Preliminary title:

Non-adherence to fluid restrictions: prevalence and the role of self-efficacy among haemodialysis patients

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Contents

Preface ................................................................................................................................. 5
Introduction .......................................................................................................................... 6
  Fluid intake behaviour ................................................................................................. 7
Theoretical framework ...................................................................................................... 9
  Biopsychosocial model ............................................................................................... 9
  Self-efficacy theory ..................................................................................................... 9
  Self-efficacy and health behaviour/adherence .......................................................... 10
Measurement of self-efficacy ........................................................................................... 10
Concepts and definitions ................................................................................................. 11
  Definition of adherence .............................................................................................. 11
  Definition of fluid adherence ...................................................................................... 12
Aims .................................................................................................................................. 13
  Study I ......................................................................................................................... 13
  Study II ....................................................................................................................... 13
  Study III ..................................................................................................................... 13
Methods ............................................................................................................................ 14
  Design ......................................................................................................................... 14
  Subjects and procedures ............................................................................................ 15
  Measures .................................................................................................................... 15
  Data management and statistical procedures .......................................................... 17
Results ............................................................................................................................... 19
  Study I ......................................................................................................................... 19
  Study II ....................................................................................................................... 20
  Study III ..................................................................................................................... 20
Concluding remarks and future directions .................................................................... 21
References ......................................................................................................................... 23
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
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<tr>
<td>CES-D</td>
<td>The Centre of Epidemiological Studies- Depression scale</td>
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<tr>
<td>ESRD</td>
<td>End-stage Renal Disease</td>
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<td>FIAI</td>
<td>Fluid Intake Appraisal Inventory</td>
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<tr>
<td>HD</td>
<td>Haemodialysis</td>
</tr>
<tr>
<td>IWG</td>
<td>Interdialytic Weight Gain</td>
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<tr>
<td>LOT-R</td>
<td>The Life Orientation Test-Revised</td>
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<tr>
<td>PD</td>
<td>Peritoneal dialysis</td>
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<tr>
<td>RMSEA</td>
<td>The Root Mean Square Error of Approximation</td>
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<td>TMSI</td>
<td>Threatening Medical Situation Inventory</td>
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Preface

The present half-time report is part of a project that constitutes the basis for a future thesis focusing on patient beliefs and personality influences on adherence to fluid restrictions. Furthermore, the project includes a theory based intervention model aimed to be used as means in the clinical nursing care to enhance adherence to fluid restrictions among haemodialysis (HD) patients. The following manuscripts are enclosed to this report:


III Lindberg, M., Högberg, H., Wikström, B., Lindberg, P. Self-efficacy as a mediator of haemodialysis patients’ adherence to fluid restrictions. (Manuscript in process, draft enclosed)
Introduction

End-Stage Renal Disease (ESRD) is incurable and afflicts individuals of all ages, ethnic groups and socioeconomic strata. The underlying etiology is most commonly due to advanced complications of other medical conditions e.g. diabetes mellitus and or hypertension. Other etiological factors for renal disease is for instance glomerulonephritis or polycystic kidney disease (Mallick & Gokal, 1999; Meldrum, 2000; Schön, Ekberg, Wikström, Oden, & Ahlmen, 2004). Consequently, whatever caused the disorder all ESRD patients face a life-threatening loss of renal functions.

Upon the cessation of renal function, excess fluid, metabolic toxins, and electrolytes accumulate in blood and bodily tissues and these substances must be removed by alternative means. Consequently, the treatment of ESRD concentrates on replacements of lost renal functions and consists of dialysis treatment (Mallick & Gokal, 1999), an extensive need of medications (Lindberg, Lindberg, & Wikström, 2007; H. J. Manley et al., 2004) and a dietary prescription composed of fluid, mineral and foodstuff restrictions (Mallick & Gokal, 1999). Current renal replacement therapies include several forms of dialysis whereas haemodialysis (HD) three times per week for four to five hours or self-administered peritoneal dialysis (PD) four times a day is the most common.

In many ways, the treatment of ERSD involves demanding tasks for the patient and may also include requirements of behavioural change during the adaptation to treatment regimen. Altering a maladaptive behaviour is often required, but challenging, for successful medical treatment (Newmann & Litchfield, 2005) thus a preserved behaviour may lead to severe medical consequences, or in worst case it could be lethal (Hamilton, 2000; Leggat et al., 1998; Vennegoor & Coleman, 2000). A deliberate preservation of mal-adaptive behaviour is often described as non-adherence to treatment regimen.

As with most chronic illnesses, non-adherence to the prescribed regimen is a pervasive problem in the ESRD population. The individual patient might be adherent to one regimen e.g. following prescribed medication, but not in another and adherence may even fluctuate within a regimen, which make the magnitude of adherence complex to measure (Kaveh & Kimmel, 2001;
Lamping & Campbell, 1990). Hence, at least 50% of the HD patients are believed to be non-adherent to some part of their treatment (Kaveh & Kimmel, 2001), whereas adherence to fluid restrictions is the most difficult to accomplish (Johnstone & Halshaw, 2003; Malick & Gokal, 1999; Newmann & Litchfield, 2005; Sagawa, Oka, & Chaboyer, 2003).

Most patients on HD have oliguria or are anuric and will because of fluid retention experience weight gain between two consecutive dialysis sessions. An unrestricted fluid intake may have serious consequences and prolonged fluid overload is a potential life-threatening condition associated with congestive heart failure, hypertension, shortness of breath, treatment related fatigue, severe muscle cramps and dizziness (Abuelo, 1998; Leggat et al., 1998; Malick & Gokal, 1999). Therefore, the HD patient is, based on evidence and best practice, advised a fluid allowance of 500 ml plus a volume equal to daily urine output (Ash et al., 2006; Dietitians-special-interest-group, 2002). Hence, in an early study have incompatible diet habits been tied to high mortality (Abram, Moore, & Westervelt, 1971) and more recent studies demonstrate that excessive fluid overload still is associated with higher risk of death (Leggat et al., 1998; Movilli et al., 2007; Ozkahya et al., 2006; Saran et al., 2003; Stegmayr et al., 2006).

**Fluid intake behaviour**

The intake of fluids may occur because of habit, customs, social rituals, disease, and dry mouth or as an accompaniment to the ingestion of food (McKinley et al., 2004). Fluid intake may also occur as a way to take prescribed medication or be a strategy to handle medication related problems (Lindberg & Lindberg, 2008). Moreover, fluid intake is a regulatory reaction to the drive of thirst, which is a physiological response to physical deficit of fluid, or to systematic hypertonicity (McKinley et al., 2004). The sensation of thirst often results in behavioural activities such as drinking whereas the onset of drinking is a result from various motivational and cognitive processes that elicits the behaviour (Aarts, Dijksterhuis, & De Vries, 2001).

The amount of fluids drunk by an individual may vary from day to day, depending on physical activity, environmental temperature, social interactions, nutrient intake and habits (McKinley et al., 2004). Drinking considerably more fluids than the advised limit is a familiar experience to many dialysis patients and most patients are aware of the need to be adherent although the desire to drink normally creates an uncomfortable state (Fisher, 2004). In addition, to be prescribed fluid restrictions often generates a treatment related stressor (Baldree, Murphy, & Powers, 1982; Gurklis & Menke, 1988; Mok & Tam, 2001; Welch & Austin, 1999; Yeh & Chou, 2007) and non-adherence is a strategy to reduce stress experiences (Welch & Austin, 1999).
The tension between treatment-related constraints and the individual’s effort to maintain a sense of autonomy has been described as a ‘compliance independence tight rope’ (Curtin, Oberley, & Sacksteder, 1997; Kutner, 2001).

Fisher (2004) has conceptualized thirst in the context of restricted fluid intake in order to describe the psychological processes contributing to excessive fluid intake in dialysis patients. Her model assumes that there is a tension between the need to restrict fluid intake and the desire to drink, and that attention to thirst will increase the thirst. Furthermore, encountering triggers e.g. to see others drink, will start processes of monitoring the degree of thirst or other somatic sensations, which all could result in feelings of powerlessness to resist the urge to drink e.g. poor self-efficacy to fluid restriction. Figure 1 displays an adapted description of her model.

Figure 1. Adapted model from Fisher (2004) describing suggested psychological processes involved in an increased perception of thirst and unhelpful drinking patterns in HD patients on a fluid restriction.
Theoretical framework

Biopsychosocial model

The biopsychosocial dimension of illness was introduced by Engel (1977) in the late 1970’s and its core value is in guiding parsimonious application of medical knowledge to the needs of each patient. The philosophy of this model gives understanding how suffering, disease and illness are affected by biological, psychological and social factors, which dictates the patient to be an active mediator of change i.e. the behavioural dimension of illness. The model also gives a practical understanding of the patient’s subjective experience of illness and the management of chronic medical problems. Hence, the biopsychosocial model considers psychological factors not only as possible consequences of illness, but also as contributing factors to its cause and maintenance. Moreover, the biopsychosocial framework is included in several social-cognitive models of health behaviour e.g. the self-efficacy theory and the social learning theory (Bandura, 2004) and its predictive value on patients’ adherence to health-promoting or treatment behaviours have been suggested by a large body of empirical findings summarized in a review by Di Matteo, Haskard, & Williams (2007).

Self-efficacy theory

The conceptual system forming Bandura’s (1977; 1982; 1991; 1997; 2004) self-efficacy theory (Figure 2) includes the characteristics of a person, the behaviour of the person and the outcomes of the behaviour. Furthermore, it also includes the person’s efficacy expectations and outcome expectations. An outcome expectation is the person’s estimate that a given behaviour will lead to a specific outcome and can take the form of physical, social or self-evaluative effects. An efficacy expectation concerns the confidence in ones capability to accomplish a specific behaviour and its magnitude and strength will determine how much effort people will mobilize and their level of persistence (Bandura, 1991). In other words, the essence in the self-efficacy theory is that the expectations of personal mastery and success determine whether an individual will engage in a particular behaviour. This means that self-efficacy is a temporary and influenceable characteristic related to situations and tasks. Moreover, the self-efficacy theory provides an opportunity for explaining the discrepancy between an individual’s knowledge and behaviour even though the person is fully aware of what should be done (Bandura, 1982).
Self-efficacy and health behaviour/adherence
The underlying variables that constitute the concept of self-efficacy appear to predict change and maintenance of health-promoting behaviours (DiMatteo et al., 2007; Strecher, DeVellis, Becker, & Rosenstock, 1986). Moreover, self-efficacy is an important determinant because the posited sociocognitive causal model described by Bandura (2004) includes paths wherein self-efficacy affects health behaviour both directly and through its impact on other determinants. Thus self-efficacy aids in the adoption and maintenance of health promoting behaviours as well as in the control of risky health habits. Individuals with high self-efficacy overcome obstacles by improvement of self-management skills and stay the course in the face of difficulties. Whereas those of low sense of efficacy do not try to adopt healthy practices and if they do try, they quickly abandon their efforts if success is not immediately achieved (Bandura, 2004).

Measurement of self-efficacy
Self-efficacy is estimated by obtaining ratings of the concepts three dimensions, namely magnitude, strength and generality. Magnitude refers to the difficulty to adopt a specific behaviour, strength refers to the certainty of performing the behaviour and generality refers to the degree self-efficacy varies across type of activity. Bandura (2006) states that scales measuring self-efficacy must be tailored to the particular object of interest because the concept is not a global trait. People differ in how they think, feel, motivate themselves and how they act in various activities. Hence, a measurement of perceived self-efficacy in an all-purposive global scale usually has limited explanatory and predictive value. Although, a general focus on mastery is applied in some studies (Oka & Chaboyer, 2001; Takaki et al., 2003; Tanner et al., 1998) focusing on adherence to ESRD treatment while other studies (Brady, Tucker, Alfino, Tarrant, & Finlayson, 1997; Zrinyi et al., 2003) have adapted a more or less domain specific measure. The questionnaire used by Brady et al (1997) is described as a proper and theoretically consistent fluid
adherence self-efficacy measure, but the original was neither obtainable through the developer nor published literature. Consequently, a scale to measure situation specific self-efficacy for constructive fluid intake behaviour in HD settings was lacking.

Concepts and definitions

Definition of adherence
Non-compliance is the first and most common term for describing the phenomenon of patients not following their treatment regimen as prescribed (Sackett & Snow, 1979). The term is, however, associated with a traditional paternalistic and unequal relationship between the patient and the physician (Chin, 2002; Trostle, 1988), e.g. the patient is a passive responder who should obey the physician’s authorial advice. According to this designation, non-compliance may be interpreted as refusing orders or showing deviant behaviour.

An alternative and less censorious term is adherence, which according to the World Health Organization (2003) is defined as “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle change, corresponds with agreed recommendations from a health care provider.” (World Health Organization, 2003, p. 17). Hence, compliance and adherence refer both to the patient’s behaviour in relation to treatment requirements, although the interpretation of adherence indicates that the patient is free to decide whether to adhere to the treatment regimen or not. The failure to adhere should not solely be blamed on the patient because adherence is the product of the patient’s behaviour in relation to the treatment, the health care provider’s behaviour in relation to the treatment as well as the environmental conditions the patient and provider operate individually and together.

The terms compliance and adherence are, however, used interchangeably within research covering the treatment of ESRD although they have different definitions. In the context of ESRD treatment, adherence has been divided into three domains, medication adherence, dietary adherence, and adherence to the dialysis prescription (Kaveh & Kimmel, 2001; Lamping & Campbell, 1990). In this thesis, the term adherence will be used to describe patients’ behaviour in relation to approved treatment. The focus will be within the dietary domain concentrating on adherence to fluid restrictions.
Definition of fluid adherence

The computation of interdialytic weight gain (IWG) is suggested as a valid and objective measure of fluid restriction adherence in ESRD patients with reduced urinary output (Leggat et al., 1998; M. Manley & Sweeney, 1986; Wolcott, Maida, Diamond, & Nissenson, 1986) and therefore widely used as an outcome measure (Christensen, Moran, Lawton, Stallman, & Voigts, 1997; Christensen, Moran, Wiebe, Ehlers, & Lawton, 2002; Kimmel et al., 2000; Lee & Molassiotis, 2002; Pang, Ip, & Chang, 2001; Sharp, Wild, Gumley, & Deighan, 2005; Tsay, 2003; Welch, Perkins, Johnson, & Kraus, 2006). The definition of fluid adherence varies, however, throughout the literature because the clinically significant cut-off remains unclear. In addition, previous studies have used two alternatives of IWG calculation. Most common is the use of a fixed boundary expressed as weight gain in kilograms. The alternative is a more individualized approach adjusting for the individual’s body size because the weight gain in kilograms is converted to percent of dry body weight. The individualized approach will be used in this thesis because it is more likely that there is a greater negative physical influence of the weight gain in a small person than in a big person. Thus the cut-off is decided to 3.5%, which is the counterpart of the most considered fixed boundary.
Aims

The overall aim of the planned thesis is to describe the prevalence of non-adherence to fluid restrictions among haemodialysis patients, to evaluate the impact of self-efficacy and other individual characteristics on adherence, and to study possible effects of a social-learning theory-based intervention designed to improve adherence behaviour.

Specific aims for the studies in this report were;

Study I
The aim of this study (I) was to describe the extent of non-adherence behaviour to fluid restrictions among haemodialysis patients, defined as high interdialytic weight gain, by using national registry data.

Study II
The aim of this study (II) was to develop and evaluate the psychometric properties of a self-administered scale intended to measure situation-specific self-efficacy to constructive fluid intake for use in haemodialysis settings.

Study III
The aim of this ongoing study (III) is to develop and test a theory-driven model of a possible mediating function of self-efficacy on haemodialysis patients’ adherence to fluid restrictions and compare it with a direct path model.
Methods

Design
The project consists of three parts (estimate prevalence, evaluate impact of self-efficacy, and intervention). In study I, a descriptive design was used, and in study II, a cross-sectional descriptive design was used and the design used in study III was correlational. In the planned study IV, an experimental single case strategy will be used in a combined ABAB and Changing-Criterion design. An overview of the studies is presented in Table 1.

Table 1. Overview of study design, statistic, sample and data collection methods used in the studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Statistics</th>
<th>Sample</th>
<th>Data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Retrospective observational</td>
<td>Descriptive Analysis of variance</td>
<td>10 133 treatment observations of 4633 haemodialysis patients</td>
<td>Registry data (national)</td>
</tr>
<tr>
<td>II</td>
<td>Cross-sectional, multi-centre</td>
<td>Descriptive Reliability Bivariate correlation Hypothesis test Confirmatory factor analysis</td>
<td>a) 15 haemodialysis patients (interpretability test) b) 37 haemodialysis patients (face validity) c) 144 haemodialysis patients</td>
<td>Questionnaires and medical record</td>
</tr>
<tr>
<td>III</td>
<td>Correlational</td>
<td>Descriptive Bivariate correlation Confirmatory structural equation modelling</td>
<td>144 haemodialysis patients</td>
<td>Questionnaires, proxy assessment and medical record</td>
</tr>
</tbody>
</table>
Subjects and procedures

Study I includes 4633 subjects registered in The Swedish Registry of Active treatment of Uremia (SRAU) and registered at least once in the Swedish Dialysis DataBase (SDDB) in 2002-2006. According to a validation procedure 2006, the SDDB covered about 95% of the Swedish HD population. Data regarding gender, age, primary renal disease, diuretic use, years on dialysis program, duration of dialysis session, height, body weight before dialysis and dry body weight were extracted from the registries for all subjects aged 18 and above, and on regular treatment with HD 3-4 times per week.

In study II, covering development and evaluation of a questionnaire, three independent samples were used of which two (marked a, and b in Table 1) were used in the development process and the third (marked c in Table 1) in the evaluation phase. All subjects were recruited consecutively among persons treated with HD at a total of 14 Swedish dialysis centres. In the two samples during development, 15 subjects from one centre agreed to participate in the interpretability test and 37 subjects from two centres agreed to participate to examine face validity of proposed questions. For the evaluation phase, 222 subjects at 11 dialysis centres met the inclusion criteria and 144 (or 65%) gave their informed consent. To be included, the patient had to be at least 18 years old, have sufficient knowledge of Swedish, and had to be able to answer the questions by themselves. In addition, in order to achieve a homogenous group with stable dialysis treatment and similar interdialytic weight gains, the patients had to have had HD treatment 3-4 times per week for at least six months. Data were collected using two self-report questionnaires in combination with extraction from the medical record regarding weight measurements before and after each dialysis session during one month.

Study III used the same sample as the evaluation phase in study II, 144 subjects’ participated (65% response rate). Data were collected using five self-report questionnaires in combination with data from medical records and proxy assessments performed by the regular nursing staff.

Measures

Study I:
Based on registry data, interdialytic weight gain was calculated by subtracting the dry body weight from the weight before dialysis. This computation is suggested to be a valid and objective measure of fluid restriction adherence, widely used in research involving fluid adherence among dialysis patients. In
order to individualize this measure, the interdialytic weight gain was further calculated as percent of dry body weight.

The rate of fluid removal at dialysis was also considered on the basis of registry data. Ultrafiltration rate during the dialysis session expressed in ml/h/kg was calculated using the dry weight in the denominator.

Study II:
The instrument “Self-efficacy for Managing Chronic Disease” was developed for the Chronic Disease Self-management Study (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001) and is considered to be internally consistent. It is a six item scale covering symptom control, role function, and emotional function and communicating with physicians, which are common domains across many chronic diseases. In this study, it was employed as a general self-efficacy measure.

The Fluid Intake Appraisal Inventory (FIAI) was developed and evaluated in this study as a situation-specific self-efficacy measure because available questionnaires were considered to give limited attention to theoretical and measurement issues. This instrument consists of 33 items and is intended to measure situation-specific self-efficacy to low fluid intake in HD patients.

Interdialytic weight gain was calculated as a percent of dry body weight and because this measure fluctuates according to the daily fluid consumption, the mean from a month was used.

Study III:
The following instruments were used in combination with demographical data, data from medical records, and proxy assessed data to build the variables in the measurement model.

The Life Orientation Test Revised (LOT-R) (Scheier, Carver, & Bridges, 1994) was used to measure the personality disposition of optimism. LOT-R is a ten item self-report questionnaire of which three items are positively worded, three are negatively worded but reversed in scoring, and four are filler items (not scored). The response format ranges from 0= I disagree a lot to 4= I agree a lot, which yields a continuous distribution of sum scores from 0 to 24, and higher score represents greater optimism. LOT-R has high reliability and validity.

The Threatening Medical Situation Inventory (TMSI) (van Zuuren, de Groot, Mulder, & Muris, 1996) was used to measure cognitive confrontation/avoidance coping style to medical threat. This instrument consists of four descriptions of medically threatening situations (stressors) and each
scenario includes three monitoring and three blunting alternatives in random order to be answered on a five point scale. Total scores are obtained by summing the monitoring and blunting alternatives separately, that is a sum ranging 12-60 is calculated for a monitoring and a blunting subscale.

The Centre of Epidemiological Studies – Depression scale (CES-D) (Radloff, 1977) was used to measure depressive symptoms. The short ten item version (Andresen, Malmgren, Carter, & Patrick, 1994) is coded on a scale ranging from zero to three and two items is reversed in scoring. By summing the score on each item a total score ranging from 0 to 30 is calculated, and a higher CES-D score indicate greater occurrence of depressive symptoms.

The Fluid Intake Appraisal Inventory (FIAI), were developed and evaluated in study II and measures situation-specific self-efficacy. The response format is a numerical rating scale where 0= not at all confident and 10=totally confident. Internal consistency is high (Cronbach’s alpha .96), and the criterion-related validity and known-group validity is supported.

Demographic data included gender, year of birth, year of initial dialysis treatment, and self-estimated urine output.

From the medical record data were obtained regarding predialysis routine laboratory measurements of phosphate and potassium in serum the previous three months, and weights before and after dialysis the previous month.

The regular nursing staff provided proxy data regarding co-habit status, problem of substance abuse and working/ sick listed / disability pension / national basic pension status for each subject.

**Data management and statistical procedures**

In study I descriptive statistics was reported regarding registry data from five annual cross-sectional cohorts. Prevalence of non-adherence was estimated and the chi-square test was used to test differences in proportions between the cohorts. Repeated measures ANOVA or one way ANOVA was used to evaluate the pattern over time and significant differences were further analyzed with Bonferroni post hoc test (Brace, Kemp, & Snelgar, 2006; Hassmén & Koivula, 1996).

In study II the aim was to evaluate the psychometric properties for the developed measure of situation specific self-efficacy. Face validity is crucial in a self-efficacy scale (Bandura, 2006); hence the evaluation procedure included insurance of item sufficiency. Cronbach’s alpha coefficient was cal-
culated to determine internal consistency reliability. Criterion-related validity (Streiner & Norman, 2003) tested how the scale related to other variables as hypothesized by the self-efficacy theory. The Spearman’s Rho was used to test concurrent validity, i.e. the correlation between situation specific scoring of self-efficacy and general self-efficacy scores. Moreover, subgroups of adherent and non-adherent patients were constituted to evaluate the known-group validity (Polit & Beck, 2004) with independent t-test. Furthermore, structural validity was tested through first-order confirmatory factor analysis (Byrne, 2005).

Study III
The first step in the analysis process was to examining descriptive statistics for all variables and to rule out possible confounder effects of the cognitive variables. No such outlier effect was detected. Moreover, an examination of univariate and multivariate normality of the data were performed because it is a critical assumption underlying all multivariate techniques including structural equation modelling (Buhi, Goodson, & Neilands, 2007). Following the 2-step modelling approach described by Buhi (2007) a measurement model was built in order to ascertain the construct validity by testing the indicator constructs relationships. The shared variance derived from the correlations/covariances take into account measurement errors in all variables and will be used for interference of the presence of a latent factor. Then the structural model will be tested, which examines the underlying relationship or structure between the latent constructs tested in the measurement model and the variables proposed by the theory. The impact of self-efficacy as a mediator will be evaluated by comparing the model fit indexes from structural equation modelling with and without the mediating factor. Data and analytic procedures in this study are preliminary.
Results

Study I
The results indicate that non-adherence to fluid restrictions was common in the Swedish HD population. The prevalence of non-adherence was estimated to about 30 %, meaning that three out of ten HD patients have a weight gain exceeding 3.5 % of dry body weight between dialysis sessions. The prevalence of non-adherence to fluid restrictions differs ($\chi^2=28.68$ (df=4) $p<.001$) between the five cross-sectional measurements and there is a tendency for lower frequency in more recent years. Estimated prevalence per annual measurement is presented in Table 2.

Table 2. Estimated prevalence of haemodialysis patients’ non-adherence to fluid restriction (annual cross-sectional measurements)

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>1717</td>
<td>1896</td>
<td>1964</td>
<td>2150</td>
<td>2234</td>
</tr>
<tr>
<td>Non-adherence %</td>
<td>36.2</td>
<td>32.0</td>
<td>32.0</td>
<td>30.7</td>
<td>28.3</td>
</tr>
</tbody>
</table>

Moreover, one of five HD patients with weight gain between the dialysis sessions was at risk for intradialytic hypotension and mortality during treatment. That is, 15-20 % had an ultrafiltration rate exceeding the cut off usually associated with such risk (10 ml/h/Kg). These patients had either consumed more fluids than could be removed at lower rates during the treatment or that the prescribed treatment time was to short for the needed removal of fluids. Estimated prevalence per annual measurement is presented in Table 3.

Table 3. Estimated prevalence of ultrafiltration (UF) rate above 10ml/h/Kg for patients with excess fluid by annual cohort.

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>1640</td>
<td>1828</td>
<td>1884</td>
<td>2056</td>
<td>2111</td>
</tr>
<tr>
<td>UF-rate above 10 ml/h/Kg %</td>
<td>22.7</td>
<td>19.4</td>
<td>19.3</td>
<td>18.1</td>
<td>15.5</td>
</tr>
</tbody>
</table>
**Study II**

Cronbach’s alpha coefficients were calculated for each subscale ($\alpha=0.85$-$0.92$) and for the total scale ($\alpha=0.96$), which means that the FIAI have high internal consistency. The scales mean inter-item correlation =0.46 (range 0.13-0.96) and the corrected item total correlation ranged from 0.46 to 0.75.

The theoretical assumptions for criterion-related validity were supported as: 1) the situation specific self-efficacy (FIAI) was significantly correlated ($r_s=0.315$ $p<0.001$) to a general self-efficacy measure; 2) the FIAI was significantly correlated ($r_s=-0.246$ $p=0.003$) to the interdialytic weight gain; while 3) the general self-efficacy measure was nearly un-correlated ($r_s=-0.005$ $p=0.950$) to interdialytic weight gain. With individually derived cut-off points for adherence, a significant difference ($p=0.001$) was found between adherent and non-adherent patients, i.e. as hypothesized, individuals with higher self-efficacy were more disposed to be adherent. Similarly, this significant difference ($p=0.005$) was also found with a fixed criteria of adherence.

The structural validity of the FIAI was not confirmed because the postulated relation among variables was only partly supported (CMIN=2087, df=489, $p<0.001$; CMIN/df=4.27; CFI=0.605; RMSEA=0.151; RMSEA 90% CI ranged from 0.144-0.157) indicating that the hypothesized four-factor model was inadequate.

**Study III**

Preliminary results are available in the enclosed draft manuscript (Table 1-3, and Figure 2).
Concluding remarks and future directions

Three of ten HD patients (study I) are at risk for medical consequences of fluid overload, meaning that interventions aimed to enhance restricted fluid intake behaviour might be needed in the same proportion. These numbers are, however, based on the assumption that the most considered boundary of fluid intake is adequate although the literature is inconsistent in this matter. More studies are, however, needed before consensus about a secure fluid allowance for HD patients’ could be realized.

In relation to prescribed treatment time and the need of fluid removal are one of five patients (study I) at risk for treatment related complications. This could either mean that the patient would benefit from an adjusted prescription or indicate that the patient might need support to improve adherence to fluid restrictions. A reduced fluid overload is, however, probably the most beneficial.

The Fluid Intake Appraisal Inventory (FIAI) (study II) is a situation specific self-efficacy scale aimed for research and to aid clinical interventions. In research, the scale might be used to study the mediating function (Study III) of self-efficacy on adherence behaviour to fluid restrictions. Whereas in daily clinical practice, the scale might be used to identify situations that are problematic and generate tension between the desire to drink and the need to restrict fluid intake. The situations that are problematic for the HD patients’ adherence to fluid restrictions could then be used as means in a tailored intervention using a behavioural approach (Study IV). The FIAI had satisfactory psychometric properties although the scale has to be used in further studies designed to provide for additional reliability and validity data.

The posited sociocognitive causal model includes two paths of how self-efficacy influences the individual’s health behaviour, e.g. adherence. To our knowledge, no previous study has examined the extent to which self-efficacy affects adherence to fluid restrictions directly and by its influence on other determinants. Thus, this will be examined in study III.

Intervention procedures that help HD patients follow their fluid restrictions are rare. In particular, interventions guided by a theoretical model are even less common. It is therefore important that clinically useful strategies are
developed to encourage and maintain the patients’ fluid control. Moreover, the strategies would favourably be based on theoretically guided behavioural approaches focusing on drinking activities and its eliciting motivational and cognitive processes. Thus, a proposed research plan (in Swedish) for study IV is enclosed. The plan involves a social learning theory-based intervention aimed to be used in the clinical practice as a mean to enhance adherence to fluid restrictions.
References


efficacy, health beliefs, and adherence in patients receiving hemodialysis. *J Ren Nutr*, 8(4), 203-211.