

**Patient Education for Renal Transplant Recipients**

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**Doctoral Thesis**

**Faculty of Medicine, University of Oslo, Norway, 2013**

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*Series of dissertations submitted to the  
Faculty of Medicine, University of Oslo  
No. 1551*

ISBN 978-82-8264-520-1

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Cover: Inger Sandved Anfinsen.  
Printed in Norway: AIT Oslo AS.

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## Acknowledgements

There are a number of people I would like to thank for their contributions and support during this project. First of all, I am indebted to all the renal transplant patients who were willing to participate in this study. Without their participation, this thesis would have been impossible.

I would like to express my sincere thanks to my main supervisor, Professor Astrid Klopstad Wahl. With her professional competence she has—from the very beginning of this project and throughout all the stages—provided me with inspiring and encouraging guidance and counseling. I want to thank Astrid for always being available to answer my questions and providing advice throughout the process.

I also wish to express warm thanks to my two co-supervisors Ole Øyen and Marit H Andersen for their discussions, invaluable advice, and ongoing support throughout the process. I am also sincerely grateful for my co-supervisor Torbjørn Moum and his statistical guidance and support as well as wise comments throughout the preparation of the manuscripts.

Furthermore, I would like to give a warm thanks to Kåre Birger Hagen for his wise guidance and co-authorship on paper 1.

I wish to thank to Fanny Bruserud and Kjersti Lønning at the Department for Transplantation Medicine Section for Transplantation Surgery at Oslo University Hospital as well as send out warm thanks to all the nurses on the ward that recruited participants for the project. In addition, I want to thank Oslo University College for the financial support and collegial support provided throughout the data-collecting phase.

Warm thanks also go to my present colleagues at the Faculty of Health Science at the University of Stavanger for their valuable support during the last phase of my work.

I want to thank my family and friends, who have put up with me and provided me with both practical and emotional support throughout this effort. All of you, especially my children Rebekka and Vegar, have been a source of joy and relaxation through the ups and downs in completing this thesis.

## Summary

**Background:** Renal recipients' knowledge about post-transplant aspects is essential in terms of coping with short-term problems posed by transplantation and the long-term outcome. This requires patient education programs that prepare patients, to the greatest degree possible, for life after returning home with a new kidney.

**Aim:** The overall aim for this study was to develop knowledge concerning patient education in the context of kidney transplantation. Through a systematic review, the content and effectiveness of patient education interventions for renal recipients were evaluated (paper 1). A questionnaire measuring renal recipients' knowledge on important post-transplant aspects was developed and the results examined in a cross-sectional study (paper 2). Finally, in a randomized controlled trial, the effect of a structured, tailored patient education program was investigated on renal recipients' knowledge, compliance, self-efficacy, and quality of life (paper 3).

**Method:** For the systematic review, 9 controlled clinical trials were included; methodological quality was evaluated according to criteria developed by the Cochrane Musculoskeletal Group. In total, 159 renal recipients participated in the current study. For the descriptive cross-sectional study, renal recipients' insights into post-transplant aspects were measured 5 days post-transplantation. For the intervention study, 82 participants were randomized into the experimental group and 77 to the control group. The patient education intervention consisted of 5 weekly tailored one-to-one sessions during the first 7 to 8 weeks post-transplantation. The control group received standard care. The primary outcome was measured by the knowledge questionnaire. Secondary outcomes were measured by The General- Self-efficacy (GSE) Scale, the Short Form 12 -Item Health Survey (SF-12), and by estimating the number of patients own graft observations (compliance). A total of 139 participants reached the

second measure point (7-8 wk post-tx), and 120 participants reached the third measure point (6 months post-tx).

**Results:** Nine trials were included in the systematic review. The quality appraisal revealed an overall high risk of bias, indicating a lack of evidence regarding the effects of educational interventions. The mean score of the knowledge questionnaire was 11 (SD, 3, 7) (53% correct answers), ranging from 0 (0.6%) as the lowest score to 19 (0.6%) as the best score out of 19 obtainable points. Lowest scores were given in relation to lifestyle issues (52% correct answers). When investigating the effect of the patient education intervention, higher levels of knowledge and compliance were found in the experimental group at second measure point ( $p = 0.002$  and  $p = 0.000$ ). At the third measure point, the experimental group reported significantly higher levels of knowledge ( $p = 0.004$ ), self-efficacy ( $p = 0.036$ ) and mental score of quality of life ( $p = 0.001$ ).

**Conclusions:** As revealed by the knowledge questionnaire, renal recipients seem to be insecure regarding some of the important post-transplant aspects shortly before being discharged from the hospital. Through this thesis, we have shown one way of providing renal transplant recipients with an effective patient education program, with beneficial effects in both short and longer terms. As previous research is limited in the area, the results from this study might provide valuable guidance for clinical practice and future research.

## List of Papers

- I. Urstad, K. H., Wahl, A. K., Andersen, M. H., Øyen, O., & Hagen, K. B. (2012). Limited evidence for the effectiveness of educational interventions for renal recipients. Results from a systematic review of controlled clinical trials. *Patient Education and Counseling*. Nov 27 doi:pii: S0738-3991(12)00427-2. 10.1016/j.pec.2012.10.020 (E-pub ahead of print).
- II. Urstad, K. H., Andersen, M. H., Øyen, O., Moum, T., & Wahl, A. K. (2011). Patients' level of knowledge measured five days after kidney transplantation. *Clinical Transplantation*, 25(4), 646–652.
- III. Urstad, K.H., Øyen, O., Andersen M.H., Moum T., Wahl A.K. The effect of an educational intervention for renal recipients: A randomized controlled trial. *Clinical Transplantation*, 26. E246–253. doi: 10.1111/j.1399-0012.2012.01666.x.





## Abbreviations

ANCOVA: Analysis of covariance

ANOVA: Analysis of variance

BMI: Body mass index

CAN: Chronic allograft nephropathy

CCT: Controlled clinical trials

CKD: Chronic kidney disease

CNI: Calcineurin Inhibitor

CONSORT: CONSolidated Standards of Reporting Trials

ESRD: End stage renal disease

GLM: General Linear Model

GFR: Glomerular filtration rate

GSE: General Self-efficacy

MCS: Mental Component Summary

MOS: Medical Outcome Study

m-TOR: mammalian Target of Rapamycin

OLS: Ordinary least squares

PCS: Physical Component Summary

QUALY: Quality-adjusted life-year

RCT: Randomized controlled trial

SD: Standard deviation

SF-12: Short Form 12 -Item Health Survey

SPSS: Statistical package for the social sciences

SPF: Sun protection factor

Tx: Transplantation

WHO: World health organization

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## 1.0 INTRODUCTION

Patients in the end-stage renal disease phase have two options in order to stay alive: life-long dialysis or kidney transplantation. Of these options, kidney transplantation is considered the treatment of choice. Compared to dialysis, transplantation offers improved quality of life, restored metabolism and freedom from the restrictions caused by dialysis (Liem, Bosch, Arends, Heijenbrok-Kal, & Hunink, 2007; Ponton et al., 2001; Tonelli et al., 2011). Patients in the end-stage renal disease phase choose kidney transplantation because they want to live a normal, healthy life (Lindqvist, Carlsson, & Sjoden, 2000; Tong, Morton, Howard, McTaggart, & Craig, 2011). The treatment is considered by patients as the gateway to personal liberation, necessary for regaining control over their life and their self (Galpin, 1992). The hope of a transplant is an important factor in people's ability to cope with end-stage renal disease and dialysis treatment (Galpin, 1992; Moran, Scott, & Dabyshire, 2011).

During the past decades, kidney transplantation has become a progressive and innovative field, and the number of kidney transplants continues to increase. Survival rates of grafts and patients have also increased dramatically (Squifflet, 2011). However, successful transplantation also brings new challenges in patients' life in terms of life-long medication, care of the graft, and necessary restrictions. In order to reduce rejection episodes, graft loss, and the negative consequences of immunosuppressive medication, renal recipients need to acquire knowledge in relation to medication regime, graft surveillance, and the benefit of specific lifestyle behavior (Luk, 2004; Murphy, 2007). The consequences of lacking knowledge can be fatal (e.g., disregarding signs of rejection). According to Osborne's logic model program, patients' insight in own chronic disease has a valuable impact on outcomes, such as self-efficacy, behavioral changes, and quality of life (Osborne, Elsworth, & Whitfield,

2007). The assumption is that, despite several factors making this outcome complex, knowledge regarding important aspects of life post-transplant is an essential first step toward enhanced coping and quality of life.

Considerable improvements have recently emerged within kidney transplantation in relation to surgical techniques and the handling of adverse events. Shorter stays in the hospital and efficient, time-saving follow-up might have imposed increased demands on the patient, particularly regarding the acquirement of necessary post-transplant knowledge. Non-compliance with post-transplant health advice appears to be unacceptably high among renal recipients (Cleemput, Kestelot, Vanrenterghem, & De, 2004; Denhaenryck et al., 2007 Dew et al., 2009; Dobbels et al., 2010). In addition, qualitative studies have revealed that patients experience the situation after the transplantation as complex (Urstad, Wahl, Andersen, Øyen, & Fagermoen, 2012; Wiederhold, Langer, & Landendberger, 2009) and that learning difficulties might occur due to physical and mental stress in the post-transplant situation (Urstad et al., 2012). Hence, patient education is of vital importance for transplant patients.

Previous research in the field of education for patients with renal diseases has focused primarily on the phase prior to transplantation. A systematic review further concluded that descriptions of effective interventions to improve adherence to medication are lacking for organ recipients (De Bleser, Matteson, Dobbels, Russel & De Geest, 2009). It has also been claimed a more holistic approach to organ recipient patient education is required (Wilkins, Bozik, & Bennett, 2003).

Increasing national and international interest in patient education has emerged, and individuals are increasingly expected to exert more self-care (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Osborne et al., 2007). However, teachings to ensure that patients and their families are competent and confident have not been supplied (Glanz, Rimer, &



Viswanath, 2008). In the context of transplantation, the importance of knowledge concerning medication, signs of rejection, and how to prevent negative consequences of life-long immunosuppressive medication requires a patient education program that, to the highest possible degree, prepares patients for life when returning home with a new kidney. Thus, it is imperative that more work be done to explore the field of patient education for this patient group. Hence, patient education for renal transplant patients is the focus of the present thesis. Knowledge developed from this thesis may be of relevance for all health care professions working within the context of renal transplantation.

## **2.0 AIM OF THE STUDY**

The overall aim of this study is to develop knowledge concerning patient education in the context of kidney transplantation. The three specific objectives for the various papers are as follows:

1. To describe the content and evaluate the effectiveness of patient education interventions for renal recipients
2. To describe the development of a questionnaire on renal recipients' knowledge on important post-transplant aspects, to examine its performance in measuring the patients' level of knowledge five days post-transplantation, and to investigate possible factors related to the knowledge level.
3. To evaluate the effect of a structured, tailored patient education program on renal recipients' knowledge, compliance, self-efficacy, and quality of life.

## 3.0 THEORETICAL FRAMEWORKS

### 3.1 Renal transplantation

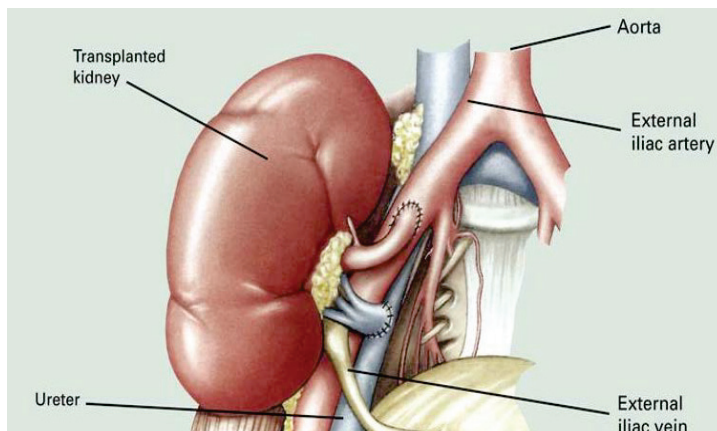
Chronic kidney disease (CKD) is defined as kidney damage lasting three or more months, due to structural or functional abnormalities of the kidney, with or without decreased glomeruli filtration rate (GFR), and manifested by either pathologic abnormalities or markers of kidney damage (including abnormalities in the composition of the blood or urine) or pathology disclosed by imaging techniques. The disease is classified into five stages according to the decline in glomerular filtration (National Kidney Foundation, 2012). Symptoms vary during the different stages of the disease, with the most severe form designated as end-stage renal disease (ESRD) (National Kidney Foundation, 2012).

Patients with ESRD are left with two options to stay alive: dialysis or transplantation. A successful transplantation increases quality of life (Fujisawa et al., 2000; Rebollo et al., 2000; Valderrabano, Jofre, & Lopez-Gomez, 2001; Wight et al., 1998), decreases mortality risk (Ojo et al., 1994; Port, Wolfe, Mauger, Berling, & Jiang, 1993), and is cost-effective compared to dialysis (Loubeau, Lobeau & Jantzen, 2001; Niakas & Kontondimopoulos, 2009). Any major comorbidity might represent a contraindication for renal tx. These include active infection, present or previous cancer, severe cardiovascular disease, and significant psychological disorders that inhibit the patient's ability to care for the transplanted organ. Some countries do not practice any upper age limit for kidney transplantation, as the psychological age is often more pertinent than the chronological age (Heldal et al., 2011; Kahan & Ponticelli, 2000; Steinman et al., 2001). It is the transplant center's responsibility to evaluate the patient as a potential transplant recipient (Neyhart, 2009).

Kidneys for transplantation come from two sources: living donor (about 35% in Norway) and

deceased donors (about 65%). Live donors can include family, friends and in-laws. Living donors should be evaluated to ensure that they have a true desire for donation and to exclude underlying psychological conditions that will affect the postoperative and long-term course. The waiting time for a deceased donor's kidney is increasingly long in many transplant centers. In Norway, patients on the waiting list are chosen based on donor match and wait time; to some degree, children and adolescents are prioritized. The number of kidney transplantations has increased in Norway during the recent years. In 2011 the single transplant center in Norway, serving the entire Norwegian population, conducted the highest number of kidney transplants in Europe per million population (302 tx; 60 per million inhabitants). Consequently, waiting lists for kidney transplants are shorter in Norway compared to other European countries (approximately 8-10 months) (Stel et al., 2012).

The kidney transplant surgical procedure lasts 1.5-4 hours. The new kidney is in most cases placed in the pelvis, outside the peritoneum, and the artery and vein of the new kidney are connected to the patient's iliac artery and vein (see Figure 1). The ureter is then anastomosed to the bladder. The initial function of the new kidney depends on donor characteristics and cold ischemia time. With a living donor, the kidney starts to function immediately in more than 95% of cases. In deceased donor cases, delayed graft function appears in 15-25% of cases (Norway).



*Figure 1. Attachment of transplanted kidney*

In the postoperative phase, the graft function is observed carefully, using ultrasound examinations when needed. Rejection occurs through specific direct attack by cells within the immune system and the production of antibodies to the foreign tissue. Acute rejection most commonly occurs within a few weeks post-tx, although it can occur later. This process might occur in response to inadequate immunosuppression. Acute rejection is in most cases reversible by means of intensified immunosuppression. Chronic deterioration of graft function is due to chronic allograft nephropathy (CAN), in which both immunological and non-immunological factors are involved (Neyhart, 2009).

After transplantation long-term immunosuppressive therapy is mandatory to prevent rejection. The immunosuppressive therapy can be tailored to suit each individual, particularly with regard to his or her immune status (Alleman & Longton, 2008; Danotvitch, 2005; Goldshayan & Pascual, 2008; Kahan & Ponticelli, 2000). Many adverse effects can result from immunosuppressive therapy; typically these involve various infections, hyperglycemia/diabetes mellitus, hypertension, impaired wound healing and increased risk of malignant tumors (Alleman & Longton, 2008; Neyhart, 2009).

The early post-operative phase observations focus on graft function, blood pressure, pain, and fluid replacement. Kidney transplantation is a surgical procedure associated with postoperative pain, nausea, vomiting, tiredness, and temporary occupational disability. Both surgery and anesthesia can cause reduced cognitive functions. The loss and lack of concentration are symptoms that frequently occur in patients who have undergone a surgical procedure (Jungwirth, Zieglgänsberger, Kochs, & Rammes, 2009; Sauer, Kalkman, & Van Dijk, 2009). In addition, emotional reactions are a well-known phenomenon after surgery in general (Johnston, 1980; Spielberger, Auerbach, Wadsworth, Dunn, & Taulbee, 1973). For renal recipients, emotional postoperative reactions seem to be associated with insecurity and anxiety during the waiting time prior to the transplantation (Herlin & Wann-Hansson, 2010; Urstad et al., 2012; Wiederhold et al., 2009).

At the hospital transplant center, nurses normally start the patient education process within the first days post-transplant. Patient education includes written material and one-to-one communication with nurses. The teaching topics cover medication, graft rejection, and lifestyle changes; it also involves practical training, such as administering drugs and observing/documenting graft function by monitoring urine production, urine chemistry (dip sticks), body temperature, and weight. A checklist is used to document the completed education. The goal is to master all topics before being discharged.

In uncomplicated cases, patients are discharged approximately one week after transplantation. For the first 10 weeks after transplantation, patients attend frequent outpatient controls at the transplant center in Oslo. Except for patients living close to the transplant center, renal recipients stay at the patient hotel situated close to the hospital. Five-year survival rates for kidney transplants in Norway are about 93% for living donor tx and about 80% for deceased

donor tx. Ten-year survival rates have been reported to be approximately 83 % for living donor tx and 59% for deceased donor tx.(Reisæter, Foss, Hartman, Leivestad & Midtvedt, 2011).

### **3.2 Patient education**

Patient education is seen as an activity that aims to improve patients' health (Bellamy, 2004; Lorig 2000). It can be seen as a planned process of enabling individuals to make informed decisions about their personal health-related behavior (Bellamy, 2004; Lorig, 2012). The primary focus of these activities includes acquiring information, skills, beliefs, and attitudes that impact one's health status (Taal, Rasker, & Wiegman, 1996). The literature shows a general consensus that patient education is a necessary element of the treatment of renal recipients (Baker, Jardine & Andrews, 2011, Kasiske et.al, 2010).

Both international and national official reports state the importance of patient education. The Norwegian law of Specialist Health Care Service states that a lack of patient education is comparable to a lack of necessary medication treatment and that patients must receive education in order to cope with chronic illness and avoid the progress of illness and complications (Ministry of Health and Care Services, 1998–1999). The Norwegian Act of Patient Rights emphasizes patients' rights to be informed in order to be able to make decisions concerning their own illness (Ministry of Health and Care Services, 1999). Today, the patients are more aware of their responsibility with regard to their own health. They have access to a diversity of knowledge and research evidence about treatment and diseases, especially via the Internet. Patients are also better informed than before (Glanz et al., 2008). The activities of a patient education program must therefore be designed to attain goals the

patients have participated in formulating and be viewed in light of the patients' total situation (Redman, 2007).

Patient education can involve a broad range of professions, disciplines, settings, and setting groups and include an assessment of patient needs, the setting of goals, implementation of interventions, and evaluation of the interventions' impact (Glanz et al., 2008; Lorig, 2001; Redman, 2007). Education providers can include physicians, pharmacists, nurses, hospital discharge planners, medical social workers, psychologists, disease or disability advocacy groups, special interest groups, and pharmaceutical companies. The literature reveals a variety of techniques and methods used, including dialogs with health professionals and peers, web education, information material (printed or internet), and classroom teaching (Glanz et al., 2008; Lorig, 2001; Redman 2007).

Patient education has the possibility to seek support in a variety of theories and framework (Redman, 2007). For instance, health psychology models, the common sense model of illness perception, social cognition theories such as the theory of planned behavior, and the stage of change model are all examples of theoretical perspectives that shed light on patient education practice (Glanz et al., 2008). Pedagogic theories on learning are important as they seek to understand learning and development in terms of cognitive processes, motivational and self-regulatory processes, social and identity-forming processes, and socio-cultural relation and processes. Today, no single theory or conceptual framework dominates research or practice in health promotion and education. Instead, one can choose from different theories (Glanz et al., 2008).

The patient education intervention developed in this thesis is based elements from different well-established pedagogic theories—namely, behavioral theory, cognitive theory, and social cognitive theory. These learning theories have derived from two major sources: stimulus

response theory (Watson, 1925) and cognitive theory (Lewin, 1951). Stimulus response theory focuses on behavior being determined by consequences or reinforcement (Skinner, 1938) whereas cognitive theories emphasize the role of subjective hypotheses and expectations held by individuals (Glanz et al., 2008). The overall theory for the patient education intervention in this thesis is cognitive theory. Cognitive theories emphasize the role of subjective hypotheses and expectations held by individuals (Glanz et al., 2008). In this view, mental processes such as thinking, reasoning, hypothesizing, or expecting are critical components in the learning process; the assumption is that humans are logical beings who make choices that make the most sense to them. Social cognitive theory posits learning within the human social context. The patient education intervention in this thesis stems from social cognitive theory based on the principle that human behavior is the product of dynamic interplay of personal, behavioral, and environmental influences (Bandura, 1977). These three factors are constantly influencing each other (Glanz et al., 2008).

In recent years, a contrasting setting of practices has emerged characterized by the patient being a passive receiver of information or the patient being a premise provider. As a possible consequence of this, the importance of tailoring the education to each patient's needs has been increasingly documented (Burton et al., 2009; Clark, Lachance, Milanovich, Stoll, & Awad, 2009; Driscoll, Davidson, Clark, Huang, & Aho, 2009; Kim et al., 2004; Noar, Benac, & Harris, 2007; Rimer et al., 1999; van der Meulen, Jansen, van Dulmen, Bensing, & van Weert, 2008,). Tailored interventions have proved to increase perceived relevance, information recall, and behavior change in different chronic diseases (Noar et al., 2007; Rimer et al., 1999; van der Meulen et al., 2008). Tailored information uses individualized characteristics to create a personalized message, which Redman (2007) described as conducting a refined assessment of the learner's need. Reports of tailored educational approaches for organ transplant patients are scarce, but reports from systematic reviews on educational interventions for patients with



different chronic diseases (e.g., asthma, stroke and cancer) show that tailoring of content is an essential element of successful outcomes (Clark et al., 2009; Hafsteindottir, Vergunst, Lindeman, & Schuurmans, 2010; Van Weert et al., 2011). Tailored interventions are more effective than standard information with respect to, for instance, perceived relevance, information recall, and behavior change (Noar et al., 2007; Rimer et al., 1999; van der Meulen et al., 2008). Clark et al. (2009) defined tailored education for patients with asthma as shaping the program to fit participants' individual needs regarding asthma control and their educational level regarding asthma, usually as a preliminary needs assessment.

Academic detailing is a method used for tailoring educational content. Normally, it involves educational outreach through a personal visit by a trained person to health professionals in their own settings (O'Brien et al., 2007). Academic detailing aims to reveal learners' baseline knowledge about the chosen topic in order to clarify preliminary educational needs. As described by Soumerai and Avorn (1990), the key components of academic detailing interventions include: (1) determine baseline knowledge and motivations that support the current behavior; (2) define clear educational and behavioral objectives; (3) use a credible individual to deliver the information; (4) stimulate active participation of the learner of the process; (5) use concise teaching materials; (6) highlight and repeat key information; and (7) provide positive reinforcement of behavior changes in follow-up visits. Various studies have demonstrated that academic detailing is effective in changing physicians' performance (Cloutier & Wakefield, 2011; Schether, Bernsetin, Zempsky, Bright, & Williard, 2011; Soumari, 1998; Somurai & Avorn, 1990). Yet key components of the detailing strategy have also been successfully implemented in the education of patients with cancer, in relation to patient education in pain management (Kim et al., 2004).

### 3.2.1 Outcome of patient education

Patient education practice aims to embrace a broad portfolio of outcomes. Patients' perceptions of symptoms, their ability for function in everyday life, and their ability to make health care decisions have been increasingly valued (Redman, 2007). However, for the group of renal recipients, patient education might also be a question of life and death. Patients' lack of knowledge concerning immunosuppressive medication intake or basic signs of rejection might ultimately lead to graft loss with its fatal consequences. Osborne et al. (2007) used the program logic model to describe how outcomes at different levels might impact further down an outcome chain. According to the model, knowledge and compliance are described as proximal outcomes whereas self-efficacy and quality of life are intermediate outcomes of patient education. These outcomes might impact more distal outcomes such as decreased or lost productivity, increased community capacity, decreased mortality and morbidity, increased healthcare service efficiency, and decreased used of acute healthcare services (Osborne et al., 2007). In this thesis, patient education's effect on patients' knowledge, compliance, self-efficacy, and quality of life were explored. In the following, our understanding of these concepts will be clarified.

No single agreed-upon definition of *knowledge* exists, and numerous theories explain it. Knowledge can be explained as familiarity with something, which can include facts, information, or skills acquired through experience or education. Rational cognition includes more than the pursuit of knowledge as knowledge has a purpose. We use our knowledge to guide us in deciding how to act; rational cognition includes the cognitive processes involved in action decisions (Ploolc & Cruz, 1999). These processes are perception, communication, association, and reasoning (Cavell, 2002). In philosophy, the study of knowledge is called epistemology. The philosopher Plato defined knowledge as justified true belief. Commonly,

one might say that knowledge is something that is true and involves certainty, involves evidence, has practical relevance, and enjoys broad consensus that it is true (Pardi, 2011). We can distinguish between different types of knowledge. Present knowledge about facts, concepts, and principles that apply within certain domains can be referred to as conceptual knowledge whereas procedural knowledge refers to the understanding of dynamic processes, actions, or manipulations found within a certain domain. Furthermore, strategic knowledge helps organize the problem-solving processes by directing which instruments to use at different stages (Jong & Fergusson-Hessler, 1996).

Within the scope of the present thesis, these different types of knowledge are all relevant, as they cover different aspects of the knowledge needed for solving post-transplant problems. For instance, if the morning dose of the immunosuppressive medication has been forgotten, procedural knowledge is needed to determine how to deal with the problem (e.g., by increasing the next dose 50% in order to avoid rejection). Strategic knowledge is needed if patients get sick, are vomiting, and are not able to take medications as described. Conceptual knowledge is a prerequisite for being aware of the symptoms of rejection (fever, pain over the transplanted kidney, decreased urine production, protein in the urine, decreased fluid retention, and general flu-like symptoms).

*Compliance* has in healthcare been described as the extent to which a person's behavior in terms of taking medications, following diets, or executing lifestyle-changes coincides with health care advice (Haynes, 1979). In the past, compliance with treatments has been frequently investigated. Research has revealed that an estimated 25-50% of patients with general medical conditions and as many as 60% of those with psychiatric illnesses fail to comply with treatment prescribed by their healthcare provider (Cramer & Rosenheck, 1998; DiMatteo, 2004). Poor medical compliance is a serious public health issue that continues to

have a lasting impact upon patient outcome (Donovan, 1995; Donovan & Blake, 1992; Morris & Shulz, 1992).

*Self-efficacy* is in this thesis understood as described through Bandura's (1994) social cognitive theory, which defines self-efficacy as confidence in one's ability to perform a task or specific behavior. Bandura (1994) explained perceived self-efficacy as people's beliefs about their capabilities to produce designated levels of performance that exercise influences over events that affect their lives. Self-efficacy beliefs determine how people feel, think, motivate themselves, and behave, and is a psychological construct defining a person's confidence in performing a particular behavior and in overcoming barriers to that behavior. According to Bandura (1994), people must therefore have a robust sense of efficacy to sustain the effort needed to succeed.

Bandura (1994) described four psychological processes through which self-efficacy affects our daily functions: cognitive, motivational, affective, and selection processes. The stronger the perceived self-efficacy, the higher the goal challenges people set for themselves and the firmer is their commitment to them (Bandura, 1994). A high sense of self-efficacy has in different patient groups been found to affect desired outcomes, such as increased self-management behavior, better disease control, better physical function, and better quality of life (QOL) (Gaines, Talbot, & Metter, 2002; Marks, Allegrante, & Lorig, 2005; Tsay & Healestead, 2002).

*Quality of life* is a broad concept that incorporates all aspects of life and has been used in a variety of disciplines, such as philosophy, medical sciences, and social sciences. Quality of life is defined differently and comprises different meanings within different studies and disciplines. It has been explained as "happiness," "life satisfaction," "well-being," "self-actualization," "fulfillment," as "a full and meaningful existence," and as "the good life"

(Rapley, 2003; Wahl & Hanestad, 2004). Researchers within quality of life research have found that a consensus about the meaning of the term or its theoretical construct seems difficult to achieve (Rapley, 2003; Wahl & Hanestad, 2004). There seems, however, to be an agreement that quality of life is a subjective and multidimensional concept that includes physical, psychological, social, and spiritual dimensions (Ferrans, 1990; Ferrans & Powers, 1985; Ferrans, Zerwic, Wilbur, & Larson, 2005).

Over the past years, quality of life has been increasingly used in medicine to measure the effect of treatment. However, quality of life research has been criticized for not clarifying the meaning of the concept when used in clinical trials (Wahl & Hanestad, 2004). In explaining how quality of life is seen in this thesis, the concept might be viewed at several levels as described by, for instance, Spilker (1996). In this model, quality of life is divided into three levels. The first level is called the global level. Here, quality of life as phenomena is in focus, including aspects like happiness, meaningfulness, and self-realization, and has a meaning beyond an individual's health. On the second level, the focus is on people's experiences of their general state of health, such as functional status, physical, social, and mental well-being; the third level includes more specific symptoms and disabilities in relation to disease (Spilker, 1996; Wahl & Hanestad, 2004). The different levels shed light on the different areas of people's lives as they focus on general experiences of life or more specific experiences and problems in relation to disease (Wahl & Hanestad, 2004). However, different levels can affect each other as well as domains within the same level (Ferrans, 2005; Osoba, 2007; Spilker, 1999). Furthermore, all the levels can include multidimensional aspects (physical, psychological, economic, spiritual, and social) (Spilker, 1996; Wahl & Hanestad, 2004).

In this thesis, quality of life is defined based on Spilker's (1996) second level, focusing on renal recipients' experiences of their general health. At this level, health is commonly

regarded according to the WHO (1948) definition of health as a “state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity” (Official Records of the World Health Organization, no. 2, p. 100).

### **3.3 Educational areas for renal transplant recipients**

Renal recipients continue to live with a chronic condition, and the situation they need to cope with is complex (Luk, 2004; Murphy, 2007). According to Miller (2000), self-care is a key concept for all chronically ill individuals’ maintenance of optimal health. The awareness of body cues, interpreting physical changes accurately, and taking appropriate action either to alter therapy or to seek help from healthcare resources to prevent a crisis are important areas for learning (Miller, 2000). This also applies for renal recipients. According to the literature, important patient education areas for this group can be systematized in three main domains: Prescribed medication, rejection, and lifestyle (Chapman, 2010; Feuerstein & Geller, 2008; Trevit, 2004; Luk, 2004; Murphy, 2007; Neyhart, 2009; Quan, 2006; Terril, 2003; Transplant Work Group, 2009). In the following subsections, each of these domains will be described.

#### **3.3.1. Medication**

All renal transplant recipients need to follow a strict and complex immunosuppressive medication regime for the life of the transplanted organ in order to block immune pathways that lead to rejection (Kahan & Ponticelli, 2000). Skipping or stretching medications can result in rejection within a short period of time. Therefore, it is essential that renal transplant recipients possess knowledge about the importance of taking the described oral doses at

correct times each day. In situations where medications for some reason are not taken as prescribed, patients need to know how to act to prevent graft rejection. The doses of medication tend to change during first year after transplant. In addition, antiviral and antibiotics medication, hypertensive medication, and proton pump inhibitors are frequently included in the post-transplant regimen (Alleman & Longton, 2008; Danovitch, 2005). Patients therefore need to cope with a large amount of pills and continual changes in doses (Alleman & Longton, 2008; Danovitch, 2005; Neyhart, 2009). Patients often believe that, after a period of time, the graft will be “adopted” in their body and immunosuppressive medication will no longer be needed (Neyhart, 2009). This misunderstanding might lead to a great risk of rejection; thus it is an important misconception to address during patient education.

### **3.3.2 Rejection**

Rejection is the body’s attempt to destroy a foreign tissue—in this case, a transplanted kidney—through the action of the immune system. This process can occur in response to inadequate immunosuppressants (Alleman & Longton, 2008; Kahan & Ponticelli, 2000). Rejection can also occur when a patient is infected and the immune system is stimulated.

Rejection is classified as acute or chronic. Symptoms of acute rejection normally include fever, pain over the transplanted kidney, decreased urine production, protein in the urine, decreased fluid retention, and general flu-like symptoms. (Alleman & Longton, 2008; Kahan & Ponticelli, 2000; Patient information booklet, Oslo University Hospital). Acute rejection is often reversible if early treatment is received. Therefore, it is important that patients have knowledge about the symptoms of rejection and how to act when a rejection is suspected. At

the Norwegian transplant center, all renal recipients are instructed to log daily graft observations in a diary. The daily observations include morning and evening temperature, weight, fluid balance, and urine control (protein, glucose, hemoglobin). The purpose of the diary is to enable the patients to interpret signs of rejection that require the involvement of competent health personnel.

### 3.3.3 Lifestyle

Because of lifelong medication and other problems caused by the transplant, renal recipients are at risk of a diversity of adverse effects. Specific lifestyle behaviors can help reduce such risks. A lowered immune system caused by the medicines increases renal recipients' risk of infections. Good personal—and especially oral—hygiene is therefore recommended in order to prevent infection (Camton, 1991). In addition, when caring for wounds and coming in contact with people with contagious diseases, renal recipients need to take extra hygienic precautions. Furthermore, medications might lead to unwanted weight gain, hyperglycemia, hypertension, osteoporosis, and muscle atrophy (Chapman, 2010; Franklin, 2002; Luk, 2004; Murphy, 2007; Neyhart, 2009; Quan, 2006; Terrill, 2003; Transplant Work Group, 2009). Renal recipients are therefore advised to do regular physical exercises and be aware of beneficial eating habits and calorie intake (Neyhart, 2009). Skin cancer is the most common cancer in renal recipients; in order to decrease this risk, patients need knowledge concerning correct sun protection, skin self-examinations, and the importance of physician examinations (Feuerstein & Geller, 2008). This is especially important for patients who are tanned, light-skinned, or freckled or patients who are planning a warm-weather vacation or time in the sun during the summer (Feuerstein & Geller, 2008). In addition, renal recipients need information about how the social security system provides economic support in different cases, such as for



dentist, physiotherapy, and laser treatment against troublesome hair growth (Patient information booklet, Oslo University Hospital). The patient organization for patients with CKD might be a valuable resource in providing renal recipients with updated information on different topics as well as providing opportunities for social networking.

### **3.4 State of the art**

In order to develop new knowledge on enhanced educational strategies for renal recipients, it is important to conduct research on already existing knowledge on the topic. In this chapter, existing knowledge in relation to the outcomes of patient education that will be explored in this thesis will be described in the context of the renal transplant population. In addition, previously reported research concerning patient education interventions for the patient group will be described. Findings from a qualitative study on renal recipients' personal experiences of patient education will be presented, as they are relevant for both the patient education intervention and the knowledge questionnaire developed in this thesis.

#### **3.4.1 Renal recipients' experiences of quality of life and self-efficacy**

Research has demonstrated that renal recipients experience improved quality of life compared to pre-transplant (Chen, Chen, Lee, & Wang, 2007; Fujisawa et al., 2000; Neipp et al., 2006; Rebollo et al., 2000; Smith et al., 2008; Valderrabano et al., 2001; Wight et al., 1998) and that the treatment of kidney transplantation provides higher scores of quality of life compared to other renal replacement therapy (Liem et al., 2007; Niu & Li, 2005). However, long-term assessment of quality of life of renal recipients has been reported to differ from the general population in relation to both psychological (Karam et al., 2003) and physical aspects (Neipp

et al., 2006). Renal recipients seem to be affected by symptoms of distress (Chen et al., 2007; De Geest & Moons, 2000; Matas et al., 2002), anxiety and depression (Perez-San-Gregorio, Martin-Rodriguez, Az-Dominique, & Perez-Bernal, 2006), medication side effects (Fujisawa et al., 2000; Hricik, et al., 2001; Matas et al., 2002) rejection, and infection (Griva et al., 2002; Rebollo et al., 2000).

Organ transplants describe the transplantation process as a mix of contradictory feelings (Forsberg, Backman, & Moller, 2000; Urstad et al., 2012; Wiederholm et al., 2009). In qualitative studies, renal transplant recipients describe the waiting time prior to the transplantation as emotionally difficult (Herlin & Wann-Hansson, 2010) and the transplantation as a “turning point” in life causing emotional reactions (Urstad et al., 2012). Further, renal transplant recipients describe pain, nausea, and frequent urination as well as increased need for rest and sleep and troublesome hygienic conditions as dominating symptoms in the post-operative phase (Urstad et al., 2012). For all organ transplants, the fear of graft rejection and potential consequences of graft loss seem to present in both the long and short term (Buldukoglu et al., 2008; Forsberg et al., 2000; Luk, 2004; Nilsson, Persson, & Forsberg, 2008; Urstad et al., 2012). Renal recipients in the early post-operative phase also describe feelings of concern for the living donor, for the long-lasting separation from relatives, and odd feelings of having another person’s kidney in the body (Urstad et al., 2012).

Weng and colleagues have investigated renal recipients experiences of self-efficacy in relation to the post-transplant situation (Weng, Dai, Huang, & Chiang, 2010; Weng, Dai, Wang Huang, & Chiang, 2008). According to their research, renal recipients seem to be quite confident about their own post-transplant behavior (Weng et al., 2010). Self-monitoring behavior (fever, weakness, cough, and tenderness at the transplant site) was found to be the most frequent behavior consistent with the goal of organ transplant care (Weng et al., 2010). In addition,

patients with higher self-efficacy and higher self-care behavior had lower depressive symptoms, and self-efficacy was a significant predictor of depressive symptoms in renal recipients (Weng et al., 2008). Self-efficacy was shown to directly affect transplants' self-care behavior and indirectly affect the mental component of quality of life (Weng et al., 2010).

Self-efficacy in renal recipients has also been investigated in relation to the specific aspect of medication behavior. By using an instrument measuring patients' self-efficacy on long-term medication behavior (De Geest, Abraham, Gemoets, & Evers, 1994), it was revealed that renal recipients' self-efficacy significantly correlated with levels of medication compliance measured by electronic pillbox monitoring (De Geest et al., 1994). Another study (Baines, Joseph, & Jindal, 2002) explored the same relationship using the same instruments and came to the same conclusion.

### **3.4.2 Knowledge and compliance in kidney transplant recipients**

Renal recipients' compliance to medication behavior has been a focus of past research. Although strict compliance to the immunosuppressive drug therapy is crucial for keeping the kidney well and patients' provide descriptions of an intensive responsibility for the new graft (Buldukoglu et al., 2008), studies show that recipients do not always adhere perfectly to their regime (Denharenryck et al., 2005; Denharenryck et al., 2008). Adult kidney transplant recipients seem to be non-compliant with immunosuppressive therapy in 3-7 % of monitored days (Feldman, Hackett, Bilker, & Storm, 1999; Nevins, Kruse, & Skeans, 2001). This non-compliance is associated with an increased number of late acute rejections, late kidney graft failure (Dobbels et al., 2004; Hildbrands, Hoitsma, & Koene, 1995; Nevins et al., 2001; Vlaminc et al., 2004), and increased healthcare costs (Cleemput et al., 2004) and has been

suggested to contribute to the stagnation of long-term survival of kidney grafts (Meier-Kriesche, Shold, & Kaplan, 2004; Meier-Krieche, Shold, Srinivas, & Kaplan, 2004).

Lately, some studies have also investigated compliance to lifestyle recommendations and graft monitoring (Gheith, El-Saadany, Buo Donia, & Salem, 2008; Kobus et al., 2011). These studies have indicated that patients are less compliant in these areas compared to medication behavior. For instance, among the 110 renal recipients included in Kobus et al.'s (2011) study, 85% did not change their diet after kidney transplantation and only one-fifth wrote a self-control diary. Furthermore, studies in the area of skin cancer prevention report that few renal recipients take adequate sun protection (Firooz et al., 2007; Mahe et al., 2004; Szepletowski, Reich, Nowicka, Welowska, & Szepletowski, 2005). Only 64% of renal recipients reported using sunscreen regularly, and only 46% used one or less tubes of sunscreen per year. Furthermore, a hat was always used by only 35% of the patients while in the sun (Mahe et al., 2004)

Renal recipients' knowledge of important post-transplant aspects has been little explored. Yet some studies have measured renal recipients' knowledge about the danger of sunlight exposure and concluded that this seems to be unsatisfactory (Firooz et al., 2007; Mahe et al., 2004; Szepletowski et al., 2005). In Szepletowski et al.'s (2005) study, which included 151 renal recipients, only 40.4% of the patients knew that the development of skin cancer is connected with exposure to sunlight, 68.2% considered renal transplantation as a high-risk group of skin cancer development, and only 11.3% could explain what the number of the SPF (sun protection factor) meant.

### 3.4.3 Previous research on patient education for renal transplant recipients

Effects of patient education are widely documented for patients with both acute and chronic illness (Brown, Clark, Dalal, Welch, & Taylor, 2012; Conn, Hafsdahl, Brown, & Brown, 2008; Cooper, Cooper, & Milton, 2001; Cummings et al., 2011; Foster, Taylor, Eldridge, Ramsay, & Griffiths, 2007; Fredericks, Guruge, Sidani, & Wan, 2010; Mimunya, Kredo, & Volmink, 2012; Roter et al., 1998; Warsi, Wang, LaValley, Avorn, & Solomon, 2004).

Beneficial effects of patient education have been found for patients with acute conditions (Lopez, Hiller, & Grimes, 2010; Fredericks et al., 2010). For patients with chronic illnesses, patient education has been reported to result in beneficial outcomes such as reduced fatigue and depression, increased disease control, and adherence to treatment (Foster et al., 2007; Idier, Untas, Koleck, Chauveau, & Rasclé, 2011; Mimunya, Kredo, & Volmink, 2012, Roter et al., 1998). Furthermore, patient education has been effective in reducing symptoms of chronic illness, such as reduced pain, fewer asthma attacks, or improvement in systolic blood pressure (Bennett et al., 2011; Foster et al., 2007).

In this section, previous research on patient education for renal transplant recipients is described. This presentation will be based on results from studies utilizing different types of designs. Some of these studies have included other organ transplant recipients as well in the same trial. However, as renal recipients are the biggest group of organ transplant recipients, they are often in the majority in the samples. As this thesis includes a systematic review of controlled clinical trials, some of the studies described in this section are also presented in paper 1.

In general, patient education for organ transplant recipients has focused on medication adherence. A systematic review of interventions to improve medication adherence in organ transplant recipients found 12 interventions studies (De Bleser et al., 2009), in which five

reported a statistical improvement in at least one medication-adherence outcome. The review indicated that combinations of different types of intervention, with both a cognitive and a behavioral focus provided by a multi-professional team, might be the most effective in a long-term perspective. However, it was concluded that the interventions included in the review were too brief and more research utilizing randomized control trial (RCT) designs was needed (De Bleser et al., 2009).

A broader approach to patient education for transplant patient was the focus in Wilkins et al.'s (2003) study. Their one-year cross-sectional research including 52 renal recipients found that a targeted multidisciplinary program of education and psychosocial support emphasizing return to normalcy and non-disability yielded high rates of return to normalcy for renal recipients. Another holistic approach was made by investigating the effect of a mindfulness-based stress-reduction program compared to a more traditional health education program for solid organ transplant recipients (Gross et al., 2010). In this study of 130 transplant recipients—the majority of them renal recipients—the intervention proved to reduce distressing symptoms of anxiety, depression, and poor sleep and improved quality of life in the experimental group compared to the control group (Gross et al., 2010).

Some patient education programs have focused on a single, specific area concerning life post transplantation, such as skin cancer prevention and dietary recommendations (Clowers-Webb et al., 2006; Patel, 1998; Robinson et al., 2010). A study reporting a review of 40 Internet websites providing information concerning the risks and prevention skin cancer concluded that more thorough and detailed education was needed and at a lower reading grade level (Robinson et al., 2010). The effect of patient education intervention in the risk of skin cancer risk has also been investigated in renal recipients by comparing intensive repetitive written education about skin cancer risks and behavior to standard episode-of-care-based education

(Clowers-Webb et al., 2006). Patients in the experimental group scored significantly better on the behavioral assessment 3 and 10 months after the intervention. No effect was found on knowledge (Clowers-Webb et al., 2006). Patel (1998) focused on diets in renal recipients. In a controlled trial, the experimental group received individualized dietary advice the first 4 months post-transplant. By the end of the intervention and at 1-year post transplantation, the experimental group had significantly lower body-mass indexes (BMI) and weight gain compared to the control group (Patel, 1998).

Other studies have focused on adolescents and children (Fennel, Foulkes, & Boggs, 1994; Freier, Oldhafer, Offner, Dorfman, & Kugler, 2010). Freier et al. (2010) utilized audiovisual interventions providing adolescent transplant recipients with a computer-based education concerning medications and illness-specific knowledge and behavior-related knowledge. Fennel et al. (1994) focused on children (mean age = 12) and their parents. This educational intervention consisted of booklet with information about transplantation, a videotape concerning compliance, a medication calendar to record medication compliance, and rewards for monitoring medication-taking behaviors. Both studies reported a significant increase in knowledge, but no effect on behavior.

#### **3.4.3.1 Focus on comparing educational methods**

Some studies of transplant recipients have focused on comparing different educational methods. Two studies used videos as an educational tool: Steinberg, Diericks and Millspaugh (1996) and Giacoma, Ingersoll, and Williams (1999). Steinberg et al.'s (1996) study included 50 organ transplants while Giacoma et al. (1999) included renal transplants only (n = 59). Steinberg et al. (1996) found no differences in outcome between patients receiving standard

teaching plus a videotape and patients receiving standard teaching only. Giacomini et al. (1999) also found equal levels of knowledge in the groups, although they reported a significant decrease in time spent by nurses on one-on-one instruction. Both studies concluded that video is an effective strategy in education, but only when used in conjunction with other methods.

Most studies documenting the use of group instruction in renal recipients have been provided in the pre-operative phase (Mason, Khunit, Stone, Farooqoi, & Carr, 2008; Sharkey & Gourishankar, 2003). Group instruction versus individual instructions has also been investigated post-transplantation. In Johnson and Goldstein's (1993) study, an experimental group consisting of 18 renal recipients was invited to three one-hour group sessions in the post-operative period. The themes were transplant medications, follow-up and monitoring, and self-management and problem solving. Participants chose their attending due to their wishes. Compared to the control group (n = 28) receiving standard one-to-one instructions, no differences were seen in knowledge, self-management, or number of calls between the groups. However, in qualitative research, participants have voiced negative attitudes toward the group method due to a regard for privacy and individual needs (Urstad et al., 2012). This skepticism is explained by circumstances in the post-operative phase that might affect an increased self-centered focus and thus less generate capacity to relate to other patients and their problems (Urstad et al., 2012).

More basic nursing strategies concerning patient education have been used in the studies of Taghavi (1999) and Barton and Wirth (1985). Taghavi's (1999) intervention consisted of implementing structured preoperative teaching. The experimental group received teaching from a registered nurse on independent functioning and compliance with medication regime, while the control group received unstructured teaching performed by nursing personnel. The experimental group increased their knowledge levels. Furthermore, shorter hospital stays in



the experimental group were reported. In Barton and Wirth's (1985) study, the experimental and control groups received a standard education program, but for the experimental group, the education was coordinated and delivered by patients' primary nurse. No differences were found between the groups in this study.

#### **3.4.4 Renal recipients' educational experiences in the early postoperative phase— Relevant findings from a qualitative study**

Findings from a qualitative study focusing on renal recipients' educational in-hospital experiences indicated several barriers toward patients' learning due the post-transplant setting (Urstad et al., 2012). Based on qualitative interviews with 16 renal recipients 4-6 weeks after their transplantation, it appeared that physical, emotional, and drug-related strains associated with receiving a kidney transplant negatively affected patients' ability to concentrate and learn. In addition to symptoms that frequently occur in patients who have undergone surgical procedures, like memory loss and lack of concentration (Sauer et al., 2009), patients explained the transplantation as being a turning point in their lives. This seemed to cause emotional reactions that affected their ability to handle a future-focused educational program. Instead the focus was the "here and now" (Urstad et al., 2012).

At the same time, the study indicated that patients were motivated to learn as participants expressed that the educational content was essential for their lives (Urstad et al., 2012). Topics related to medication and rejection seemed to be considered most important. This might be explained by the fact that graft rejection will have an obvious negative short-term impact on patients' lives whereas long-term aspects such as lifestyle changes might appear fainter and less important (Urstad et al., 2012). Furthermore, the previous focus on

compliance to medication instead of a holistic/whole person approach (Hamiwka, Cantell, Crawford, & Clark, 2009; Wilkins et al., 2003) might have resulted in a devaluation of aspects concerning lifestyle (Urstad et al., 2012).

Urstad et al.'s (2012) findings revealed that each patient's individual life situation seemed to affect what was perceived to be missing in the educational content. Individual issues created a need for further details in certain areas (Urstad et al., 2012). This indicated the need for individually designed patient education, based on the underlying disease, level of insight, and social context and support. Regarding education in groups, results from the qualitative study tended to be less favorable regarding the assumed beneficial effects (Urstad et al., 2012). Renal recipients in the qualitative study voiced negative attitudes toward the group method due to a regard for privacy and individual needs. This skepticism can be explained by circumstances in the postoperative phase that might result in an increased self-centered focus and thus less capacity to relate to other patients and their problems.

The findings also suggested a troublesome link from knowledge to practicing. Renal recipients described a "transformation gap" after discharge. It is a well-known challenge to transfer knowledge from one setting to another, relating the assumed abstract nature of theory to the assumed real nature of practice (Evans, Guile, Harris, & Allan, 2010). In general, patients expressed feel in control of their situation on the hospital ward, but this changed after discharge (Urstad et al., 2012).

This section has described how kidney transplantation might impact both physical and psychological aspects of life in the short and long term. Research has further indicated that recipients' compliance to medication intake, graft monitoring, and lifestyle behavior do not seem to be satisfying. Patients' knowledge in post-transplant aspects and self-efficacy has been little explored, but self-efficacy has been found to be a positive predictor for increased

self-care behavior and depressive symptoms. The learning situation seems to be difficult in the postoperative phase as patients describe both physical and emotional barriers toward learning. They also express the need for individualized patient education and practical contextualizing. Previous patient education programs have mainly focused on compliance to medication; a broader, “whole person” approach seems to be lacking. Some studies in this area have focused on specific groups of patients, such as adolescents or children, while others have focused on specific aspects, such as dietary advice or medication compliance. Educational methods that have been used include video, computer-based education, group-education, and the use of a primary nurses coordinating all patient education. However, studies with stronger designs and better reporting quality continue to be lacking.

#### **4.0 METHODS**

The present study consisted of three designs. To address aim 1, a systematic review was conducted (paper 1). To address aim 2, a descriptive cross-sectional design was used (paper 2). The measurement point for this study was 5 days post transplantation. To evaluate the effectiveness of a structured, tailored patient education program on renal recipients’ knowledge, self-efficacy, and quality of life (aim 3), a randomized controlled trial was conducted (paper 3). Outcomes were measured 7-8 weeks post transplantation and 6 months post transplantation.

## **4.1 Study population and recruitment**

### **4.1.1 To describe the effectiveness of educational interventions for renal transplant recipients (paper 1)**

To address aim 1, all randomized controlled trials (RCTs) and quasi-randomized trials using the inadequate generation of sequence allocation and controlled clinical trials (CCTs) concerning educational interventions for renal recipients were considered for inclusion. We included all renal recipients, both male and females and of all ages, as potential participants. All types of educational and counseling interventions were included. Relevant outcome measures were included according to Osborn's program logic model (Osborn et al., 2007). In this model, outcomes of health education are divided into three levels: proximal outcomes (i.e., knowledge, compliance), intermediate outcomes (i.e., decreased symptoms, self-confidence, health-related quality of life), and distal outcomes (i.e., use of acute healthcare).

The following databases were searched up to May 2011: Cochrane Central Register of Controlled Medline, Cochrane Library, ERIC, Embase, Psycinfo, and CINAHL. In the search, we used the following MeSH terms: "kidney transplantation as topic" (including transplantation kidney, kidney transplantations, transplantations, kidney, transplantation renal, renal transplantation, renal transplantations, transplantations renal, grafting kidney, kidney grafting) combined with "patient education as topic" (including education of patients, education, patient, patient education) and "kidney transplantation as topic" combined with counseling defined as "the giving of advice and assistance to individuals with educational or personal problems."

Searches in Medline with the limitation "clinical trial" resulted in 12 hits. After excluding papers dealing with dialysis patients, four studies were included (De Geest et al., 2006;

Fennel et al., 1994; Giacomini et al., 1999; Taghavi, 1995). When the limitation “clinical trial” was removed, the number of publications increased to 315. However, after going through titles/abstracts/full text, only two of these were found to meet the inclusion criteria (Freier et al., 2010; Patel, 1998). Furthermore, a search in Embase resulted in two additional relevant publications (Barton & Wirth, 1985; Johnson & Goldstein, 1993). Two more relevant were trials retrieved from the reference list of a systematic review (De Bleser et al., 2009) regarding medication adherence for organ transplant recipients (Chisholm, Mulloy, Jagadeesa, & DiPiro, 2001; Dejan et al., 2004). One of these was an abstract published in a conference proceeding, but because of the lack of further available information about the trial, it was not included (Dejan et al., 2004). In total, nine studies were ultimately included.

#### **4.1.2 To describe renal recipients’ levels of knowledge and to investigate the effect of a tailored patient education program (papers 2 and 3)**

For studies 2 and study 3, participants were recruited within the first days post transplantation. Criteria for inclusion were being over 18 years old; recently having had a kidney transplant; being able to speak, understand, and read Norwegian; and being mentally able to participate in the study. An exclusion criterion was concurrent participation in drug (immunosuppressive medication) studies, but an exception was made for the CENTRAL study, in which randomization (to everolimus or continuation of CNI) was first performed beyond 7 weeks post-tx.

Among the 382 patients undergoing kidney transplantation from October 2007 to March 2009, 21 patients were not included because of a recruitment break in the holiday (July to August 2008). In addition, 19 eligible patients were not asked to participate because nurse

staff occasionally forgot or did not prioritize recruiting patients on busy days. The remaining 255 patients meeting the inclusion criteria were asked to participate in the study by the trained nurse staff, and 174 patients agreed. Among these 174 patients, 5 failed to complete the questionnaire due to postoperative complications. Three patients decided to withdraw before completing the baseline questionnaire, and seven patients were excluded for not completing the questionnaire within the scheduled time. The total sample of study 2 therefore resulted in 159 kidney recipients.

For study 3, participants were randomized in blocks of 20 (a series of 20 envelopes contained 10 assignments in each group). An impartial person mixed the envelopes, and envelopes were drawn continuously by the research nurse as patients agreed to participate. Altogether, 77 patients were randomized to the experimental group and 82 to the control group.

The second measurement point (T2) was set to 7-8 weeks post transplantation and was reached by 139 patients (87% response rate), including 71 in the experimental group and 68 in the control group. The reasons for dropouts from baseline were as follows: not able to start intervention program because of complications that required prolonged hospitalization, other health problems making participants unable to complete the program (influenza, gastroenteritis), and non-attendance to scheduled intervention appointments (total dropout from baseline: 13%).

*Table 1: Demographics of total sample of study 2 and study 3*

	<i>Study 2 (n =159)</i>			<i>Study 3 (n =139)</i>		
<b>Baseline characteristics</b>						
Age Year (mean) sd	21-77	51	14	21-76	50	14
Male (n) (%)	110		69	95		69
<b>Marital status(n)(%)</b>						
Married/cohabitant	96		60	85		61

Single, divorced, separated	57		36	49		35
Widow/widower	6		4	5		4
<b>Co residency (n)(%)</b>						
Living alone	37		23	32		23
<b>Level of education (n)(%)</b>						
Primary and secondary school (7-10 years)	27		17	23		17
High school (10-13 years)	71		45	60		43
College or university, less than 4 years	30		19	28		20
College or university, more than 4 years	31		19	26		19
<b>Employment status (n)(%)</b>						
Paying job	78		49	71		52
Disablement insurance or retirement pension	69		43	56		40
Other (student, unemployed, fulltime housework)	12		8	12		8

Ultimately, 120 participants reached the third measurement point (T3), which was set to 6 months post transplantation. This sample included 56 participants in the control group and 64 in the experimental group (75% response rate from baseline). In addition, 10 patients (9 = control, 1 = experimental) who did not respond at the second measurement responded at the third measurement. Dropouts from the third measurement were not significantly different from the sample at the second measurement in terms of gender, age, educational level, or clinical characteristics.

## 4.2 Development of instrument

Developing questionnaires is a complex process, and before starting such work it is imperative to consider the availability of previously tested and validated instruments (DeVet, Terwee, Mokkink, & Knol, 2011; Fayers & Machin, 2007). Based on our search of the literature, it seemed clear that an appropriate, validated, and reliable instrument for measuring renal recipients' level of knowledge in post-transplant aspects was missing. It was therefore decided to develop a knowledge questionnaire specifically for this purpose.

Questionnaires generally aim to describe people's behaviors, attitudes, or knowledge (Taylor-Powell, 1998). Types of questions vary due to the type of information wanted from the questionnaire. For instance, questions tapping into attitudes aim to describe people's values, ideas, and ways of thinking in relation to their situation, whereas behavioral questionnaires want to describe what people actually did or tended to do in different situations (Taylor-Powell, 1998). For the development of the questionnaire in this thesis, the aim was to describe patients' basic knowledge concerning post-transplant aspects by developing items that could be framed as right or wrong. These factual knowledge items might be less complex compared to questions regarding values, beliefs, or attitudes.

The development of the questionnaire was guided by the different steps as recommended by Fayers and Machin (2007), including clarification of the research question, definition of the target population, and a literature search. It was recommended to contextualize a validated knowledge questionnaire for use with the specific group of renal recipients. The Pain Experience Scale (PES) knowledge questionnaire (Ferrell, Rhiner, & Rivera, 2003; Kim et al., 2004) was developed for knowledge about pain in cancer, but was adapted for the current study by contextualizing the content to renal recipients' post-transplant knowledge.

In order to make explicit the underlying relationship between the items and the construct to be measured, Fayers and Hand (1997) introduced a distinction between a reflective and formative mode. The construct underlying the current questionnaire can be described as "knowledge of post-transplant aspects." In reflective models, a set of items are assumed to be manifestations or effects (indicators) of an underlying construct, which implies that the items have a common underlying cause and for this reason will correlate with each other; in addition, they are assumed to be parallel or can replace one another (De Vet et al., 2011; Fayers & Hand, 1997). In a formative model, which is used for the current questionnaire, each



item contributes a part of the construct, and the items as a whole form the entire construct. The items do not necessarily correlate with each other (De Vet et al., 2011).

A formative model might encounter a challenge in identifying all items that contribute substantively to the construct (De Vet et al., 2011). According to Fayers and Machin (2007), the involvement of relevant healthcare workers and interviews/discussions with patients is essential to cover all relevant issues. When developing the items for the questionnaire in this thesis, a team at the single transplant center in Norway carried out a literature review of essential issues in relation to knowledge needed for renal recipients' post-transplant coping. The team consisted of two clinical expert nurses with more than 10 years of experience with the patient group, one experienced kidney tx surgeon, and the PhD student of this thesis, also with 10 years of clinical experience with the patient group. A previous qualitative study concerning renal recipients experiences of the patient education post-transplant and their perception of the different areas in the knowledge base being taught (Urstad et al., 2012) was also used as a source in the developing of the items. Based on the literature search and the qualitative interviews, three areas emerged as essential for knowledge post-transplant: medication, rejection and lifestyle (Chapman, 2010; Feuerstein & Geller, 2008; Franklin, 2002; Transplant Work Group, 2009; Murphy, 2007; Neyhart, 2009; Quan, 2006; Terrill, 2002; Urstad et al., 2012). The 19 final items ultimately selected address knowledge in these three main areas.

Four items in the questionnaire focused on immunosuppressive medication (i.e., the importance of the medication, the consequences of not taking the medication, taking medication at prescribed times, absorption of the medication), four on rejection (i.e., what is rejection, signs of rejection, consequences of rejections, and 11 on lifestyle (i.e., preventing side effects of medication, physical activity, eating habits, diabetes, hygiene, kidney

transplant association, sun protection, re-transplantation). The last area is the widest and complex one, consisting of a variety of issues; therefore, the majority of the items address this domain.

Following the recommendations of De Vet et al. (2011), items were selected so as to be comprehensible and specific, avoiding terms with multiple meanings, and ensuring that each item comprises only one question. The questionnaire was pilot tested with 9 renal transplant recipients aged between 29 and 68, including 5 men and 4 women. Five of them were presented with the questionnaire 5 days after their kidney transplant. The patients filled in the questionnaires on their own. After completing the questionnaire, the patients were interviewed about their experiences of the content and form.

Each item was rated using a five-point scale, anchored on the left with the wording “totally disagree” (i), “slightly disagree” (ii), “neither agree nor disagree” (iii), “slightly agree” (iv) and to the right with “total agree” (v). Response alternatives were chosen to reveal uncertainty among participants and to reduce the risk of correct answers based on guesswork. Patients were asked to circle a number to indicate their level of agreement with each item. Some items were reverse coded so that each item was scored to reflect the degree of correctness.

### **4.3 The intervention**

The guidelines state that interventions should be developed systematically by using the best available evidence of the appropriate theory (Craig et al., 2008). The patient education intervention in this thesis is based on the educational principles of the pro-self program (Kim et al., 2004; Rustoen et al., 2012; Sutters, Savedra, & Miaskowski, 2011; West et. al, 2003). This education program consists of three main elements defined as provision of information,

skill building, and interactive nursing support aimed at teaching patients how to prevent and manage the side effects of their disease and treatment (West et al., 2003). The pro-self program is based on elements from established pedagogic theories and Orem's (2001) self-care theory. The pro-self-program has been found to be effective in educating cancer patients about pain management (Kim et al., 2004; Rustoen et al., 2012; West et al., 2003).

A review of the relevant literature on life post-transplant and findings from the qualitative study of renal recipients' experiences of patient education in the early post-operative phase (Urstad et al., 2012) guided the content and structure of the current patient education. The qualitative study revealed barriers toward learning in the post-operative phase and the need to accommodate individual needs via the educational content (Urstad et al., 2012). These findings were taken into consideration during the planning of the intervention. Aspects concerning medication, organ rejection, and lifestyle emerged as essential for coping with the post-transplant situation and were included in the educational content (Chapman, 2010; Feuerstein & Geller, 2008; Franklin, 2002; Transplant Work Group, 2009; Murphy, 2007; Neyhart, 2009; Quan, 2006; Terrill, 2002; Urstad et al., 2012).

The strategies of "academic detailing" were used as a guide to achieve individualization. This strategy is based on adult learning principles and includes determining the learner's baseline knowledge and motivation (Somurai & Avorn, 1990). By measuring patients' knowledge using a questionnaire 5 days post-tx, relevant areas for learning in each patient were revealed. Parts of the intervention were pilot-tested on representatives from the patient group to ensure that the intervention could be delivered as intended. Participants in the pilot-test were asked to evaluate the education sessions afterwards so that changes in the intervention could be made based on their feedback.

### 4.3.1 Structure

The intervention program consisted of five one-to-one education sessions. The sessions were conducted by the PhD student of this thesis, who has more than 10 years of nursing experience with transplant patients. The first session was held during the first week after discharge, when patients were attending outpatient controls. Despite the expressed learning difficulties, renal recipients expressed high motivations for learning in the early post-operative phase (Urstad et al., 2012). Sessions were held every week during the first -week period. Between the fourth and the fifth (last) sessions, there was a period of 2 weeks, which provided the opportunity for support over a somewhat longer period. This seemed important due to renal recipients' experiences of a knowledge "transformation gap" when returning to a more normal home setting (Urstad et al., 2012). Every session lasted 40-60 minutes. Renal recipients had further expressed that continuity of teaching nurses made it easier to open up and talk about difficult topics (Urstad et al., 2012). Thus, the same nurse followed participants from beginning to end.

### 4.3.2 Content

The five sessions had specific focuses: (1) baseline knowledge, patient disease history, practical skill practice; (2) topics emerging from patients' need/situation; (3) basic knowledge of rejection and medication; (4) home situation; and (5) summary and follow-ups at home. During the five sessions, basic information on the three knowledge areas—medication, organ rejection, and lifestyle—was provided. These areas were also covered in the standard written information handed out for all renal recipients post-transplant, which was used as a basic tool for the sessions. The content was contextualized and further detailed based on each patient's

needs and life situation. Learning areas were continuously revealed throughout the one-on-one sessions and through participants' answers from the knowledge questionnaire at baseline.

*Table 2: Intervention session focuses and timing*

	<b>Session 1</b>	<b>Session 2</b>	<b>Session 3</b>	<b>Session 4</b>	<b>Session 5</b>
<b>Focus</b>	Determine baseline knowledge, patient disease history, practical skills	Topics emerging from patients' need/situation/lifestyle	Basic knowledge on rejection and medication	Home situation	Summary, and follow-ups at home
<b>Time</b>	First week post discharge	Second week post discharge	Third week post discharge	Fourth week post discharge	Sixth week post discharge

#### **4.4 Standard care**

All the participants in the experimental and the control group received ordinary care. Ordinary care consisted of patient education during hospitalization. This included written material and one-to-one communication with nurses. The teaching topics covered medication, graft rejection, and lifestyle changes. It also involved practical training, such as administering drugs and observing/documenting graft function by monitoring urine production, urine chemistry (dip sticks), body temperature, and weight. A checklist was used to document completed education. When discharged approximately one week post-tx, all patients attended outpatient controls. These controls were focused on graft function and physical condition in relation to the transplant.

## 4.5 Instruments

### 4.5.1 Primary outcome

#### Knowledge: The Renal transplant knowledge questionnaire

The primary outcome was measured using the 19-item knowledge questionnaire for renal recipients developed in this study. When scoring the questionnaire, only completely correct answers were counted. Alternatives indicating a lower degree of answering correctly—“slightly disagree,” “neither agree nor disagree,” “slightly agree,” or no degree of agreement (i.e., “neither agree or disagree”)—were all counted as incorrect answers. A total score of correct answers was summarized (for further information, see p. 47).

### 4.5.2 Secondary outcomes

#### Compliance: Number of patient observations

Compliance was measured using the number of patient observations. Due to standard care at the ward, all renal recipients were instructed to log daily graft observations in a diary. The daily observation included morning and evening temperature, weight, fluid balance, and urine control (protein, glucose, hemoglobin). The purpose of the diary was to enable patients to interpret signs indicating rejection or other conditions that require the involvement of competent healthcare personnel. Compliance was measured by counting the number of missed observations from the start throughout the 7- to 8-week period.

#### Self-efficacy: The Generalized Self-efficacy Scale

Self-efficacy was measured using the Generalized Self-efficacy (GSE) Scale, which is designed to assess optimistic self-beliefs in coping with a variety of difficult demands in life. The scale was developed by Matthias Jerusalem and Ralf Schwarzer in 1981 and has been used extensively around the world (Scholz, Gutiérrez-Doña, Sud, & Schwarzer, 2002; Schwarzer, Bassler, Kwiatek, & Schroder, 1997; Schwarzer, Born, et al., 1997; Schwarzer & Jerusalem, 1995). The questionnaire consists of 10 items, and the scaled score for each item ranges from 1 to 4. Higher scores indicate a patient's stronger belief in self-efficacy. To score the questionnaire, all responses are added to a sum score. The range is from 10 to 40 points. The GSE Scale has been found to be reliable and valid in numerous studies (Schwarzer, Bassler et al., 1997; Schwarzer, Born, et al., 1997), and the questionnaire has been translated into a Norwegian version (Røysamb, Schwarzer, & Jerusalem, 1999). In the present study, internal consistency was evaluated using the Cronbach's alpha. A Cronbach's alpha value higher than 0.70 can be considered satisfactory (Polit, 2004; Polit & Beck, 2006). In this study, the GSE Scale's Cronbach's alpha was found to be 0.85 at the second measure point (T2).

#### *Quality of life: Short Form Health Survey (SF-12)v2*

Quality of life was measured using the Short Form 12 -Item Health Survey (SF-12) v2, which is a short version of the Short Form 36-Item Health Survey (SF-36), developed within the framework of the Medical Outcome Study (MOS) (Ware, Kosinski, & Keller, 1996). SF-36 and its scaled-down siblings, the SF-12 and SF-8, are the most widely used and validated measure of health related quality of life in the nephrology literature (Goodkin, Mapes, & Held, 2001; Liem et al., 2007; Wight et al., 1998).

SF-12 is a generic measure of health status. By using 12 items, the SF-12 assesses two main dimensions of quality of life: physical and mental health (PCS and MCS, respectively) (Ware et al., 1996). Scores are coded, summed, and transformed into a scale from 0 (worst possible health status) to 100 (best possible health status) (Ware et al., 1996). In this study, the acute version of SF-12 was used, with a 1-week recall period instead of the original 4-week recall period. The rationale behind the development of the acute version was that shorter recall periods would be more sensitive than longer recall periods to recent changes in health status (Sf-36.org, 2012). For the current study, the acute version was considered more sensitive to the changes occurring from the transplantation and the patient education intervention.

The SF-12 has shown satisfying psychometric properties in the Norwegian language (Gandek et al., 1998). The questionnaire has been used in renal transplantation population in the United States (Chisholm, Spivey, & Nus, 2007) and SF-36, the original version of SF-12, has been used in the Norwegian kidney transplant population (Aasebo, Midtvedt, Hartman, & Stavem, 2005). In this thesis, the Cronbach's alpha was 0.85 (mental score: 0.73, physical score: 0.80).

#### **4.6 Ethical issues**

This study was performed in accordance with ethical guidelines of the Helsinki Declaration of 1975 (World Medical Association, 2009). These guidelines state that the investigator's duty is solely to the patient and that the patient's welfare must always take precedence over the interests of science and society, while ethical considerations must always take precedence over laws and regulations. The protection of dignity, privacy, and the respect for the individual as well as participants' right to self-determination and to make informed decisions regarding participation in research—both initially and during the course of the research—are



important principles in these guidelines (World Medical Association, 2009). The study was approved by the Regional Committee for Medical Research Ethics South Norway (ref: S-07266a) and the Data Protection Supervisor at Oslo University Hospital (2007. /5345). The study was also registered at Clinical Trials.gov (Clinical Trials.gov Identifier: NCT01184937).

The risk involved for patients participating in the present study was regarded as minimal and involved mainly time consumption. When asking patients if they were willing to participate in this study, they were informed about the purpose of the study and the right to withdraw at any time. It was emphasized that no reason for withdrawing from the study was needed and that it would not in any way affect standard future treatment at the hospital. Furthermore, they were informed that confidentiality was guaranteed. Both written and oral information was given, and participants signed forms of informed consent. All patients were recruited by trained staff nurses, not by persons from the research team, in order to reduce the influence from the researchers' interest. Patients might be considered to be in a vulnerable state regarding emotional and physical stressors in relation to the transplantation when being introduced to the study. They were, however, given the opportunity to contact the doctoral student for further questions about the study both via phone and e-mail.

Baseline self-reported questionnaires were completed 5 days post-tx. At this stage, most patients have to some extent recovered from the surgery. However, some of the questions were of a sensitive nature and might cause mild psychological stress. There was also a risk that patients randomized to the control group might feel disappointed by not having the opportunity to receive the patient education intervention in the study. The aim of the intervention was to provide renal recipients with a tailored patient education program starting in the early post-operative phase and lasting 7-8 weeks post-transplant. For this reason there

was no option to provide the control group with the patient education intervention at a later stage—nor was it considered practically possible to do as patients returned to their homes approximately 3 months post transplantation and would no longer be at the outpatient clinic at Oslo University Hospital. However, both experimental and control groups received patient education as per standard treatment, and nothing was removed from the standard care of the patient group.

In this study, the necessary sample size was initially estimated at 128 participants. A study comprising an unnecessarily large sample could be regarded as unethical because of the unnecessary burden of involving extra participants. On the other hand, a study with a sample that is too small would be unable to detect clinically significant effects or run the risk of committing a Type 2 error. Such a study could be scientifically useless and hence, unethical in terms of its use of patient and other resources (Altman, 1980, Emanuel, Wendler, & Grady, 2000; Halpern, Karlawish, & Berlin, 2002). Thus, it seemed important for ethical reasons as well that the recruitment of patients continued until the required sample size was reached, while taking into account the risk of a sizable number of dropouts. Based on this, a number of 159 participants were recruited to the study.

## **4.7 Analyses**

### **4.7.1 Article analysis (paper 1)**

For the literature review (paper 1), two researchers independently assessed a list of titles and abstracts for a full-text review. Full-text review articles were obtained for all potential relevant studies fulfilling the criteria when insufficient information could be obtained from the title and abstract alone. All full-text articles were again independently assessed and

included in the review if all selection criteria were met. Two reviewers independently assessed each study according to guidelines developed by the Cochrane Musculoskeletal Group (Maxwell et al., 2006). The criteria in this methodological appraisal are generated from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green, 2005) and are addressing generic items. Seven quality criteria were assessed for each study: random generation of allocation, concealment of allocation, outcome assessment, co-intervention, losses to follow-up, blinding of provider or patient, and intention-to-treat analyses. Based on this assessment, studies were grouped into low (met six or seven criteria), moderate (met three to five criteria), or high risk of bias (met fewer than three criteria) (Hagen, Byfuglie, Falzon Olsen & Smedslund, 2009).

#### **4.7.2 Statistical analyses (papers 2 and 3)**

In papers 2 and 3, the statistical analyses were performed using SPSS package version 16 and 17 (SPSS Inc. (17), Chicago, Illinois, USA). Several statistical procedures were applied depending on the research question: descriptive statistics, Pearson's product moment correlation, reliability testing, and multivariate linear regression analyses.

Based on an effects size of 0.5 standard deviations, a significance level of 5%, and a power of 80%, it was estimated that 64 participants were needed in each group for the randomized controlled trial (paper 3). The total sample of 159 participants at baseline in the RCT was also the sample in the descriptive cross-sectional study (paper 2). Descriptive analyses were performed to assess the characteristics (papers 2 and 3).

For the descriptive cross-sectional design (paper 2), scores from the knowledge questionnaire were initially screened for normality. This screening indicated a normal distribution (SD: 3.76

mean 11.02), which was essential for further analysis. Pearson's  $r$  analyses were used to identify significant correlations among items in the scale. Pearson's  $r$  was also used to explore possible significant associations between selected demographic and clinical factors and the level of knowledge. These factors were age, gender, education level, previous kidney transplant, diabetes or heart diseases, marital status/co-habitation, important life events, length of time since diagnosis of kidney disease, post-operative complications, and long-term dialysis treatment prior to transplantation. The level of significance was set at  $p < 0.05$ .

To test for differences between the experiment and the control groups in the randomized controlled trial (paper 3), multivariate ANCOVA [SPSS General Linear Models (GLM), Unianova] was conducted for each outcome measure separately. The ANCOVA used is a linear regression analysis (OLS) adjusting for baseline scores as a covariate. As no baseline data for compliance existed, a simple  $t$ -test (ANOVA) was conducted for this measurement. Once again, tests were considered significant if  $p < 0.05$ .

To evaluate whether the effect of the intervention was confounded by an uneven distribution across the intervention and control groups with respect to gender, education level, age, or duration of dialysis prior to inclusion, ANCOVAs were performed adjusting for the effect of these variables. To test whether the effect of the intervention was particularly strong for specific subgroups regarding gender, age, educational level, and time of dialysis, interaction terms involving these variables and the variable of group membership were also included in the equations, one pair at a time.

## **5.0 MAIN RESULTS**

### **5.1 Aim 1: To describe the content and evaluate the effectiveness of patient education**

## **interventions for renal recipients (paper 1)**

Previous reviews in the field of renal diseases have focused primarily on patient education prior to the transplantation; in the most recent review, renal recipients were excluded because of their specific educational needs. The objective of this paper was to describe the content and evaluate the effectiveness of patient education programs for the specific group of renal recipients, including a broader outcome focus than previous reviews have reported.

All RCTs and CCTs were identified through systematic literature searches in the Cochrane Central Register of Controlled Trials, Medline, Embase, CINAHL, and ERIC. In addition, reference lists and reviews were examined. Methodological quality was evaluated according to seven criteria developed by the Cochrane Musculoskeletal Group (Maxwell, 2006).

Interventional effects were summarized qualitatively.

In total, nine trials were included in this review. Three of them were RCTs. The educational interventions varied in terms of focus, timing, and intensity. In general, interventions used educational/cognitive strategies or a combination of educational/cognitive strategies and counseling/behavioral strategies. Overall, methodological assessment scores were poor. All non-RCTs were found have a high risk of bias (met fewer than three assessment criteria), whereas the three RCTs were categorized with medium risk of bias (met three to four assessment criteria). Two of the RCTs reported a beneficial effect in favor of the educational intervention. The strongest evidence was found for the use of preparatory video-assisted teaching prior to the discharge and monthly pharmaceutical counseling.

Knowledge was the most frequent endpoint tested, but all studies reported various tools, although few of them were validated, indicating a lack of available and validated instruments for measuring educational outcomes. The majority of the studies measured outcomes within

fewer than 6 months post transplantation. Furthermore, the strongest designs had a narrow focus, focusing on compliance to medication.

In conclusion, limited evidence was found for effectiveness of educational intervention in renal transplant recipients. For future research, studies with stronger designs and improved reporting standards are needed. Educational interventions should include a holistic educational approach and be provided in both early and later stages post-tx. In addition, more long-term outcome measures are needed. Educational outcomes should be measured on different levels—at both personal and society/economical levels.

**5.2 Aim 2: To describe the development of a questionnaire on renal recipients' knowledge on important post-transplant aspects, to examine its performance in measuring the patients' level of knowledge five days post transplantation, and to investigate possible factors related to the knowledge level (paper 2)**

Renal recipients' knowledge is important in terms of coping with short-term problems posed by transplantation and the long-term outcome; however, little attention has been given to the development of instruments for measuring patients' knowledge in this field. In the absence of an appropriate instrument for knowledge-testing among adult renal recipients, the aim of this paper was to describe the development of such a questionnaire, examine its performance in measuring the patients' level of knowledge 5 days post-transplantation, and investigate possible factors related to the knowledge level

The total sample consisted of 159 renal recipients at a Norwegian transplant center. They answered the questions 5 days post-transplantation. The mean score of the questionnaire was 11 (53% correct answers), ranging from 0 (0.6%) as the lowest score and 19 (0.6%) as the

best score (SD, 3,7) out of 19 obtainable points. The highest knowledge scores were found in relation to medication with 72.5% correct answers, 58% correct answers were given in relation to rejection, and 52% correct answers were given concerning lifestyle. The questionnaire measured basic knowledge concerning life post-transplant, and patients were discharged and finished their education process approximately two days later. Based on this timing, one could argue that knowledge scores should be somewhat higher.

No statistically significant correlations were found between total knowledge level and age, gender, education, marital status, previous kidney transplants, diabetes or heart disease, cohabitation, or important life events. However, a statistically significant relation was identified for the length of time since diagnosis of kidney disease and higher levels of knowledge. Furthermore, lower knowledge scores were found for patients suffering from complication within the first days of the kidney transplant and for long-term dialysis treatment prior to the transplant.

### **5.3 Aim 3: To evaluate the effect of a structured, tailored patient education program on renal recipients' knowledge, compliance, self-efficacy, and quality of life (paper 3)**

The purpose of this randomized controlled trial was to test the efficacy of a tailored educational intervention on renal recipients' knowledge, compliance, self-efficacy, and quality of life. In total, 159 renal recipients were randomized to the intervention (n= 77) or control group (n= 82). A total of 139 participants reached second measure point (7-8 weeks post-tx), and 120 participants reached third measure point (6 months post-tx). The primary outcome was measured using a knowledge questionnaire. The secondary outcome was

measured using the GES Scale, Sf-12, and the number of patient observations logged in a diary (i.e., compliance).

A significantly higher level of knowledge was found in the experimental group compared to the control group, measured 7-8 weeks post-tx ( $p = 0.002$ ). No significant differences were found regarding gender, age, or education level on the effect of the intervention. However, a subgroup of patients with more than one year of dialysis history prior to the transplantation turned out to benefit more from the intervention at the second measure point ( $p = 0.04$ ). Compliance was further significantly higher in the experimental group ( $p = 0.00$ ) 7-8 weeks post-transplant. Compliance correlated significantly with higher levels of knowledge ( $r = 0.246$ ,  $p = 0.006$ ).

At the third measurement point, patients in the experimental group reported significantly better scores on levels on knowledge ( $p = 0.004$ ), self-efficacy ( $p = 0.036$ ), and mental scores of quality of life ( $p = 0.001$ ). In conclusion, the results of the study indicate that a tailored educational program in the post-transplant phase seems effective in increasing renal recipients' knowledge, compliance, self-efficacy, and quality of life.

## **6.0 DISCUSSION OF CORE FINDINGS**

Through this study, we have gained increased insights into the area of patient education for renal recipients concerning post-transplant aspects. The overall aim for this study was to develop knowledge in relation to patient education in the context of kidney transplantation. The three specific objectives for the various papers were to define existing evidence of effective patient education for the patient group (paper 1), develop an instrument and measure renal recipients' level of knowledge on post-transplant aspects (paper 2), and investigate the



effect of a tailored patient education program (paper 3).

The systematic review revealed limited evidence for effective patient education interventions for the patient group (paper 1). Only two studies with moderate risk of bias reported beneficial effects. The strongest evidence was found for the use of video-assisted teaching prior to discharge and for monthly pharmaceutical counseling. We concluded that more research was needed concerning effect of patient education for renal recipient utilizing a stronger design.

A knowledge questionnaire was developed due to the lack of an appropriate existing questionnaire for use in this study (paper 2). This knowledge questionnaire revealed insecurity regarding different important post-transplants aspects among recipients shortly before their discharge from the hospital. Most insecurity was found in the area of lifestyle, indicating a lack of emphasis on this area in the content of patient education. Patients with long dialysis duration pre-transplantation and patients suffering from postoperative complications exhibited significantly poorer levels of knowledge and might require more intensive patient education post transplantation.

The intervention study (paper 3) provided valuable knowledge on how to increase renal recipients' ability to cope with their new situation post-transplant. The tailored patient education program investigated in this study was effective in increasing renal recipients' levels of knowledge concerning important post-transplant aspects and compliance to self-report of graft function. Furthermore, we found that self-efficacy and mental scores of quality of life were higher in the experimental group after 6 months. The program logic model, used for describing the different outcomes of patient education, supported the effects from the patient education intervention investigated in this study (Osborne et al., 2007). This model describes - in the form of an outcome hierarchy - how education for patients with chronic

diseases might affect different levels down an outcome chain, including outcomes on both the individual and societal levels. According to this model, the outcomes investigated in this study are placed at the individual levels' proximal stage (knowledge, compliance) and the intermediate stage (self-efficacy, quality of life).

In the following section, the core research findings will be discussed, followed by methodological considerations.

## **6.1 Effect of patient education**

Patient education for renal recipients is essential for life post-transplant; however, evidence of effective patient education programs among this group of patients is lacking. Although beneficial effects of tailored patient education programs have been documented for patients with chronic illnesses (Burton et al., 2009; Clark et al., 2009; Driscoll et al., 2009; Kim et al., 2004; Noar et al, 2007; Rimer et al., 1999; Van der Meulen et al., 2008), this has not previously been investigated for renal recipients. The testing of this tailored, structured education program for this specific group of patients was therefore of high importance.

### **6.1.1 The effect on knowledge**

Despite the importance of patients' knowledge of post-transplant aspects, little effort has previously been made to describe renal recipients' insights into these areas. Knowledge testing of patients is considered a valuable tool, aimed at identifying factors and interventions that might improve their insights. Thus, the ability to describe this population's knowledge seems important. A review of existing literature did not identify an appropriate, already

available knowledge questionnaire for the patient group. Previous questionnaires have been produced on knowledge to test pediatric kidney recipients (Beck et al., 1980; Fennel et al., 1994), in the specific area of sun protection (Firooz et al., 2007; Mahe et al., 2004; Szepietowski et al., 2005) or in the field of organ transplantation in general (not specifically confined to kidney recipients) (Giacoma et al., 1999; Steinberg et al., 1996). Although different organ recipients might need some of the same knowledge concerning immunosuppressive medication and aspects of lifestyle changes to prevent adverse medication effects, specific knowledge is needed related to each organ. For instance, the signs of rejection, the importance of fluid intake, and the consequences of rejection are specific for renal transplantation. Using questionnaires confined to all organ transplants was therefore not deemed to be appropriate. Yet two knowledge questionnaires were found constructed for adult renal recipients. One of these (Barton & Wirth, 1985) was considered outdated given recent developments within the treatment of renal recipients. Furthermore, the questionnaire used a mix of open-ended and multiple-choice questions, which was not considered appropriate for the analyses planned for the study. The other questionnaire (Johnson & Goldsten, 1993) was also a multiple-choice questionnaire. Although multiple choices is a common method of measuring knowledge, it was considered to be confusing and too challenging for patients in the early post-operative phase to choose between similar alternatives. Given the lack of an appropriate instrument for knowledge testing in adult kidney recipients, it was necessary to develop one in this study (paper 2).

The response alternatives for each item in the current questionnaire were chosen to reveal insecurity among the patients and to reduce the risk of correct answers based on guesswork. As a formative model was used in the current questionnaire, psychometric analysis, factor analysis or estimating Cronbach's alpha was considered irrelevant. Yet, the questionnaire was sensitive to the intervention tested in this study.

Shortly before being discharged from the hospital (5 days post-tx), patients in this study scored 11 out of 19 obtainable correct scores on the knowledge questionnaire (paper 2). The somewhat low score of totally correct answers indicates that, in many areas, the patients did not have certain knowledge about how to cope with the situation post transplantation (paper 2). Although few other studies have measured renal recipients' levels of knowledge, existing studies in the field support this finding. Three studies have investigated renal recipients' knowledge in the specific area of sun protection, concluding that patient education is needed in the field (Firooz et al., 2007; Mahe et al., 2004; Szepietowski et al., 2005). During recent years, there have been considerable improvements within the transplant field in terms of immunosuppressive medication, surgical techniques, and the handling of adverse events. The resulting shorter stay in hospital and the reduced need for frequent follow-up, together with the experienced barriers toward learning in the post-operative phase (Urstad et al., 2012; Wiedehold et al., 2009), might have imposed increased demands on the patients regarding the acquirement of important knowledge. As described by the outcome model of health education (Osborne et al., 2007), patients' knowledge about the disease might be the first step in the outcome chain, impacting other important aspects of life for patients with chronic illness. Thus, focusing on increasing renal recipients' level of knowledge seems relevant.

The patient education intervention in this study increased renal recipients' knowledge significantly in both the short and longer term. An essential question to be asked is whether the observed statistical significant improvement is practically meaningful. For this question, the nature of the knowledge questionnaire and the post-transplant situation should be discussed. In this study, the experimental group on average answered correctly on 1.5 more of the 19 questions. Although this might seem like a small increase, it should be seen in relation to the content of the items in the questionnaire. The questionnaire was not aimed at a difficult level, but was focusing on basic, practical aspects of life post-transplant. Unlike other studies

measuring knowledge concerning post-transplant sun protection only (Firooz et al., 2007; Mahe et al., 2004; Szepietowski et al., 2005), the knowledge questionnaire in this study embraces a wider area of important post-transplant aspects. For instance, the only item concerning sun protection revealed whether patients knew the basic fact that one has to protect the skin from the sun after transplantation. Furthermore, a lack of knowledge in items asking for the importance of immunosuppressive medication to be taken regularly twice a day or if a rapid increase in weight or protein in the urine can indicate a rejection of the graft, might have severe consequences. Thus, much importance was placed on every item, and small improvements in scoring might be of clinical importance. To further investigate this possible impact, outcome measures might include more objective facts, such as renal function (creatinine levels, number of rejection episodes), weight gain, diabetes, or skin cancer rates among the participants. In addition, including outcomes measure described as the distal level of Osborne et al.'s (2007) outcome chain (i.e., acute health care usage, patient's level of lost productivity, mortality) among the participants might provide more persuasive arguments for further testing and implementing of the patient education intervention in this study.

### **6.1.2 Effect on compliance**

Participants in the experimental group conducted significantly more observations in their self-control diary measured 7-8 week post transplantation. Although compliance has been thoroughly investigated in renal recipients, the focus has mainly been on medication compliance and less on signs of rejection; it was recently been reported that only one-fifth on renal recipients write a self-control diary on graft function (Kobus et al., 2011). Self-control is considered important for observing signs of rejection and being able to receive treatment as soon as possible, and the increased levels in these observations in the experimental group

might be of importance. At the Norwegian transplant center, it is recommended that self-control observations start in the early post-operative phase; however, at this stage, frequent blood-tests controls will reveal a rejection at an early stage—before patients are able to observe the clinical signs of rejection. Despite this, patients are recommended to practice self-controls as soon as possible post-transplant in order to hone their skills and establish routines for this upon returning home. Thus, the status of patients' self-reports 7-8 weeks post-tx might be an important indication of patients' understanding and willingness to do what is recommended from health personnel to protect their new graft, and the intervention's effect in this area should therefore be considered as important.

As little previous attention has focused on self-controls of graft function, no gold standard for this outcome is discussed in the literature. However, the registration of all patients' graft observations in the self-control diary should be considered a reliable outcome measure.

Although patients' self-reports of medicating compliance are commonly used and considered to be a key component for assessing compliance, the risk of reporting bias is more present as patients might report more favorable compliance behavior. The copies made of the patients' diaries seem more objective and could be compared to the electronic monitoring pillbox, considered the gold standard for measuring medication compliance (Cramer, 1995; Cramer, Mattson, Prevey, Scheyer, & Quelette, 1989; Cramer & Rosenheck, 1998; De Geest & Vanhaecke, 1999).

There is an ongoing discussion concerning the relation between knowledge and compliance for patients with chronic diseases, and reports from research are split (Bailey & Kodack, 2011; Huff et al., 2011; Moradkhani, Kerwin, Dudley-Brown, & Tabibian, 2011; Nielsen et al., 2010). The extent of this relationship might depend on the context, the patient group, and the severity of non-compliance consequences. For renal recipients, consequences of non-

compliance very rapidly might result in severe consequences . For instance, a rejection process might occur within 48 hours if immunosuppressive medication is not taken as prescribed. Furthermore, patients have hoped and waited for a new kidney and perceive the kidney as a gift for life, which could result in feelings of intense responsibility for the new graft (Buldukoglu et al., 2005; Nilsson et al., 2008). Indications of the connection between knowledge and behavior have also recently been demonstrated in a study of adolescent renal recipients (Freier et al., 2007). In this study, illness-related knowledge and illness-related behavior correlated significantly when measured by a 9-item questionnaire embracing both knowledge of medications and behavior in medication taking. Thus, increasing knowledge seems to be an important factor in increasing compliance for this specific patient group.

### **6.1.3 Effect on self-efficacy and mental quality of life**

The patient education intervention increased patients self-efficacy and mental quality of life. The patient education interventions' impact on patients' lives in this degree provides evidence of a strong intervention. According to the hierarchy of outcomes of patient education described by Osborne et al. (2007), increased quality of life is placed at the top of outcomes affecting patients' at the individual level. Osborne et al. (2007) argued that quality of life is the ultimate anticipated outcome for individuals attending patient education programs. From this perspective, the patient education program might be considered to be of high value.

The effects on increased self-efficacy and mental component of quality were first found after patients returned home. This might be explained by the nature of the intervention aimed at increasing patients' knowledge in important post-transplant aspects. At the second measurement point (7-8 weeks post-transplant), patients were still living in the patient hotel

close to the hospital, attending regular and frequent outpatient controls. In this situation, graft function was frequently monitored, regular physiotherapy-guided training programs were offered, healthy foods were served at every meal, and health personnel were available. It is when finding themselves in a normal home setting after approximately 3 months post-transplant that patients might experience the full benefit of the intervention, as patients will then experience the increased responsibility of their own situations. In patients' own perception, leaving the hospital and retuning home after transplantation is regarded as challenging in order to cope with the new challenges post-transplant (Urstad et al., 2012).

The stressors in managing the complex chronic health situation and the continuous risk of graft rejection are considered to be explanatory factors for renal recipients' physiological status (Karam et al., 2003; Neipp et al., 2006). Measures of quality of life for the patient group reveal that the psychological domain and the general health perception domain are mostly affected among renal recipients (Karam et al., 2003). Renal transplant recipients, even when having a good function of their transplanted organs, seem to be affected by symptoms of distress, anxiety, and depression (Chen et al., 2007; De Geest & Moons, 2000; Gross et al., 2010; Matas et al., 2002; Perez-San-Gregorio et al., 2006). The patient education intervention in this study aimed to meet each patient's unique and concrete educational needs to make them confident in aspects of life post-transplant, which might contribute to reducing some of the feelings of insecurity. Self-efficacy has previously been little investigated in renal recipients. However, Weng and colleagues have measured self-efficacy in renal recipients (Weng et al., 2008; Weng et al., 2010). Their 2010 study reported that renal recipients seem to have acceptable levels of self-efficacy, but participants were not recruited until 6 months (or later) post-tx. Thus, little is known of renal recipients' self-efficacy in the first and possible most vulnerable phase after the transplantation. However, an important result of this study is the connection of self-efficacy and renal recipients' mental status. Self-efficacy was found to



directly affect depressive symptoms and, through self-care behavior, indirectly affect the mental quality of life measured by SF-36 (Weng et al., 2010). In addition, their 2008 study revealed self-efficacy to a powerful and modifiable determinant of depressive symptoms in renal transplant recipients, which supports the importance of this study's intervention effect on self-efficacy for the patient groups.

The intervention did not impact renal recipients' physical quality of life. Maybe in order to be able to observe any possible impact on this aspect of quality of life, one ought to have investigated the effect of the patient education intervention from a longer perspective. Most side effects from the immunosuppressive medications (e.g., skin cancer, weight gain, heart disease or diabetes) occur at a point beyond later than six months (which was the time of last outcome measure in the current study). The patients' increased knowledge concerning lifestyle and important observations in relation to these risk factors might provide beneficial effects in the longer term. This time perspective might be an explanatory factor for the lack of effect on physical quality of life for the patients receiving the patient education intervention.

## **6.2. Methodological considerations**

### **6.2.1 Representativeness of the evidence of patient education for renal recipients (paper 1)**

Existing evidence of patient education for renal recipients was presented by a systematic review including 12 studies. In such reviews, there is always a risk of bias influencing the available pool of evidence (Scholey & Harrison, 2003). The inclusion criteria in this review might represent a certain risk of bias, as only published studies written in English were included. Publication bias has been defined as the tendency on the part of investigators to

submit or - on the part of the reviewers and editors - to accept manuscripts based on the direction or strength of the study findings (Scholey & Harrison, 2003). In other words, studies reporting positive effects of patient education might be overrepresented in the sample. Furthermore, the choice of including only English language studies might cause bias as authors are more likely to report in an international, English-language journal if results are positive whereas negative findings to a greater extent are published in local non-English journals (Egger et al., 1997). As 80% of the studies reported positive effects of their patient education intervention, this might indicate an overrepresentation of studies with positive results in the sample. Nevertheless, one should conclude that the sample of studies is representative due to the available pool of evidence existing in relevant research databases when the searches were performed.

The quality appraisal used for reporting bias within each study did have some limitations in relation to the nature of the interventions under the scope of this review. Blinding of participant or provider was one of the 7 quality criteria. Blinding is however not practically possible for the current type of intervention. Consequently, included studies did not have the possibility of meeting more than six criteria. However, the majority of the studies were categorized in the group of high-risk bias; the increase in 1 point of score would not have affected the conclusion of the lack of existing evidence for effective patient education interventions for renal recipients.

### **6.2.2 Representativeness of sample of renal recipients (papers 2 and 3)**

This study excluded patients who were not able to speak, understand, and read Norwegian. Translating and validating questionnaires into different unknown languages seem practically

complicated. The group of foreign language-speaking renal recipients was therefore not represented in this sample. Perception of illness varies by culture, and these individual preferences can affect the approaches to healthcare, influence how people seek health and how they behave toward healthcare providers, and influence perceptions on how illness might be cured or treated as well as who should be involved in the process (Cross, Barzon, Dennis, & Isaacs, 1989). This excluded group of patients might be significantly different from the general renal transplant population concerning effect of the patient education intervention, reception to information provided, and their willingness to use it. Although no estimate is done for the size of this group in the renal transplant population, one might assume that it is increasing due to the increase of foreign language-speaking patients in Norwegian hospitals in general. This specific group of renal recipients should therefore be taken into consideration when implementing the patient education intervention in practice.

Another weakness for external validity of the sample seems to be caused by the vulnerability in the recruiting situation in terms of both the patients and the nursing staff recruiting patients. Although personnel were informed and regularly reminded about the project, busy days at the ward and substitute nursing staff made it challenging to provide all eligible patients with information about the patient education project. Furthermore, as many as 31% of the asked, eligible patients refused to participate. Emotional and physical strains in relation to the transplantation (Urstad et al., 2012) might make it hard to consider participation in the project in the early postoperative phase. Patients with deceased donors are unaware of the time for the transplantation until a graft is available. These patients might experience even more stress during the early post-operative situation, which could explain the somewhat higher rate of participants receiving kidneys from living donors in the sample (50% of the study population compared to 40% in Norway during recent years) (Witczak et al., 2009).

An important question to be asked is whether patients refusing to participate did not believe that patient education was important for them. This might result in a sample that is more aware of their situation and their need for patient education in managing their lives post transplantation. Motivation is an essential factor in the process of learning (Redman, 2007), and this factor might be overrepresented in the sample. Taking these limitations in consideration, caution should be used when drawing conclusions regarding all Norwegian transplant recipients, and in particular when it comes to the group of foreign language speaking recipients.

The larger number of male transplant recipients in the study sample (69%) is in accordance with the reported number of male patients suffering from CKD as 67.1% of patients in need of replacement therapy in Norway in 2010 were male (Norwegian Renal Registry, 2010). Furthermore, the mean age of patients receiving kidney transplants from 1989 to 2007 was 51.2 (Witczak et al., 2009), similar to the baseline mean age in the current study population.

At the third measurement point in the RCT study (paper 3), the dropout rate from baseline was 25%. According to guidelines for assessing methodological quality of studies, dropout rates exceeding 20% could cause bias (Maxwell et al., 2006). Both the somewhat high dropout rate and the unknown reasons for dropouts at this measurement point should be considered limitations to the representativeness of the sample. The fact that patients are at an increased risk of complications related to the surgery, infections, and rejection of the graft during the first post-operative months (Djamali et al., 2006) might provide explanatory factors for dropout. In addition, at the third measurement point, the questionnaires were sent by post. Increased rates of dropouts when using postal questionnaire are a widely experienced problem (Polit & Beck, 2004). However, no significant differences in the study sample in terms of gender, age, educational level, and clinical characteristics were found between the second and

third measurement points. Thus, one should conclude that the representativeness of the sample at both measure points is strong enough to provide us with valuable insights in renal recipients' levels of knowledge 5 days post-transplant and the effect of the patient education intervention.

### **6.2.3 The randomized controlled design (paper 3)**

To test the effect of the patient education intervention, we used a randomized controlled design. Such a design is often referred to as the gold standard. Yet many challenges occur when testing a complex intervention in a randomized controlled trial. The CONSORT statement emphasizes the importance of complete transparency from authors in all stages when reporting a randomized controlled trial ([www.consort-statement](http://www.consort-statement.org)). This statement provides a checklist intended to improve reporting to enable readers to understand the design and assess the validity and applicability of its results.

When considering the quality of the RCT report in the current study based on this checklist, 19 items were found to be met out of 22 possible. The RCT report lacks sufficient information regarding concealment of allocation, blinding status, and information on who was generating the concealment and enrolling participants. However, the CONSORT statement does not address all specific issues that apply to non-pharmacologic trials, such as the intervention in this study (Bhandari, Guyatt, Lochner, & Sprauge, 2002; Boutron, Tubach, Giraudeau, & Ravaud, 2003). For instance, blinding is more difficult to achieve (Boutron, Tubach, Giraudeau, & Ravaud, 2004). Furthermore, interventions such as patient education are more difficult to describe, standardize, reproduce, and administer consistently to all patients. In order to address specific issues related to such interventions, an extension for these guidelines

has been developed (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). According to these extensions, information concerning how the intervention provider adhered to protocol was missing in the RCT report. In the further discussion, these missing items due to the CONSORT statement and the extension for non-pharmacological treatment areas will be clarified.

In the current study, it was not possible to blind either intervention provider or participants. The PhD student of this thesis played multiple roles as the intervention provider and the primary investigator responsible for the different aspects of the research. Such multiple roles might have increased the risk of experimenter bias, occurring when the researcher inadvertently affects the outcome by non-consciously behaving differently to members of control and experimental groups (Polit & Beck, 2006). It was originally planned that nurses working at the outpatient clinic would be responsible for providing the intervention, but short before the data collection was planned to start, it turned out that resources for this work was lacking. The PhD student therefore had to deliver the intervention instead. However, the PhD student had 10 years of experience from the transplant clinic and was therefore competent for providing the intervention. An advantage of this decision might be that, if nurses at the outpatient clinic had delivered the intervention, it would have been difficult to avoid intervention nurses from treating patients from both the experimental and control groups. There would also be a risk for those elements of the tailored intervention inadvertently being provided to patients in the control group. The primary investigator did not work at the hospital during the research period and did not take part in the general care of the participants. The contact with the control group was limited to two meeting points: at baseline (5 days post-tx) and at the second measurement point (7-8 weeks post-tx).

Concerning the patients' awareness of group assignment, it has been reported that individuals

might change their behavior due to the attention they are receiving from researchers rather than because of any manipulation of independent variables. Many mechanisms, such as anxiety reduction, expectancy, spontaneous improvements, additional care and attention given to research participants, and social attention have been considered as contributing to this change. (Mattocks & Horowitz, 2000; McCarney et al., 2000). To reduce this variety of factors and biases that might influence outcomes in a trial, a usual care control group might not be sufficient. Including an attention control group as a part of the design might help clarify to which extent the attention from the intervention nurse contributed to the experimental group's increased well-being. The lack of such a group in the trial should therefore be considered a limitation. One benefit, though, is that the patients in the control groups received frequent follow-ups and stayed in close contact with health personnel during the intervention period. This might have reduced the differences between the groups. In addition, the increased mental summary scores of quality of life in the experimental group were first found at the third measurement (6 months post-tx), after patients returned home, not shortly after the intervention. This supports the view that mental summary scores on quality of life and self-efficacy are affected by renal recipients' increased insight in important aspects of their health conditions.

Except for patients living close to the transplant center, renal recipients stayed at the patient hotel situated close to the hospital for the first 10 weeks after transplantation. As patients from both the experimental and control groups stayed together in the same hotel, the risk of intervention diffusion was present. The possibility of moving one of the groups was considered, but found to be unethical because of the extra strain on the patients due to a longer distance to the hospital. However, the intervention was tailored to each patient's specific needs and life situation; therefore, the relevance of the intervention was closely tied to each individual patient.

In this trial, block randomization (balanced) was used. This type of randomization strives for comparison of the groups of about the same size throughout the trial (Schulz & Grimes, 2002). This was important for balancing the workload of the intervention provider. In addition, a balanced assignment would ensure that trends in recruiting were balanced through the study, which in this setting could be addressed to differences in the workload at the outpatient clinic, thereby impacting the care given to patients at the regular controls. Each block consisted of 20 assignments; using sealed envelopes ensured concealment. An impartial person mixed the blocks each time. When block size remains fixed throughout the trial, as in this current randomization procedure, it is thought to be possible to predict group assignments when all 10 envelopes have been drawn for one of the groups. To avoid this risk of selection bias, it is recommended to use randomly varied block sizes (Schulz & Grimes, 2002). Larger block sizes rather than smaller block sizes helps preserve unpredictability, and the number of block sizes (20) used in this trial is considered a large size, decreasing the risk of selection bias (Schulz & Grimes, 2002).

#### **6.2.4 Statistical validity**

Statistical validity refers to whether a study is able to draw conclusions that are in agreement with statistical and scientific laws. The two main threats to statistical validity are described here: low statistical power and inappropriate use of statistical techniques (Lund, 1996).

In the RCT in this study (paper 3), the power calculation was based on the secondary outcome (quality of life) as little previous research has been done on primary outcome (patients' knowledge level). The sample size needed was determined to be 128—64 in each group—in order to have the ability to draw correct conclusions and avoid the accepting of a wrong null



hypothesis (Type 2 error). In many clinical trials, sufficiently large samples are not achieved, and the risk of type 2 error may be considerable (Moher, Dullberg, & Wells, 1994). In the current study, we were able to obtain the sample size needed within the scheduled recruiting time, estimated at being 159 patients, taking probable dropouts into consideration. At the second measurement point, the 139 remaining participants were sufficient for the sample size required. However, at the third measurement point, the sample size of 120 was somewhat below the estimated necessary number of 128 participants, although we were still able to find significant differences between the groups in terms of both primary and secondary outcomes at the chosen significance level (0.05).

Furthermore, in the statistical analyses of differences between the groups, we used ANCOVA [SPSS General Linear Models (GLM), Unianova], which is a regression analysis (OLS), adjusting for baseline scores. By controlling for baseline measures in the randomized controlled trial, we were able to adjust for imbalances that might have accidentally occurred in the randomization procedure. GLM was conducted for each outcome, except for compliance, for which no baseline data existed.

As gender, education level, age, and duration of dialysis might impact how the patient education intervention affected patients, it seemed important to evaluate whether the effect of the intervention was confounded by an uneven distribution across the intervention and control groups for various sociodemographic and clinical variables. ANCOVAs were therefore performed, adjusting for the effect of these variables.

### 6.2.5 The patient education intervention—A complex intervention (paper 3)

The tailored, patient education intervention is a complex intervention containing several interacting components. Because of the methodological and practical challenges in testing such interventions, their effectiveness is often uncertain (Craig et al., 2008). Craig et al. (2008) highlighted that developing and evaluating complex interventions should be seen through different dynamic, interacting phases. In addition to the evaluation of the intervention, the process of development and implementation are given due weight in this framework, paying attention to the context of the intervention in order to be better able to consider the practical relevance of a complex intervention (Craig et al., 2008).

According to this framework, a key question in evaluating a complex intervention relates to the practical effectiveness—namely, whether the intervention works when implemented in everyday practice (Craig et al., 2008). It is important that the evaluation is intervention-specific, not only outcome-specific, and it is emphasized that an intervention cannot be evaluated without reference to the costs and inconvenience. Seen from the patients' perspective, one might assume that—in addition to the time spent on the intervention—the patient education program must be considered an intervention causing minimal risk of side effects. One could therefore argue that small effects would also be worth perceiving from the patients' view. Regarding economic costs, the implementation of the patient education intervention might require some extra economic resources. However, by providing renal recipients with the patient education intervention while attending the outpatient clinic, one might be able to take some of the work burden from nurses at the transplant ward, where standard treatment is that patients are provided with all necessary knowledge for post-transplant life within the first 7 days post-tx.

Another important concern in terms of the practical importance of the intervention is the patient's own perception of the intervention. User involvement and patients' perceptions about whether the effects of treatment are large enough to make the costs, inconvenience, or harm worthwhile should be valued (Craig et al., 2008; Ferreira & Herbert, 2008). In this study, the participants' evaluations of the patient education intervention as useful both shortly after the intervention and 6 months after the transplantation should contribute to the evaluation of the intervention as practically important.

## **7.0 GENERAL CONCLUSION**

The main aim of this thesis was to develop knowledge concerning patient education in the context of kidney transplantation. The three specific objectives for the various papers were to define existing evidence of effective patient education for the patient group, develop an instrument measuring renal recipients' knowledge levels, and investigate the effect of a tailored patient education intervention.

A systematic review revealed limited evidence for the effectiveness of patient education interventions for renal transplant recipients. Few studies have previously focused on testing educational intervention for renal recipients, and existing studies seem overall difficult to rely on because of poor methodological quality. This situation indicates the need for more research in the area with stronger designs.

The lack of an appropriate instrument for measuring renal recipients' knowledge made it necessary to develop such an instrument for this study. By using this instrument in a cross-sectional design, it was revealed that renal recipients seem to be insecure regarding some of the important post-transplant aspects shortly before being discharged from the hospital. Most

uncertainty seems to relate to issues concerning lifestyle, indicating the possibility of a lack of sufficient emphasis on this area in the content of patient education provided to the patients at the ward.

By investigating a tailored patient education intervention, we have produced valuable knowledge on how renal recipients can be provided with effective patient education. By utilizing an RCT design, the structured, tailored patient education intervention tested in this study proved to increase patients' insights in post-transplant aspects and their compliance to graft observation. In the longer term, beneficial effects were also found in terms of patients' self-efficacy and mental quality of life. As previous research is limited in the area of patient education for renal recipients, the results from this study might provide valuable guidance for clinical practice and for future research.

### **7.1 Suggestions for future research**

In the current intervention study, the last outcome measure was conducted 6 months post-tx. However, intervention effects beyond this measurement point would be of interest. It is recommended that more long-term follow-up be attempted as it seems essential to determine whether changes persist over time (Craig et al., 2008). It is further recommended that, if an intervention is translated into routine practice, monitoring be undertaken to detect adverse effects or long-term outcomes that could not be observed directly in the original evaluation or to assess whether the effects observed in the study are replicated in routine practice (Craig et al., 2008).

When investigating these long-term effects, it might also be beneficial to include other, more objective outcomes. Graft function, diabetes, weight change, and infections could be

interesting to investigate in relation to the patient education intervention. According to Osborne's outcome chain of health education, patient education might also impact on society outcomes (Osborne et al., 2007). Acute healthcare usage, patients' level of lost productivity, and mortality might be important long-term outcome measures in this perspective.

It is also recommended that a thorough cost-evaluation of interventions be undertaken to ensure that the costs of the study are justified by the potential benefit of the evidence it will generate (Craig et al., 2008). Quality-adjusted life-year (QALY) is a parameter that combines length of life and health into a single index number (Prieto & Sacrsitan, 2003). This parameter can be used to compare the cost-effectiveness of any treatment. The use of SF-12 in measuring health-related quality of life in the current study provides possibilities of an economic evaluation as QALYs can be generated from SF-12 measures. An economic evaluation of the patient education intervention would therefore be an important focus for future research. The educational impact on different levels, such as personal and society/economics, might provide more persuasive arguments for testing and implementing effective educational interventions for renal recipients.

## **7.2 Possible implications for clinical practice**

It is important to transform the findings into useful and practical intervention strategies for clinical practice when possible (Kralik, Paterson, & Coates, 2010). The findings in the current study might provide healthcare practitioners with valuable insights concerning patient education for the group of renal transplant recipients. The indications of patients' lack of insights in post-transplant aspects might indicate a need for increased healthcare focus in this field of patient education for this population.

The beneficial effects of the tailored, structured patient education intervention tested in this study might provide health personnel with a concrete, effective program for use in practice. It seems important that the education content implement a holistic approach to life post-transplant—not only focusing on medication adherence, but also including aspects of lifestyle (e.g., activity, diet, sun protection) and signs of graft rejection. The measurement of patients' baseline knowledge prior to the patient education program gives possibilities of tailoring the education content according to individual needs. However, due to new experiences and questions when practicing the new knowledge, learning areas should continuously be revealed through one-to-one sessions.

Because of the urgent need for knowledge in some aspects of the education content (e.g., medication intake), it seems necessary for the education program to start in the early postoperative phase. However, other aspects of the education content are more important in the longer term; thus, it seems beneficial that the education continue over a longer period as life becomes closer to a normal “home setting.” Furthermore, due to subgroup analyses conducted in this study, it seems important to focus special attention on renal recipients with a long dialysis history pre-transplantation because they seem more vulnerable in terms of acquiring new knowledge after the transplant. This group might therefore be prioritized, as they seem to benefit more from the patient education.

This study included only renal transplant recipients. Despite the fact that signs of rejection vary among the different organ transplants, knowledge about the immunosuppressive regimen and lifestyle changes might to some degree be comparable to heart, lung, and liver transplants. Experiences of the transplantation as a “turning point in life,” providing barriers to learning in the postoperative phase (Urstad et al., 2012), might create the same need for patient education throughout the postoperative phase for other organ transplant recipients as

well. As dialysis is not an option for other organ transplant candidates, the pressure from being on a waiting list might be even more intense. Findings in the current study might therefore also be useful for health practitioners working with other groups of organ transplant recipients. However, the applicability of the structure of the patient education intervention program in other transplant centers and for other organ transplants would depend on their post-tx follow-up practices for transplant recipients. Still, the principles of the intervention regarding tailoring, practical skill training, and the time perspective of the education might be transferable to both renal and other transplant recipients in other transplant centers.

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# APPENDIX

## Quality assessment

### **Random generation of allocation**

○MET: Resulting sequences are unpredictable (explicitly stated use of either computer-generated random numbers, table of random numbers by drawing lots or envelopes, coin tossing, shuffling cards or throwing dice).

○UNCLEAR: Vague statement that the study was randomised but not describing the generation of the allocation sequence.

○NOT MET: Explicit description of inadequate generation of sequence (i.e. using case record numbers, alternation, date of admission, date of birth) or clear that allocation concealment was not used.

### **Concealment of allocation**

○MET: Indicates adequate concealment of the allocation (for example, by telephone randomization or use of consecutively numbered, sealed, opaque envelopes).

○UNCLEAR: Indicates uncertainty about whether the allocation was adequately

○NOT MET: Indicates that the allocation was definitely not adequately concealed (for example, open random number lists or quasi-randomisation such as alternate days, odd/even date of birth. Or hospital number).

### **Co-intervention avoided or comparable**

○MET: interventions other than the intervention of interest avoided, controlled or used similarly across r:omparison groups

○UNCLEAR: use of interventions other than of interest not reported and cannot be verified by contacting the investigators

○NOT MET: dissimilar use of interventions other than of interest across comparison groups

### **Losses to follow-up**

○MET: losses to follow up less than 20% and equally distributed between comparison groups

○UNCLEAR: losses to follow up not reported

○NOT MET: losses to follow up greater than 20%

### **Intention to treat**

○MET: intention to treat analysis performed or possible with data provided

○UNCLEAR: intention to treat not reported

○NOT MET: exclusions not reported and cannot be verified by contacting the investigators

### **Outcome assessment**

○MET: assessor unaware of the assigned treatment when collecting outcome measures

○UNCLEAR: blinding of assessor not reported and cannot be verified by contacting investigators

○NOT MET: assessor aware of the assigned treatment when collecting outcome measures

### **Blinding of provider or patient:**

○MET: The patient or the provider was blinded for the intervention. We will note if one or both.

○UNCLEAR: Blinding not reported

○NOT MET: The patient and the provider were not blinded for the intervention.



## KUNNSKAPSPØRSMÅL

Vurder i hvilken grad du er enig eller uenig i følgende utsagn. Noen av utsagnene er riktige og noen er feil. Sett ring rundt det tallet som best illustrerer ditt svar.

1. Hvis jeg slutter med de immunhemmende medisinene, vil nyren slutte å fungere

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

2. Det er ikke så nøye om ikke de immundempende medisinene tas både morgen og kveld, så lenge totaldosen for dagen tas.

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

3. Det er viktig å drikke minst to liter til dagen også etter at jeg er utskrevet fra sykehuset.

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

4. Dersom jeg kaster opp medisinene, må jeg kontakte lege

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

5. Jeg bør ikke drikke grapefruktjuce etter transplantasjonen

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

6. Avstøtning vil si at kroppens immunforsvar forsøker å angripe nyren

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

7. Dersom jeg får avstøtning, mister jeg nyren.

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

8. Dersom urinstix gir positivt utslag på protein, kan dette være tegn på avstøtning.

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

9. Rask økning i vekt kan være tegn på avstøtning

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

10. Det er lite jeg kan gjøre for å forebygge medisinenes bivirkninger

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

11. Etter nyretransplantasjonen er immunforsvaret mitt så nedsatt at jeg ikke kan ta bussen eller annen offentlig transport

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

12. Dersom urinstix viser 2+ på glucose, kan dette bety at jeg har fått sukkersyke/diabetes

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

13. Jeg får dårlig matlyst av medisinene og må spise mat med høyt kalori-innhold

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

14. Etter transplantasjonen må jeg være påpasselig med å beskytte meg mot solen

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

15. Etter at jeg er skrevet ut av avdelingen, bør jeg være forsiktig med å ta smertestillende medisiner

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

16. Det er viktig å ta det med ro og ikke trene det første året etter at man er transplantert

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

17. Det er vanlig å oppleve endringer i humøret den første tiden etter transplantasjonen

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

18. Jeg har ikke mulighet til å bli transplantert mer enn en gang.

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig

19. Nyreforeningen kan være en ressurs for meg også nå etter at jeg er utskrevet fra sykehuset

1	2	3	4	5
Helt uenig	Ganske uenig	Verken enig eller uenig	Ganske enig	Helt enig





## **Erratum**

Reference Mandakini & Patel, 1998 in article 1 is not correct. The correct reference is:  
Patel M.G (1998). The effect of dietary interventions on weight gains after renal transplantation. *Journal of Renal Nutrition*, 8 (3), 137-141.

Reference Higgins and Greens, 2011 in article 1 is not correct. The correct reference is:  
Higgins J.P.T., Green S. E. (2005). *Cochrane handbook for systematic reviews of interventions* (Version 4.2.5) (updated May 2005) In: The Cochrane Library, Issue 3, Chichester, UK: John Wiley & Sons

Correction of table 3 in article 3: Correct numbers of participants at baseline in experimental group is 77 (not 78) and control group 82 (not 81).