
intervention with insignificant difference reported in all studies.

Although the studies were covered wide types of outcome measure, the particular
concern was comparing IDWG. Only one study did not clearly mention the
instruction on measuring IDWG (Molaison et al., 2003), but the well-known equation
for calculating IDWG and data collection was done in the same way from different
groups ensured minimization of performance bias. The participants in all studies were
followed up with different time interval, ranged from 2 to 6 months. Nurses were
reported to be educated in measuring IDWG in 2 studies (Moattari et al., 2012 &
Sharp et al., 2005). Measuring instruments were used in most of the studies where
objective outcomes were covered, such as self-efficacy questionnaire. The mean of
IDWG and standard deviation were reported in all studies, and the P-value was also
reported to show significance differences between groups. However, only 2 studies
clearly reported with obtaining 95% confidence intervals (Moattari et al., 2012 &
Sharp et al., 2005).
Drop out only reported in 2 studies (Sharp et al., 2005, Tsay, 2003). The dropout rate was satisfactory and ranged from 0%-17.85%. The intention to treat the analysis was incorporated in only one study (Sharp et al., 2005).

5 selected articles were multi-site studies, no site specific data were given in all 5 articles (Baraz et al., 2010, Aliasgharpour et al., Molaison et al., 2003, Sharp et al., 2005 & Tsay, 2003).

Given the selected studies included wide range of patient characteristics, which was similar to the proposed target population, the intervention and findings are applicable to local settings.

2.4 Data Synthesis

(1) Effectiveness of education for reducing IDWG

Significant reduction of IDWG with education intervention was shown in 5 of the 6 studies (Moattari et al., 2012; Baraz et al., 2010; Sharp et al., 2005; Tsay, 2003, Aliasgharpour et al.), only one study shown insignificant relation (Molaison et al., 2003). The finding of exception was rejected because the limitation of study designs. This study was graded as 1- with the lack of randomization and concealment method mentioned and no blinding introduced, the high risks of bias limited the credibility of the findings. Apart from this, this study included measuring both primary and secondary outcomes. However, the design might not be specific to relate the secondary outcome, IDWG, with intervention. On the other hand, the primary outcome, knowledge score, was shown significant increased with intervention and it related to learning ability through actions. Among these, education was considered as an effective intervention for reducing IDWG.

Outcomes measurement was done at baseline and different time interval in all studies.
Apart from baseline measurement, 2 studies measured outcomes at post intervention (Baraz et al., 2010 & Tsay, 2003) with showing significant relation with intervention. Another study compared outcomes at baseline and follow up (Moattari et al., 2012), significant difference was identified. 2 studies compared outcomes at both post intervention and follow up (Aliasgharpour et al., 2012 & Sharp et al., 2005), significant difference at both intervals were only shown in one study (Aliasgharpour et al., 2012). In another study (Sharp et al., 2005), differences of IDWG changes between baseline and post intervention were non-significant (p> 0.05). However, the differences in findings between baseline and follow-up were significant (p< 0.001). It reflected improved compliance over time.

(2) Incorporating education components

Group interactive session

Group interactive session was incorporated into educational intervention and significant reduction of IDWG was shown in 5 studies (Aliasgharpour et al., 2012, Baraz et al., 2010, Moattari et al., 2012, Molaison et al., 2003 & Sharp et al., 2005). Providing social supports, building motivation and developing strategies to cope problems and emotions are the focus of group intervention. Through sharing and discussing on live patients’ experiences, role-playing and question and answer techniques, patients’ awareness, coping strategies and problem solving techniques are able to developed.

Individual counseling
Individual counseling session was incorporated into educational intervention and significant reduce in IDWG was shown in two studies (Moattari et al., 2012, & Tasy., 2003). Apart from developing necessary skills and self-awareness in fluid compliance, it also helps patients with chronic disease to adjust physical and emotional stress (Tsay, 2003). Participation of family members and care providers to counseling sessions is recommended. It provides individual support and enhances engagement of family members and care providers in the problem solving process (Moattari et al., 2012).

Hence, both of the group interactive and individual counseling sessions are considered as effective components of education in reducing IDWG.

(3) Education approach

Oral education was incorporated in all studies. One study was focus on comparing the effectiveness of oral and video approached in education. Both of the approaches were related to significant reduction in IDWG individually, and no significant difference was shown in the effectiveness of oral and video approaches.

Oral approach is recommended to be the basic education, video education is recommended as alternative approach for particular patients. Video education is used for the benefit of old aged patients. As most of ESRF patients are elderly with limited educational level, written informative booklets may not be feasible in education. Videotaped education offers clear way to acquire knowledge.

Moreover, video approach is recommended in educating patients on nocturnal home hemodialysis (NHHD). In most of the countries, accessing HD centers or hospitals may not be feasible because of long transportation time, hence, NHHD is a common
mode of treatment for ESRF patients. Video approach allows continuous education for those patients. In Hong Kong, although NHHD is not as common as in other counties, there are increasing numbers of patients trained with NHHD. Moreover, video education allows self-revision at any time for all patients, hence, both oral and video educations are recommended.

(4) **Number of participants for group interactive session**

Only 2 of the 4 studies reported the number of participants for group interactive session with significant reduction of IDWG (Aliasgharpour et al., 2012 & Sharp et al., 2005). 3 to 8 patients are recommended to be included in each group as adequate number of participants enables patients to explore more scenarios and experiences.

(5) **Education initiation**

Only 1 study mentioned about initiation of education. Early initiation of education was related to significant reduction of IDWG (Sharp et al., 2005). Under the evidence of high mortality rate in patients in the first year of HD (Himmelfarb & Lkizler, 2010), it is recommended to offer education once patients diagnosed with ESRF and HD started.

While patients just enter into a life-changing treatment of chronic diseases, it is understandable that they may ignore the major adaptation required, such as dietary and fluid intake restriction. Without sound knowledge and understanding of the rationale of treatment, effective self-care and maintenance of motivation on intake restriction would be unlikely. However, the ignorance relates to poor prognosis for effective management. Introducing informative education, discussing reasons for building fluid intake compliance and effective strategies in managing problems before
staring HD is able to maintain patients’ long-term self-regulation of behavior. Hence, importance of fluid restriction should be emphasized to patients in early period.

(6) Length of time

Total length of education intervention were reported and ranged from 1 to 12 hours in selected studies. The large difference of the range was probably based on the incorporating of individual counseling. Without introducing individual counseling, the length of education ranged from 1 to 9 hours (Aliasgarpour et al., 2012, Baraz et al., 2010, & Sharp et al., 2005). 2 of the studies incorporated individual counseling, so it required more time where 9 to 12 hours were required (Moattari et al., 2012 & Tsay, 2003). In order to minimize risk for dropout from education, the intervention should be designed to be brief and not time-consuming (Baraz et al., 2010). On the other hand, building up compliance is a long process, continuous education and support is recommended. Hence, setting adequate length of education with previous consideration could increase patients’ motivation and ensure efficiency. A total of 4 hours basic education is recommended, with 1 hour per session and range from 2-4 sessions. If there are poor compliance notices, extended education and reinforcement are recommended.

(7) Incorporating supplementary strategies

With incorporating various supplementary strategies, significant reduce in IDWG was shown in all studies.
Goal Setting & self-monitoring

Strategies allow participants to develop self-management with disease through setting goals and self-monitoring. Setting attainable and achievable objectives with patients is recommended. Praise and recognition rewards are given if the goals are achieved. Through setting simple goals at the beginning, such as ‘reducing a cup of tea or water a day’, the misconception on difficulties and impossibilities of intake restriction could be minimized. Through constructing situations with achieving realistic daily performance goals and encouragement in supportive environment, patients are assisted to adopt self-care strategies (Sharp et al., 2005; Moattari et al., 2012; Tsay, 2003)

Continuous Revision

Revision is recommended as continuous education. Booklet on dietary and fluid restriction information and updating bulletin board displays allow patients to maintain intake compliance (Baraz et al., 2010; Sharp et al., 2005; Aliasgharpour et al., 2012; Molaison et al., 2003). Under limited resources and increasing demand of HD in public HD centers, patients are required to wait for availability of HD machines during visit. Educating patients by introducing regular updated bulletin board displays in the waiting room could allow well utilization of time and resources.

Regular evaluation

In order to ensure the effectiveness of education, evaluation should be performed through regular feedback and laboratory result review. Each visit of HD treatment lasts 5 to 6 hours for most of the patients, which offers plenty of time for carrying out feedback and review. Each nurse is allocated with a group of patients; he or she is
responsible for monitoring patients’ behavior and process in health related issues. Those measures enable continuous maintenance of patients’ compliance behavior, ability to make decision on weights monitoring and overcoming the barriers of fluid intake (Moattari et al., 2012; Tsay, 2003; Molaison et al., 2003; Aliasgharpour et al., 2012).

**Stress management**

Patients would be stressed with adapting different limitation in life. Muscle relaxation workshop should be encouraged managing stress (Sharp et al., 2005; Moattari et al., 2012; Tsay, 2003; Aliasgharpour et al., 2012). Doing exercises is considered to be unfeasible for HD patients due to limitation by physical illness and vascular access. Exercise training was proved with significantly reduce in emotional distress and improve heart rate variability (Kouidi et al., 2010). Through life long HD treatment, patients may encounter psychological problems with further complication and comorbidity. Gentle exercises, such as stretching, are recommended to manage stress.
Chapter 3 Implementation Potential

3.1 Target Setting/ Audience

Target setting

The proposed evidence-based clinical guidelines are implemented in the Renal Unit in a local teaching public hospital. The target setting is an outpatient HD day center, which provides services for around 80 chronic cases and acute cases transferred from other wards within hospital. The educational programme is introduced to newly diagnosed cases. Chronic cases, which HD has been started for more than 1 month, are excluded from innovation.

The implementation involves nursing staffs at management level included the Chief of Service (COS), Department Operation Manager (DOM), Ward Manager (WM), and also 33 clinical nurses. Various ranks of clinical nurses are included, the Nurse Consultant (NC), Nursing Officers (NOs), Advanced Practice Nurses (APNs), Nurse Specialist (NS) and Registered Nurses (RNs).

Target Audience

The target audiences are the outpatients with following criteria,

- Aged 18 or above;
- Newly diagnosis of End Stage Renal Failure (ESRF);
- Started temporary or permanent HD treatment &
- Out patients

3.2 Transferability of the findings
3.3 Setting and Audience

All reviewed studies were conducted in outpatient HD centers and two of them were conducted in university-based teaching hospitals (Aliasgharpour et al., 2012 & Baraz et al., 2010). The participants in the reviewed studies and the target audience were similar with background, diagnosis and treatment. Both male and female participants were recruited, and all of them were in adult group. All of them were diagnosed with ESRF and on HD treatment. Therefore, the settings and the characteristics of the patients are also highly transferable to target setting and audience.

Philosophy of care

Providing people-centered service is the value of the target setting (Hospital Authority 2014). It states two-way communication is important for understanding and meeting patients’ needs.

The goal of care in the target setting is to provide high quality of care and support to patients with ESRF, their families to go through the lives with chronic diseases. There are various life style changes and adaption that patients needed to be gone through. Controlling diet and fluid intake is a big challenge for patients, the implementation of innovation assists nurses to educate and communicate with patients to achieve better patients’ outcome and satisfaction. Therefore, providing patient care with evidence-based practices shares the same value of the philosophy of care.

Number of clients benefited

The innovation could bring lasting benefits to all the hemodialysis patients. More than 1000 patients newly accepted RRT programmes in 2011 (Hong Kong Renal Registry Report 2012). With particular concern, 25.9% of all dialysis patients were on HD.
Accordingly, it is estimated around 300 patients will be benefited from the new programme each year in Hong Kong.

**Implementation and evaluation**

Nurses were responsible in implementing the education in five of the articles (Moattari et al., 2012, Aliasgharpour et al., 2012, Baraz et al., 2010, Sharp et al., 2005, Tsay, 2003 & Molaison et al., 2003). Nurses in target setting have already gained skills and knowledge consistent with the educational programme.

Monitor IDWG and laboratory blood result were carried out at regular interval for evaluation in the reviewed studies, the same actions were done in the target settings.

**3.3 Feasibility**

**Workplace atmosphere**

A positive teaching and learning atmosphere facilitates implementation. A local university-based teaching hospital is the target setting, where diverse opportunities are available for implementing academic research and evidence-based practices.

In target settings, nursing care and practices were modified regularly with updated academic and research findings. The NC and NS were responsible in reviewing and introducing new findings. Moreover, numerous nursing research projects have been carried out in past few years. An evidence-based nursing practice was introduced to provide quality care and better outcome for patients. Several research projects have been innovated in 2013, for example, evidenced based guidelines of hemo-filtration (HDF) administration enhanced nurses’ knowledge and skills in HDF, moreover, an
educational self-care programme are establishing in progress. Hence, nurses have the freedom to carry out the innovation.

**Administrative support**

It is feasible to obtain administrative support since the innovation is basically the improved version of the traditional practices, where limited manpower and resources are required. In order to promote the innovation, evidence based literatures review, guidelines framework, resources budget and action plans of implementation are necessary to introduce to different parties. The details will be discussed in the next chapter.

In addition, the DOM supports WM with autonomy to initiate clinical innovations within specialty, where nurses are allowed to raise opinions or terminate if necessary. Previous successful development of evidence based practices in target setting suggested support from administrative level.

**Consensus**

The innovation should be implemented in collaboration with nurses and physicians. Nurses are the main personnel of implementation; it is necessary to reach a consensus between nursing staffs. The availability and workload of nurses should be considered.

The innovation provides an evidence-based framework guiding nurses to educate patients. Therefore, no extra nursing staffs and additional workload will be allocated. Moreover, as mentioned in previous section, the educational programme could enhance the fluid and dietary restriction compliance. By reducing mortality and hospitalization rate, the innovation is considered as an alternative strategy to achieve adequacy, comfort and benefit of patients.
The benefits of innovation are clearly supported with evidence. However, some potential resistances needed to be overcome before implementing the innovation in the target setting. As suggested by the Lewin’s Force-Field Model (1951), overcoming inertia and dismantling the existing mindset are involved in the first stage of change. People may not be willing to accept new changes as fear of the unknown may be caused by sudden changes. In target setting, nurses have been adapted to the current practices for years, and there were no obvious harm brought from the traditional practices, so some staffs may resist trying something new.

In order to reach consensus among the nursing staffs, reinforcement and communication are essential for collaborating colleagues. The benefits of the innovation should be introduced with providing evidences among nursing staffs. To ensure adequate communication between the proposer and colleagues, nurses are allowed to provide feedback for the innovation.

On the other hand, the consensus with physicians should be reached. In clinical setting, nurses report the problematic cases with severe weight gain to the physicians. They prescribe hemodialysis regimen and refer nurses to provide education to patients. The physicians support evidence-based nursing practice and rely much on the nurses to educate patients behavior.

**Staff development**

Changes may cause fear and uncertainties. In order to support nursing staffs to accept and implement the innovation, training and evidence-based guideline should be prepared for utilization. In target setting, all nursing staffs have already gained knowledge in educating patients on fluid and dietary advices through working experiences. To standardize teaching materials, evidence based guidelines and booklet
would be prepared. Moreover, workshop will be organized, such as scenario, to provide nurses practising how to educate problematic patients with severe IDWG.

**Availability of Resources**

The need material for the innovation is mainly utilized to produce education booklets. A single page of pamphlet is given to patients during face-to-face interview in current settings. In the proposed programme, each patient will be given with an informative booklet. Therefore, a photocopy machine and paper are the equipment needed.

Time allocation is another important resources to be concerned. The education is suggested to be given to patients during the HD treatment, the treatment time takes usually 5-6 hours. During the treatment, the main routines is to monitor vitals signs hourly and observe any changes of patients’ conditions, nurses could utilize the long treatment time as education. Therefore, no extra time is needed to allocate the education work.

**Availability of Evaluation tools**

Both patients and nursing staffs are encouraged to perform evaluation for the innovation. A continuous IDWG monitoring, monthly blood laboratory monitoring and regular questionnaire on reviewing compliance and knowledge could assess the effectiveness of innovation. Nurses are encouraged to fill in questionnaire about the process and content of education programme.

**3.4 Cost/ Benefit ratio of the innovation**

**Risks of patients**
As the innovation is an educational programme, there is very limited potential risk that may harm the patients’ health. Stress may be the only risk caused through the learning process.

The innovation is able to strengthen the current dietary and fluid education to patients. As discussed in previous section, the traditional education is a too simple and may not fit specific patients. Patients may not be able to get the idea and wrongly control their intake amount, finally cause fatal consequences. Therefore, providing patients supportive education to assist them adapting lifestyle change is needed.

**Potential benefits**

The target audiences could experience the sustainable benefits such as improved quality of life and also comfort with better control of their fluid status.

On the other hand, nurses could gain numerous sustainable potential benefits from the innovation. The minimal workload to carry out education could reduce IDWG and HD treatment related complication rate, which could sustainably minimize stress and workload of nurses.

Moreover, the development of nursing autonomy and professionalism could be facilitated through implementing EBP guidelines. With providing opportunities for promoting patient care and comfort, influencing decisions on patient care and profession development, nurses are able to experience greater satisfaction towards their works (Buerhaus, DesRoches, Donelan, & Hess, 2009).

Based on the clinical experience, patients with excessive IDWG require extended HD treatment time. The extended treatment increases the costs of services, which will be discussed in following part. Therefore, the innovation could minimize the additional
costs spent on unnecessary services.

**Material Cost**

**Education equipment**

Equipment is already available in the target setting; therefore, there is only low material cost of the proposed innovation. The booklets are designed and produced by the NC and proposer of innovation and there are printing machines and paper available in the target setting, so the cost of the materials is mainly utilized on printing the information booklet. In traditional practices, single piece of black and white pamphlet costs HKD 0.1. In proposed innovation, the costs are calculated based on a 10 pages colorful booklet, which costs HKD 2 each. As mentioned in previous part, 300 new patients are recruited into HD programme yearly; hence, the total costs of traditional practices is HKD 30; the total costs of the innovation are estimated as HKD 600 each year.

**Nursing staffs**

To compare the costs on employing nursing staffs, as nurses are recommended to provide education with fully utilization of the long treatment time, no extra working time is required for the nurses for implementation. Hence, the costs of employing nurses are the same in both traditional practices and innovation.

**HD treatment**
The innovation could reduce the frequency of extended HD treatment. In 2013, there were 96 hours reported as non-scheduled treatment time, which were the unnecessary treatment for patients with excessive weight gained and extended HD time. A standard five hours HD treatment costs minimal HKD 3000, which included the costs of dialysate, dialyzer, tubing, basic electricity and specialized treated water supply, excluded the maintenance of HD machine, water supply system. Therefore, the cost of an hourly HD treatment is estimated as HKD 600. After implementing the innovation, the cost of maintaining HD treatment could be reduced with maximum HKD 57600.

**Non-Material Cost**

Nurses need to spend extra time on understanding the guidelines and content of the innovation. However, since the nurses have already gained the knowledge, therefore, the current staff function will not be interfered much.

A briefing session will be continuous proceeded during everyday handover session for a week to ensure acknowledging the innovation to colleagues.
4.1 Aim, Objectives

The aim of the innovation is to provide renal nurses evidence-based guidelines on educating fluid intake compliance in HD patients. The objectives are summarized as follows:

- To strengthen fluid intake knowledge for HD patients
- To enhance nurses to set framework for educating HD patients
- To minimize IDWG for HD patients

4.2 Target group

The target users are the nurses in renal unit and the population is the target audience mentioned in previous part.

4.3 Recommendations

Recommendation 1 (Grade A)

*Educational programme as an effective tool for enhancing fluid compliance*

Evidence:

In 4 of the reviewed studies, there were significant reduce in IDWG with introducing educational programme (Moattari et al., 2012; Baraz et al., 2010; Sharp et al., 2005; Tsay, 2003, Aliasgharpour et al.). (1+; 1++; 1++;1+,1-). Insignificant relation of education and IDWG was only shown in 1 of the studies. However, an increased in knowledge score was shown. The insignificant relation may be caused by the study design. The design was basically designed to investigate the primary outcome, such as
knowledge score, where the effect in IDWG was the secondary outcome. (Molaison et al., 2003) (1-)

**Recommendation 2** (Grade A)

*The optimum length of education session is suggested to be 1 hour per session, range from 2-4 sessions.*

Evidence:

One of the study suggested the education should be designed to be brief and not time-consuming to minimize drop out rate. A total of 4 hours basic education is recommended, with 1 hour per session and range from 2-4 sessions. Extended education and reinforcement are recommended if poor compliance is found. (Baraz et al., 2010; Sharp et al., 2005) (1++;1++)

**Recommendation 3** (Grade A)

*Individual and group counseling enable all rounded education.*

Evidence:

3 studies supported significant effect of individual counseling on reducing IDWG. Individual sessions enable the development of necessary skills and self-awareness in building fluid compliance. (Moattari et al., 2012; Tsay, 2003; Molaison et al., 2003) (1+; 1+; 1-). 4 studies supported the effectiveness of group sessions. It provided patients with social support and motivation, they could share experiences and develop coping strategies through discussion and role playing. (Baraz et al., 2010; Sharp et al., 2005; Molaison et al., 2003; Aliasgharpour et al., 2012 ) (1++; 1++; 1-; 1-)
**Recommendation 4** (Grade A)

*Both oral and video approaches are effective in educating fluid restriction*

Evidence:

Both oral and video approaches shown significant reduce in IDWG. There was no significant difference in the effectiveness of two approaches (Baraz et al., 2010) (1++)

**Recommendation 5** (Grade A)

*Supplementary Strategies should be incorporated to enrich education.*

Evidence:

Various supplementary strategies as follow:

- Setting goal (Sharp et al., 2005; Moattari et al., 2012; Tsay, 2003) (1++; 1+; 1+)
- Self monitoring (Sharp et al., 2005; Tsay, 2003) (1++; 1+)
- Providing feedback (Moattari et al., 2012; Tsay, 2003; Molaison et al., 2003; Aliasgharpour et al., 2012) (1+; 1+; 1-; 1-)
- Laboratory blood test review (Moattari et al., 2012; Molaison et al., 2003) (1+; 1-)
- Providing booklet (Baraz et al., 2010; Sharp et al., 2005; Aliasgharpour et al., 2012; Molaison et al., 2003) (1++; 1++; 1-; 1-)
- Muscle relaxation workshop for stress management (Sharp et al., 2005; Moattari et al., 2012; Tsay, 2003; Aliasgharpour et al., 2012) (1++; 1+; 1+; 1-)
Chapter 5 Implementation Plan

In this chapter, the implementation of fluid intake education for HD patients will be discussed with the communication and pilot study.

5.1 Identification of stakeholders

Stakeholders are the persons with the power to make change happen (Andrew, 2009). The stakeholders are identified, as follow, the significance and responsibilities of the stakeholder will be discussed in the next section.

1. Nurse Consultant (NC), Nurse Specialist (NS) & Advanced Practice Nurse (APN)
2. Chief of Service (COS), Department Operative Manager (DOM) & Ward manager (WM)
3. Physicians in Renal team
4. Nurses in unit

5.2 Communication with potential users

NC, NS and APN

In clinical settings, experienced senior clinical staffs, such as NC, NS and APN, are essentials persons in maintaining quality and standard of nursing care from clinical aspects. Firstly, they take roles in facilitating changes. Nursing practices with positive outcomes could be achieved through implementation of evidenced-based practices (EBP). They are competent and responsible for reviewing current treatment protocols, related studies and literatures, then evaluate and apply findings to current nursing care.

In addition, there is a growing recognition of NC in providing quality care among
nurses, doctors and clients. Therefore, in order to get approval and comments on new innovation, approaching NC as initial step is beneficial and essential.

The communication process with NC, NS and APN aimed at seeking feedback and comments. A proposal of the new guidelines will be prepared with introducing the needs and contents of innovation. It included the aims, objectives and content of guidelines, empirical evidence of the significance, the needs for the change and the summary of six reviewed articles in form of table of evidence. The implementation potential will then be discussed, which included expected resistance and the possible solutions. The information allows stakeholders to understand the needs, concepts and possibilities of the new guidelines.

**COS, DOM & WM**

Approval from staffs in management level is essential in initiating innovation. Gaining support from experienced clinical senior staffs could leverage staffs in management aspects, such as the COS, DOM and WM.

In order to achieve the permission regarding in management aspects, a formal meeting will be organized as promotion. During the meeting, a presentation of a group of information will be introduced, such as evidence of existing problem, budget and workforce planning and time framework of the implementation. Consulting senior clinical staffs is beneficial in understanding and meeting concerns in management aspects.
Renal Medical Team Physicians

Positive nurse, patient and physician outcomes could be achieved by promoting collaborative communication among different parties (Boyle & Kochinda, 2004). Therefore, physicians are another stakeholders as they play dominant role in providing treatment and monitoring disease progress. For example, in case of fluid overloaded during the implementation, medical officers are responsible to diagnose and prescribe treatment such as extra HD treatment time. Hence, gaining their acceptance and cooperation in implementing the innovation is necessary.

The significance of preventing fluid overloaded by education will be the focus of the presentation to the physicians. Their roles in the implementation will also be introduced. In order to facilitate understanding of innovation, the guidelines will be printed in hard copy and delivered for their reference.

Nurses in Unit

Nurses are another important stakeholders as they are the main users of EBP guidelines. The dietary education is able to minimize workload of nurses, where the benefits were discussed with existing evidence published in various nursing journal. However, in real clinical setting, there are obstacles to implement, such as lacking access in reviewing related evidence (Gale & Schaffer, 2009).

Hence, facilitating nurses to support the change through establishing strategies is essential. A Train the Trainer workshop will be arranged to prepare and support the nurses to implementation.

No new skills are required during implementation as the guidelines acts as a clear framework for carrying out education. Hence, the one-hour workshop will be targeted
on highlighting the change from current practice. In example, teaching in documentation will be included in the workshop. Hard copies of the education progress form for patients will be printed and introduced to nurses. Also, educating skills will be reviewed and reinforced, such as how to define optimum hydration level, or handle patients with excessive weight gain.

As there are numerous nursing staffs in the unit, APN and senior nurses will be assigned to participate the workshop first, they will be the mentors of educating colleagues afterward. Other nursing staffs will also be invited and encouraged to attend the workshop on a voluntary basis.

A channel, ward meetings, should be established to maintain continuous communication between decision makers, guidelines proposer and frontline nurses. It provides opportunities for nurses to raise their concerns, where issues arising during implementation could be discussed. It will be under the purview of the WM or DOM. The NC, NS and APN and guidelines proposer will also be invited for exchanging ideas and information.

5.3 Formation of taskforce for innovation

After communicating and gaining approval from stakeholders, forming a team of taskforce is essential. The team is responsible in processing and evaluation of implementation.

The guidelines proposer and three RNs will be the member of the team. The NC, NS and APN will be invited to be the advisor during the process of developing the guideline. Voluntary basis will the preference during recruiting member instead of nomination by WM.
A training section holding by NS, APN or guidelines proposer will be provided for the members, which allows them to be familiarized with the guidelines. After that, they will provide training and support to remaining staffs in unit.

5.4 Pilot Study Plan

Starting the implementation with a pilot study allows assessing the feasibility of conducting the implementation on a larger group of patients. It also allows identifying any obstacles and unexpected difficulty in time and budget management that could occur during a real implementation. Amendments of the guidelines could also be made after interpreting the problems.

Ethical Consideration

In order to prevent violation of ethical issues relating to clinical research, the pilot study will be designed according to the recommendation by the hospital Clinical Research Ethics Committee (Hospital Authority, 2007). Taskforce team members will explain the pilot study and obtain informed content with the participants. Each participant will be given with an information sheet in Chinese or English, which prepared by members.

Design and Sampling

One group pretest-posttest design will be used. The outcome measure is the IDWG recorded before and after implementing the new guidelines in continuous three months.

It will be carried out in the HD center in a local public hospital. As the target population is newly diagnosed renal failure patients who have just started HD
treatment, all new patients newly entering HD program will be recruited. Thirty eligible patients will be recruited in 12 weeks.

**Objectives**

The following points are the objectives,

1. To establish baseline IDWG.
2. To investigate the incidence of excessive weight gain during the implementation.
3. To determine the feasibility.
4. To assess frontline staffs and patients’ acceptability.
5. To estimate planning on time, budget and logistics.
6. To identify obstacles.

**Outcome measures**

The following outcome will be measured.

1. **Baseline of IDWG**

Quantitative and qualitative methods will be applied to collect the data. Establishing baseline information is important, as there is lack of official statistical data and formal documentation on excessive weight gain in target setting. An individual training record (Appendix 6) for each patient will be prepared, the IDWG and others laboratory blood reports will be filled in by nurses in each HD section.

2. **Incidence and severity of excessive weight gain**

The overall incidence and severity of excessive weight gain will also be observed and recorded before and after the implementation. As mentioned in previous section,
IDWG more than 5.7% of the dry weight (Leggat, 1998) is considered as overweight which indicate problematic adherence. Participants with IDWG exceed the ideal IDWG will be recorded in Record of Problematic weight gain sheet (Appendix 7).

3. **Satisfaction and acceptability of nurses and patients**

The acceptance of nurses on the guidelines will be investigated by inviting nurses to complete a questionnaire on the satisfaction before and after the implementation (Appendix 8). They will also be invited to participate in ward meetings to raise their concerns.

Patients’ opinion on the education will be investigated by completing the questionnaire before and after the implementation (Appendix 9), especially the change of satisfaction level on weight control. For those who are not able to fill in the questionnaire, such as the elderly or with low educational background, conducting face-to-face interviews will be feasible.

4. **Compliance of nurses**

Compliance to the guidelines could be ensured and assessed by reviewing individual training record (Appendix 6). The training progress is required to be filled and signed by nurses each time. Therefore, the signature of nurses represents the compliance with guidelines.
5. **Implementation cost & unexpected difficulties**

Cost will be estimated for budget planning in the actual implementation of the new guidelines. Review and amendments of proposed guidelines will be allowed by identifying the previous outcomes findings and other unexpected obstacles associated with the guidelines during pilot study.
Chapter 6 Evaluation Plan

In an entire evaluation plan, the benefits and effectiveness of the innovation should be demonstrated by providing scientific data. Therefore, the evaluation plan is essential in gaining approval and recognition from stakeholders to continue the implementation of guidelines in the future.

6.1 Identifying outcomes

For patients

The effectiveness of patient education on fluid restriction could be reflected by the change in IDWG. A decrease in IDWG is suggested to be the primary outcome, therefore, the innovation is considered to be effective if the IDWG is reduced.

For healthcare provider

Satisfaction to work is an essential element, which helps nurses in delivering high-quality patient care (McNeese-Smith & Nyamathi, 1999). Therefore, the level of satisfaction and acceptance on innovation will be evaluated.

On the other hand, the compliance to the guidelines will also be evaluated as the effectiveness of innovation depends on the compliance of nurses (Kinsman, 2004).

For system

Any extra expenditure contributed to the innovation will be included. It included the cost for preparing the educational materials, such as booklets, questionnaire and assessment chart. Additional manpower will also be considered.
6.2 The nature and number of clients

The clients of the innovation and the population in target setting mentioned in previous chapters are identical. It refers to the patients who are newly diagnosed with renal failure and have started HD for less than 1 month. They admit the HD day center to have dialysis twice or three times a week.

The number of clients to be involved is based on the primary outcome, IDWG. Therefore, the evaluation aimed at determining whether the IDWG will be reduced with implementing patient educational programme. The innovation targeted at achieving 0.05 of the level of significance and 80 percent of the statistical power. The estimated sample size is 45, which is calculated by an online programme (Length, 2006-9). Based on the reviewed articles, the attribution rate is approximately 10 percent. Hence, the approximately estimated sample size is 50. Four to six months of sampling will be taken.

6.3 Time of measurements

Building up compliance is a long process, which requires continuous support and education. The follow up were ranged from two to six months in the six reviewed studies. Therefore, the outcomes will be measurement at three time interval, the first, third and sixth month, after starting patient education, where allows investigating short, intermediate and long-term effects of the guidelines.
6.4 Data collection and Analysis

Patient outcomes

Change in IDWG

Patients are weighed before and after each dialysis session. The IDWG is the difference of post HD weight and the pre HD weight of the next dialysis session. The change in IDWG will be compared before and after the implementation.

Satisfaction level

By filling a self-administered questionnaire (Appendix 9), patient satisfaction and acceptance level could be assessed. The taskforce team is responsible in interpreting their comments and feedback. Descriptive Statistical Method will be used for collecting and analyzing data.

Health Care provider outcomes

Satisfaction and Acceptance level

A self-administered questionnaire (Appendix 8) will be collected from frontline nurses to evaluate their satisfaction level in implementing the new guideline. Five-point Likert Scale will be used to rate their satisfaction level. The data will be collected and analyzed by t-test and descriptive Statistical Method to determine the significance of the changes in satisfaction scores. After that, will be used to analyze the data.

The feedback collected will be interpreted for reviewing and modifying the guidelines. The findings will be presented and discussed in ward meetings.
Compliance

Nursing audit will be arranged for assessing nurses’ compliance to the new guidelines. The quality of patient care and clinical practice could be enhanced by clinical audit (Cooper & Benjamin, 2004). The workforce team will assess the individual training record. The rating given and signed by the nurse represents completion of the documentation is assessed and analyzed.

The attendance rate of the workshop and ward meeting provides data to estimate the compliance to new change as well. Only a certain number of nurses will be assigned to officially join the workshop and ward meeting under the environment with high workload and limited manpower. Therefore, the number of participants represents the compliance, which will be recorded and analyzed. The reasons causing non-compliance could also be investigated in the questionnaire (Appendix 8).

System Outcomes

Expenditure spending on the cost and manpower will be calculated for analysis.

The major cost will be spent on paperwork for example booklets, questionnaire and assessment chart, other expenditure include holding workshop and meeting. Those quantitative data will be analyzed monthly with computerized system, and compare with the costs spending on current practices. The difference is able to represent the cost effectiveness.
6.5 Criteria for considering the effectiveness of practice

Reducing the IDWG by establishing patient education on fluid restriction is the main objective of the innovation. IDWG, which considered as the primary outcome, represents the effectiveness of the guidelines. Patients with IDWG exceeding 5.7% of the dry weight (Leggat, 1998) are considered as overweighed with problematic adherence. Therefore, the new guidelines are considered to be significance statistically effective if the IDWG is less than 5.7% of the dry weight.

In view of healthcare outcome, over 90% of the nurses are able to give fluid restriction education to patients, and correctly complete the individual training record form are the targeted compliance rate, which fulfilled the standard of nursing audit in the target setting. For the staff training, 100% of the nursing staffs receive training on new innovation are targeted, which could be received in training workshop or trained by taskforce members.
Chapter 7 Conclusion

The problem of poor fluid restriction compliance is common and significant in HD patients. Patients with excessive IDWG will have increased risks of experiencing life threatening adverse symptoms and complication. However, there is no well-established intervention to help patients to go through the challenging life style changes in local settings. Therefore, developing an education based educational programme is necessary to enhance fluid intake compliance in HD patients.

In this translational nursing research, evidence-based practice educational guidelines on fluid restriction are established. Through reviewing and appraising the selected six studies, an educational intervention was related to reduction in IDWG. An implementation and evaluation plan has also been developed. A pilot study plan is recommended to investigate the feasibility of the implementation of innovation.

The proposed guidelines will be disseminated in the target HD center in local setting. The aim of the guidelines is to enhance the framework for nurses to strengthen fluid intake knowledge for HD patients. At the same time, it also aimed at minimizing IDWG by an evidence-based practice.

This innovation could help ESRF patients to adapt the life changes with chronic diseases. Through implementing the guidelines, the fluid restriction compliance of patients, hence the quality of life and physical health could be enhanced. On the other hand, for the healthcare system, minimizing extra service for fluid overloaded patients could also reduce the workload of healthcare providers.

(9582 Words)
References


- Davenport A (2009): Can advances in hemodialysis machine technology


244-266.


• Length. (2006-9). Java applets for power and sample size.


### Appendix 1: Summary of searching keywords

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### Appendix 2: Summary of Electronic database search

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<td>Combine Databases &amp; Remove Duplication</td>
<td>6</td>
</tr>
</tbody>
</table>
## Appendix 3: Table of Evidences

<table>
<thead>
<tr>
<th>Bibliographic Citation</th>
<th>Study Type/ Country of study</th>
<th>Evidenc e level</th>
<th>Patient Characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures’ Result/ Effect size*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moattari et al., 2012</td>
<td>Randomized controlled trial</td>
<td>1+</td>
<td>HD patients of HD center (n= 50)</td>
<td>Empowerment program (n=25)</td>
<td>Usual care (n=25)</td>
<td>3 months</td>
<td>Primary: (1) Self-efficacy score (2) QoL score Secondary: (3) IDWG (kg) (4) SBP (mmHg) (5) Lab blood tests results e.g. Na+ (mEq/L), Cr (mg/dL) Measured at baseline and follow up At 6 weeks (1) 12.02 (p= &lt;0.001) (2) 2.93 (p= &lt;0.001) (3) -0.44 (p= &lt;0.039) (4) -14.35 (p= &lt;0.001) (5) Na+: -1.96 (p= &gt;0.086 Cr: -0.24 (p= &gt;0.677)</td>
</tr>
<tr>
<td>Aliasgharpour et al., 2012</td>
<td>Randomized controlled trial (Quasi-experimental)</td>
<td>1-</td>
<td>HD patients of 2 HD unit (n= 63)</td>
<td>Self-efficacy promotion training program (n=32)</td>
<td>Routine care (n=31)</td>
<td>2 months</td>
<td>(1) IDWG (kg) (2) Self-efficacy score Measured at baseline, post-intervention &amp; follow up At 14 weeks (1) -1.13 (p=0.02) (2) 0.84 (p=&lt;0.001)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Location</td>
<td>Sample Size</td>
<td>Sample Characteristics</td>
<td>Intervention A</td>
<td>Duration</td>
<td>Outcome Measures</td>
</tr>
<tr>
<td>-----------------------</td>
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<td>-------------------------</td>
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</tr>
<tr>
<td>Baraz et al., 2010</td>
<td>Randomized controlled trial</td>
<td>Iran</td>
<td>1++</td>
<td>HD patients of 3 HD centers (n= 63)</td>
<td>Video education teaching program (n=31)</td>
<td>2 months</td>
<td>Within group (pretest &amp; posttest)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gender: Male 52.4% Mean Age 34.8 years Mean length time of HD: 55.2 months from 6 to 96 months, Educational level: college education 52.4% high school 28.6% primary school 19%</td>
<td>Duration: 1 hour Nature: Group session</td>
<td></td>
<td>(1) IDWG (kg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Between group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Measured at baseline &amp; post intervention</td>
</tr>
<tr>
<td>Sharp et al., 2005</td>
<td>Randomized controlled trial</td>
<td>UK</td>
<td>1++</td>
<td>HD patients from 4 HD unit (n= 56 )</td>
<td>Immediate-treatment (n=29)</td>
<td>2.5 months</td>
<td>Within group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gender: Male 67.8% Mean Age: 54.35 years Mean length time of HD: 53.95 months Educational level: college education 21.42% high school 8.93% none: 57.14%</td>
<td>Receive immediate GULP Duration: 4 hours Nature: Group session</td>
<td></td>
<td>(1) IDWG (kg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Between group:</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Acute Phase (from baseline to post-intervention, represent between group no-treatment control)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Longitudinal Phase: BASELINE TO POST-TREATMENT:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Baseline to follow-up:</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Baseline to follow-up:</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Setting</td>
<td>Study Design</td>
<td>Participants</td>
<td>Intervention</td>
<td>Control</td>
<td>Duration</td>
<td>Outcomes</td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
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<td>--------------</td>
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</tr>
<tr>
<td>Tsay, 2003</td>
<td>Taiwan</td>
<td>Randomized controlled trial</td>
<td>HD patients in 3 outpatient HD centers (n= 62)</td>
<td>Self-efficacy training programme plus usual care (n= 31)</td>
<td>Routine care (n= 31)</td>
<td>6 months</td>
<td>(1) Weight gains (kg) at baseline, 1, 3 and 6 months post intervention</td>
</tr>
<tr>
<td>Molaison et al., 2003</td>
<td>South Louisiana</td>
<td>Randomized controlled trial</td>
<td>HD patients in 10 HD centers (n=316)</td>
<td>Nutrition education (n=216)</td>
<td>Usual protocol (n=100)</td>
<td>3 months</td>
<td>(1) Proportion of participants in each stage of change (%) e.g. pre-contemplation stage (2) Knowledge scores (3) IDWG (kg) at baseline, 6 and 12 weeks</td>
</tr>
</tbody>
</table>

**Abbreviations:**
- **IDWG:** Inter-Dialytic Weight Gain
- **QoL:** Quality of Life
- **BP:** Blood Pressure
- **Na+:** Sodium ions
- **PO4-:** Phosphate ions
- **K+:** Potassium ions
- **Cr:** Creatinine
- **GULP:** Glasgow University Liquid-Intake Program
- **HADS:** Hospital Anxiety and Depression Scale
- **NS:** Not Significant

* Values shown as Mean difference(intervention – control)
Appendix 4: SIGN methodology checklist

### Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline topic: An evidence based educational programme to enhance fluid compliance for hemodialysis patient</td>
<td>Key Question No: 1 &amp; Reviewer: Ho Nga In</td>
</tr>
</tbody>
</table>

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:**

1. Paper not relevant to key question  
2. Other reason: (please specify):

**SECTION 1: INTERNAL VALIDITY**

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| **1.1** The study addresses an appropriate and clearly focused question. ¹ | Yes ■  
Can't say □  
No □ |
| **1.2** The assignment of subjects to treatment groups is randomised. ² | Yes □  
Can't say ■  
No □ |
| **1.3** An adequate concealment method is used. ³ | Yes □  
Can't say □  
No ■ |
| **1.4** Subjects and investigators are kept 'blind' about treatment allocation. ⁴ | Yes ■  
Can't say □  
No □  
Nurses were blinded to allocation during intervention and data collection |
| **1.5** The treatment and control groups are similar at the start of the trial. ⁵ | Yes □  
Can't say □  
No □ |
| **1.6** The only difference between groups is the treatment under investigation. ⁶ | Yes ■  
Can't say □  
No □ |
| **1.7** All relevant outcomes are measured in a standard, valid and reliable way. ⁷ | Yes ■  
Can't say □  
No □ |
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? viii  
4%

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). ix  
Yes □  Can't say □  No □  Does not apply □

1.10 Where the study is carried out at more than one site, results are comparable for all sites. x  
Yes □  Can't say □  No □  Does not apply □

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias?  
*Code as follows:* xi  
High quality (++) □  
Acceptable (+) □  
Unacceptable – reject 0 □

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?  
Significant IDWG falls within the confidence interval, the intervention was responsible for the change in the study

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?  
Yes. IDWG of experimental group was significantly lower than control group, which reflect the effectiveness of the intervention for HD patients.

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.  
Empowerment program is able to reduce IDWG through individual and group counseling session. Review and feedback should be given to individual for enhancing adherence behavior and decision making to monitor weight and overcome the barriers of fluid intake.
Methodology Checklist 2: Controlled Trials

### Study identification
*Include author, title, year of publication, journal title, pages*

<table>
<thead>
<tr>
<th>Guideline topic: An evidence based educational programme to enhance fluid compliance for hemodialysis patient</th>
<th>Key Question No: 2</th>
<th>Reviewer: Ho Nga In</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:
1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

1.1 The study addresses an appropriate and clearly focused question. 
Yes ☐ Can't say ☐ No ☐

1.2 The assignment of subjects to treatment groups is randomised.
Yes ☐ Can't say ☐ No ☐

1.3 An adequate concealment method is used.
Yes ☐ Can't say ☐ No ☐

1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.
Yes ☐ Can't say ☐ No ☐

1.5 The treatment and control groups are similar at the start of the trial.
Yes ☐ Can't say ☐ No ☐

1.6 The only difference between groups is the treatment under investigation.
Yes ☐ Can't say ☐ No ☐

1.7 All relevant outcomes are measured in a standard, valid and reliable way.
Yes ☐ Can't say ☐ No ☐

1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?
23%
1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). \textsuperscript{xx}

<table>
<thead>
<tr>
<th>Yes □</th>
<th>Can't say □</th>
<th>No □</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Does not apply □</td>
</tr>
</tbody>
</table>

1.10 Where the study is carried out at more than one site, results are comparable for all sites. \textsuperscript{xxi}

<table>
<thead>
<tr>
<th>Yes □</th>
<th>Can't say □</th>
<th>No □</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Does not apply □</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

#### 2.1 How well was the study done to minimise bias? 

\textit{Code as follows:} \textsuperscript{xxi}

- High quality (++)
- Acceptable (+)
- Unacceptable – reject

#### 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

Although the study design was with high risks of bias due to lack of mentioning randomization method, blinding, and concealment, selection of outcome measures (comparing IDWG) enabled minimization of bias.

The interview for measuring self efficacy score brought high risks of bias, but it was not the main outcome concerned in the guidelines.

#### 2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

Yes, there was significant relation shown between intervention and IDWG.

#### 2.4 Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The findings support the short and long term effectiveness of educational intervention on reducing IDWG and increasing self-efficacy ability. Education should include providing feedback, helping patients to identify strategies.
Methodology Checklist 2: Controlled Trials

Study identification  (*Include author, title, year of publication, journal title, pages*)

Guideline topic: An evidence based educational programme to enhance fluid compliance for hemodialysis patient  
Key Question No: 3  
Reviewer: Ho Nga In

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

#### In a well conducted RCT study…

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| 1.1 | The study addresses an appropriate and clearly focused question.  
*xxiii* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.2 | The assignment of subjects to treatment groups is randomised.  
*xxiv* | Yes ☐  
Can't say ☐  
No ☐  
Computer-generated random numbers |
| 1.3 | An adequate concealment method is used.  
*xxv* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.4 | Subjects and investigators are kept 'blind' about treatment allocation.  
*xxvi* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.5 | The treatment and control groups are similar at the start of the trial.  
*xxvii* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.6 | The only difference between groups is the treatment under investigation.  
*xxviii* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way.  
*xxix* | Yes ☐  
Can't say ☐  
No ☐ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?  
*xxx* | Nil |

58
<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Yes</th>
<th>Can't say</th>
<th>No</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th>2.1</th>
<th>How well was the study done to minimise bias?</th>
<th>High quality (++)</th>
<th>Acceptable (+)</th>
<th>Unacceptable – reject 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Code as follows:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>The effect is considered to be due to the intervention as the study was designed with randomization with recruiting suitable participants with wide range of age group and educational level, which could represent the population of targeted patient group.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes. The findings significantly support the effectiveness of education to increase dietary and fluid restriction compliance with either oral or video approach, hence, reduce IDWG.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>Educational intervention, either through an oral or video approach, could increase the fluid and dietary compliance of patients having haemodialysis. There was no difference between the effectiveness of oral and video education.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Methodology Checklist 2: Controlled Trials

**Study identification**  *(Include author, title, year of publication, journal title, pages)*

**Guideline topic:**
An evidence based educational programme to enhance fluid compliance for hemodialysis patient  

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Ho Nga In</td>
</tr>
</tbody>
</table>

**Reason for rejection:** 1. Paper not relevant to key question 2. Other reason (please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
<td>Yes ☑ Can’t say ☐ No ☐</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑ Can’t say ☐ No ☐</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
<td>Yes ☑ Can’t say ☐ No ☐</td>
</tr>
<tr>
<td><strong>1.4</strong> Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes ☐ Can’t say ☑ No ☑ Open Non-blind Study, selection of outcome measures enabled minimization of bias</td>
</tr>
<tr>
<td><strong>1.5</strong> The treatment and control groups are similar at the start of the trial.</td>
<td>Yes ☑ Can’t say ☐ No ☐</td>
</tr>
<tr>
<td><strong>1.6</strong> The only difference between groups is the treatment under</td>
<td>Yes ☑ No ☐</td>
</tr>
<tr>
<td>Section</td>
<td>Question</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| SECTION 2: OVERALL ASSESSMENT OF THE STUDY | How well was the study done to minimise bias?  
*Code as follows:* | High quality (+++) | Acceptable (+) | Unacceptable – reject 0 |
| 2.1       | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | As a pilot study, the significance was detected with 70-80% power, the randomized controlled design could prove the significant effectiveness of the intervention with minimal bias. The effect is considered to be due to the intervention. |
| 2.3       | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. The results suggested the long term effect of the interventional program |
| 2.4       | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Intervention is able to improve adherence to fluid restriction and reduce IDWG over long time. Also, early session of the intervention would be more effective in educating fluid restriction. |
Methodology Checklist 2: Controlled Trials

**Study identification** *(Include author, title, year of publication, journal title, pages)*

**Guideline topic:** An evidence based educational programme to enhance fluid compliance for hemodialysis patient

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer: Ho Nga In</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes □ No □ Can't say □</td>
</tr>
</tbody>
</table>

1.1 The study addresses an appropriate and clearly focused question.\(^{xliv}\)

1.2 The assignment of subjects to treatment groups is randomised.\(^{xlvi}\)

1.3 An adequate concealment method is used.\(^{xlvii}\)

1.4 Subjects and investigators are kept 'blind' about treatment allocation.\(^{xlviii}\)

1.5 The treatment and control groups are similar at the start of the trial.\(^{xlix}\)

1.6 The only difference between groups is the treatment under investigation.\(^{l}\)

1.7 All relevant outcomes are measured in a standard, valid and reliable way.\(^{l1}\)

1.8 What percentage of the individuals or clusters recruited into each group have a follow-up measurement?\(^{l2}\)

3.13%
1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  

<table>
<thead>
<tr>
<th>Code</th>
<th>Yes</th>
<th>Can't say</th>
<th>No</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

1.10 Where the study is carried out at more than one site, results are comparable for all sites.  

<table>
<thead>
<tr>
<th>Code</th>
<th>Yes</th>
<th>Can't say</th>
<th>No</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias? 

*Code as follows:*  
- High quality (++)
- Acceptable (+)
- Unacceptable – reject 0

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? 

- Although randomization method was not mentioned, adequate sample recruited with 80% of statistic power and significant findings was able to prove the overall effect is due to the intervention

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline? 

- Yes, the patient from the study and targeted group share same background

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

- The findings significantly proved the self-efficacy training could reduce the weight gains for up to 6 months following intervention (p=0.006), it suggested nurses should support patients through setting own goals and provide guidance
Methodology Checklist 2: Controlled Trials

Study identification  (Include author, title, year of publication, journal title, pages)

Guideline topic: An evidence based educational programme to enhance fluid compliance for hemodialysis patient

Key Question No: 6
Reviewer: Ho Nga In

Before completing this checklist, consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.1</td>
<td>Yes □ No □ Can’t say □</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.2</td>
<td>Yes □ No □ Can’t say □</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.3</td>
<td>Yes □ No □ Can’t say □</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.4</td>
<td>Yes □ No □ Can’t say □ Strict instruction on avoiding contamination between group</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.5</td>
<td>Yes □ No □ Can’t say □</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias? Code as follows: High quality (++), Acceptable (+), Unacceptable – reject 0</td>
<td>There was risk of bias in study, as the randomization method was not stated clearly. Although there were significant increase in knowledge and stage of change, there was no significant change in IDWG, it may due to the inaccurate perception of intake associated with season change where study was carried out between summer and winter.</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes, the significant increase in knowledge relate to building fluid restriction compliance</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>The intervention could increase knowledge of fluid restriction, education should be incorporated at the initiation of HD to ease motivation of making dietary changes</td>
</tr>
</tbody>
</table>

2.4 **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.
### Appendix 5: Summary of SIGN methodology checklists

<table>
<thead>
<tr>
<th></th>
<th>Moattari et al., 2012</th>
<th>Aliasgharpour et al., 2012</th>
<th>Baraz et al., 2010</th>
<th>Sharp et al., 2005</th>
<th>Tsay, 2003</th>
<th>Molaison et al., 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focused question addressed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Randomization applied</td>
<td>Can’t say</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>Concealment used</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Blinding used</td>
<td>Yes</td>
<td>No</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Similarity at start</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Treatment be the only difference</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Reliable outcome measures</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Drop out rate</td>
<td>4%</td>
<td>23%</td>
<td>Nil</td>
<td>17.85%</td>
<td>3.13%</td>
<td>Nil</td>
</tr>
<tr>
<td>Intention to treat analysis used</td>
<td>No</td>
<td>No</td>
<td>Does not apply</td>
<td>Yes</td>
<td>No</td>
<td>Does not apply</td>
</tr>
<tr>
<td>Compare result for multi site</td>
<td>No</td>
<td>Can’t Say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>Level of Evidence</td>
<td>1+</td>
<td>1-</td>
<td>1++</td>
<td>1++</td>
<td>1+</td>
<td>1-</td>
</tr>
</tbody>
</table>
Appendix 6:

Fluid Restriction Education
Individual Training Record

Name:
ID No.:
Sex:
Dry Weight:
# Ideal Interdialytic weight gain (IDWG):

<table>
<thead>
<tr>
<th>Date</th>
<th>1. SOB</th>
<th>2. Edema</th>
<th>1. Inter-dialytic weight gain (IDWG)</th>
<th>2. IDWG&gt; Ideal IDWG</th>
<th>3. BP for Hyper/Hypotension</th>
<th>4. Laboratory Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

C. Blood Test (*weekly)
Assessed by Nurse (Signature)

Please enter
‘1’ : Problem
‘0’ : No Problem
‘NA’ : Not applicable

# Excessive IDWG= Dry Weight x 5.7%
* Blood x Renal Function Test (RFT)
Appendix 7:

Record of Problematic Weight Gain

<table>
<thead>
<tr>
<th>Name</th>
<th>HD</th>
<th>* Problematic Weight Gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
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<td>4</td>
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<td>5</td>
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<td>6</td>
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</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Refer to Individual Training Record

* Please enter following key
  ‘1’  If Interdialytic weight gain (IDWG) >= Ideal IDWG
  ‘0’  If IDWG< Ideal IDWG
  ‘NA’  Not applicable
Appendix 8:

Fluid Restriction Education
Questionnaire on Satisfaction of Nurses

Rank:

Please tick a box on each line to indicate how much you agree or disagree with each of the following statements.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am confident in educating patients with problematic weight gain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The guidelines provide framework in educating patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The education can reduce patients’ interdialytic weight gain</td>
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<tr>
<td>The workshop helps me to understand the content of guidelines</td>
<td></td>
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</tr>
<tr>
<td>Not much extra skills required to implement the education</td>
<td></td>
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</tr>
<tr>
<td>I can handle the patient education together with my usual work routine</td>
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<td></td>
<td></td>
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<tr>
<td>The workforce team and related staffs offers help whenever I need</td>
<td></td>
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</tr>
</tbody>
</table>

Difficulties to comply the implementation:

Other comments:
## Appendix 9:
### Fluid Restriction Education
#### Questionnaire on Satisfaction of patients

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid restriction causes great disturbance in daily life</td>
<td></td>
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</tr>
<tr>
<td>I know the reasons of restricting fluid intake</td>
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<tr>
<td>I know the volume of fluid I can take everyday</td>
<td></td>
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</tr>
<tr>
<td>I have done my best to lower my Interdialytic weight gain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My interdialytic weight gain is at acceptable level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The content of education is easy to understand</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>The duration of education is optimal</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>The booklet is useful</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Nurses gives useful advices on fluid restriction</td>
<td></td>
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<tr>
<td>The group discussion can provide chances to share ideas with other patients on fluid restriction</td>
<td></td>
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<tr>
<td>I can disclose my concerns on fluid restriction to nurses during individual counseling</td>
<td></td>
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<tr>
<td>Overall, the education can help in restricting fluid intake</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other comments:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>