

# Life after stoma creation

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## PAPERS INCLUDED IN THE THESIS

1. Danielsen AK, Soerensen EE, Burcharth K, Rosenberg J. Focus group interview: Impact of a temporary stoma on patients everyday-lives: feelings of uncertainty while waiting for closure of the stoma. *Journal of Clinical Nursing* 2012: in press.
2. Danielsen AK, Soerensen EE, Burcharth K, Rosenberg J. Learning to live with a Permanent Intestinal Ostomy: Impact on everyday life and Educational Needs. *Journal of Wound, Ostomy and Continence Nursing* 2012: in press.
3. Danielsen AK, Burcharth J, Rosenberg J. Spouses of patients with a stoma lack information and support and are restricted in their social and sexual life: a systematic review. *International Journal of Colorectal Diseases* 2012: in press.
4. Danielsen AK, Burcharth J, Rosenberg J. Patient education has a positive effect in patients with a stoma – a systematic review. *Colorectal Disease* 2012: in press.
5. Danielsen AK, Rosenberg J. Health related quality of life increases when patients with a stoma attend patient education – a case control study. Submitted.
6. Danielsen AK, Rosenberg J. Decreased costs with patient education after stoma creation. *Danish Medical Journal* 2012: in press.

## BACKGROUND

### Stoma creation

Stoma creation is a surgical operation where the surgeon makes an artificial opening on the abdomen from where the bowel is taken out. It is a radical treatment with permanent physical signs of bodily change (1). In general, it leads to loss of a central and personal physical function, as well as an alteration in the bodily design.

In Denmark, there is no central registry of either incidence of stoma creation per year or prevalence of persons living with a stoma. Furthermore, we do not have data on demographic variables in persons who have had a stoma created, nor do we have

any nation-wide data on reasons for stoma creation. However, we do have local data from the Capital Region of Denmark, suggesting an incidence rate of 4000 stoma creations per year in Denmark, and a national prevalence of persons living with a stoma being 10000 and 12000 (2).

There are different disease-related reasons for construction of a stoma in the gastrointestinal tract. These are primarily cancer, inflammatory bowel disease and traumas, where the treatment or the palliation of the patient leads to a need to divert fecal flow. Furthermore, the enterostoma may be created in the small intestine or the colon leading to an ileostomy or a colostomy, respectively. Additionally, the enterostoma may be permanent or temporary, and both types may be constructed in the small intestine as well as the colon. Thus, there is no unequivocal picture of the circumstances leading to creation of a stoma, and as there are different kinds of stomas the concept may seem unclear. Moreover, living with a stoma is not a uniform condition, as the adaptation to living with a stoma is affected by several different factors (3). It is questioned whether and how these factors may affect the individual person, covering amongst many: late and early complications (4,5) related to stoma creation, stoma type (6), gender (7), age (8), underlying disease (9,10), personality (11), religious creed (12), occupational habit (13), and marital status (14). Some of these factors are stabilizing forces and some of them may lead to different problems, such as; bandaging, dehydration, sexual problems, skin problems, development of hernia or bulging of the stoma (15), negative feelings related to change in body image. All these problems may have a harmful effect on the adaptation to living with a stoma and on health related quality of life. Furthermore, the creation of a stoma may also be surrounded by positive feelings as it is part of a lifesaving or relieving treatment (16). In addition, the importance of the stoma may be placed in the background by other adjacent processes, for instance, parenteral nutrition (17), complications (18), fecal incontinence (19) and cancer disease (20). However, the physical changes do seem to have significance to the individual, both emotionally, socially and psychologically (3).

In general, living with a stoma for a longer or shorter period may affect the individual, and adaptation to living with a stoma may be improved by different interventions. As such, it was obvious for us that the exploration of methods that would enhance the adaptation to living with a stoma had not been scrutinized sufficiently during the past years. Therefore, we wanted to examine, interpret and understand how stoma creation affects persons. In addition, we were impelled to explore, assess and evaluate how the establishment of a specific patient education program aimed at rehabilitation and adaptation to a life with a stoma would affect health related quality of life of the participants.

For many years, specialist nurses within the field of stoma care have educated and guided their patients without having focused on a research-based exploration of the effects of their interventions. With this study, we hoped to be able to gain results that could inform health professionals, and be applied in the clinical setting.

## PURPOSE

The overall purpose of this ph.d.project was to create new knowledge and understanding related to living with a stoma and the process of learning how to live with the stoma. Furthermore, to explore methods of how to intervene with focus on establishing and testing a patient education program lead by stoma therapists from the Department of Surgery, Herlev Hospital. The project was based on 5 studies resulting in 6 papers, and the specific objectives of the project were:

- To explore the experiences related to living with a temporary stoma, and the recommendations for patient education aimed at temporary adaptation to life with a stoma (paper 1).
- To explore the experiences related to living with a permanent stoma, and the recommendations for patient education aimed at adaptation to life with a stoma (paper 2).
- To review the literature exploring and describing how stoma creation affects spouses or near relatives of a patient with a stoma (paper 3).
- To review the literature exploring the effect of patient education related to patients with a stoma (paper 4).
- To explore the effect on health related quality of life, when establishing a patient education program aimed at patients with a stoma (paper 5). Furthermore, to assess the health economic effects when establishing a patient education program aimed at patients with a stoma (paper 6).

## SPECIFIC APPROACH

The specific approach in the thesis is the description and discussion of central themes related to living with a stoma, and to educational processes connected with it. Methodologically, the project is implemented as a mixed methods study in which qualitative interview studies and two systematic literature review identified interventions, which were subsequently tested in a clinical case/control study. Finally the case/control study was made subject to an economic analysis.

First, the conceptual framework of the thesis is described with the aim of presenting the different perspectives and methodologies of the project. This will not be an exhaustive unfolding of the differences in paradigms, and is to be viewed as a way of unveiling how the thesis is organized.

In order to understand how the patient with a stoma is met by the health care sector in Denmark, the specialist stoma therapist and the patients' general pathway is depicted. Moreover, the relevancy of some concepts and theories: health related quality of life, patient education and the underlying educational assumptions and theories are presented, and tied to the patient with a stoma.

After a short presentation of the included papers, and a more extensive discussion of strengths and limitations related to each paper, the thesis moves on to discussing the following themes: Educational strategies for patient education programs aimed at patients with a stoma, health economic assessments related to clinical research, patient reported outcome and the assessment of health related quality of life.

Finally, the thesis concludes on the specific objectives and suggests implications for practice and future research.

## CONCEPTUAL FRAMEWORK

The scientific approach to the design of this ph.d.project is described in brief in the following section. The thesis is based on a mixed methods approach (21), and concentrates on patients with a stoma as well as concepts of health related quality of life and patient education. The literature search was directed by these concepts and they have formed the theoretical framework for the studies.

The research design and use of mixed methods approach was applied as a study design that was fixed (22), and the collection and analysis of qualitative data was followed by the collection and analysis of quantitative data (23). The objectives when using different scientific research methods were to provide power to the study, and to make up for the limitations of both quantitative and qualitative research (24,25). The strategy was first to collect and analyze the qualitative data, followed by the collection and analysis of quantitative data.

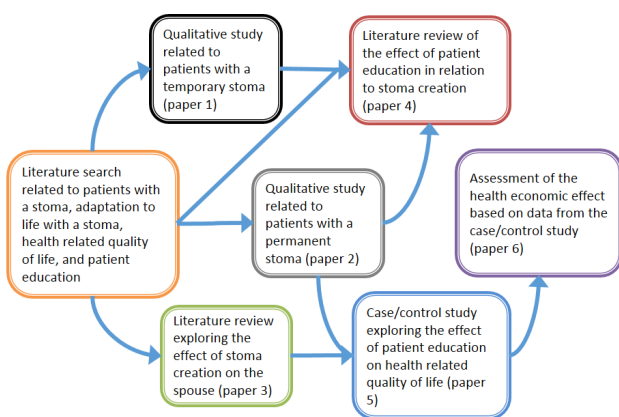
The initial literature search formed a basis for the planning and description of the studies in the ph.d.project. It was comprehensive and reflected the open and explorative approach of the project (see figure 1 on the following page).

The qualitative studies were a means of exploring how stoma creation affected patients with a stoma and to elicit their recommendations for patient education (paper 1+2). We conducted focus group interviews with a phenomenological and hermeneutic approach, and we analyzed the interviews according to qualitative content analysis. On the basis of our initial literature search and on the interviews, we reviewed the literature systematically in order to explore the evidence related to how spouses were affected by the stoma creation. In this manner, we did an integrative systematic review and included both qualitative and quantitative studies (paper 3). Additionally, we systematically reviewed the literature in order to identify evidence on the effect of patient education as there seems to be a large quantity of studies describing the author's personal experiences and preferences. The search was aimed at including both quantitative and qualitative results, but eventually only included quantitative studies (paper 4). The case/control study was planned on the basis of the interviews, on the opening literature search and the systematic review, and compared the impact of a patient education program on health related quality of life (paper 5) and costs (paper 6).

The progress and the differences between the studies are presented in the figure 1.

### *The enterostoma therapist (ET) and the patient's pathway*

Since the education of the first ET in the 1960's the teaching and guiding of patients related to handling the stoma has been performed by registered nurses, who have specialized training in this special area of the surgical treatment and care (26). Their primary role is informing and preparing patients and relatives pre-operatively, and in addition they stay in contact with patients after surgery in the rehabilitation course (27,28). The current approach to colostomy care, which has changed little over the years, is based on the patients' need to be self-sufficient and being in personal control. The aim is to let the person at risk of living a restricted life due to social, physical or mental restricting conditions have the possibility to live a self-determining and coherent life. Some of the central issues are training by specialist nurses in the appropriate use of stoma appliances and offering advice on dietary behaviors related to bowel control. So far, there has been only limited evaluation of the impact the care delivered by ETs, but important improvements have been reported in the few studies which have evaluated it.



**Figure 1**  
*Different methodologies and methods applied in the ph.d. project. Orange box: the initial literature search. Black box: paper 1. Grey box: paper 2. Green box: paper 3. Red box: paper 4. Blue box: paper 5. Purple box: paper 6.*

The information and guidance of patients admitted for creation of a stoma often starts preoperatively in Denmark. All major hospitals in Denmark have established an out-patient-clinic for the population (29). ETs in Denmark are often trained in specialized stoma care on a certificate level, and some may even be educated at a master's level. There are no uniform requirements regarding education and training, but as the ETs in Denmark are few in numbers they may in general have equal qualifications and competencies. Additionally, the professional association for ETs in Denmark (30) organizes conferences and meetings in order provide network and professional sparring. In general, ETs are employed in specialized hospitals in Denmark, and the out-patient clinic functions as a connection between the hospital course and the following course after leaving hospital. However, the primary sector in Denmark does also have a part of the responsibility for the rehabilitation related to disease prevention. So, ETs may in the future be placed in the communities.

The patient having a stoma is offered visits before surgery (if not having acute surgery), and during the hospital stay. These visits during hospital stay are often restricted to clinical situations where the nurses in the surgical department request the specialized assistance. After leaving hospital patients are offered visits in the out-patient-clinic and the number of visits varies throughout the country. Often patients attend the clinic for a year after stoma creation and some even longer. Furthermore, patients have the offer of telephone support from the enterostoma nurses in the out-patient clinic.

A prospective study exploring the effects on health related quality of life when establishing an out-patient-clinic for patients with a stoma, showed an increase in health related quality of life in patients receiving information and guidance by an ET (31). The results probably reflect that patients in the control group received no intervention by an ET, as the control group was found retrospectively. A study reviewing the literature in part with a focus on the impact of the ET did not find evidence showing the influence on health related quality of life of the patients (32). Similar results have been found in a study questioning patients 10 weeks and 1 year after surgery (33). Other studies have pointed at a beneficial effect of the ET related to health related quality of life (34), and that patients opt for the possibility of guidance, support and

information by the ET (35). Nevertheless, although patients in Denmark in general have a broad access to stoma care they still seem to be marked by psychosocial distress and a tendency of depressive symptoms (36).

### **Patient education and health education**

During the past 20 years there has been a dramatic increase in public, private and professional interest in preventing disability and death through lifestyle changes and participation in screening programmes (37). Much of this interest in health promotion and disease prevention has been stimulated by the epidemiological transition from infectious to chronic diseases as leading causes of death, the ageing of the population, rapidly escalating healthcare costs, and data linking individual behaviors to increased risk of morbidity and mortality (38). Increased interest in behavioral determinants of health and disease has furthermore drawn attention to the importance of health behavior change and resulted in numerous training programs in public and commercial service programs (39).

The point of view, that the health education in various clinical settings is an instrument of change, has been renewed and invigorated during the past years (40). The central concern of health promotion and health education is health behavior (41). As such, the patient with a stoma would be expected to take responsibility for handling the stoma, for using the correct bandage, and for the general adaptation process aimed at living with a stoma.

Programmes aimed at patient education are typically targeted either at a generic level or a disease specific level. The generic programmes are focused on themes that may be common for patients across specific diagnoses. In these programmes the main objective is for the participant to achieve competencies in handling the problems and issues related to chronic disease or conditions. This could for instance be issues like nutrition, exercise, and smoking cessation (42).

Whereas the generic programmes focus on general and non-specific symptoms or conditions, the disease specific programs are aimed at patients with certain diseases and conditions. The programs have some common objectives such as obtaining competencies related to self-care and mastery. However, when attending a disease specific program the objective is strictly focused on the exact condition, and the correct treatment or prevention of further development of it (42).

A randomized controlled study focusing on patient education aimed at patients with arthritis concluded that a disease oriented program may have advantages over a generic program (43). In relation to stoma creation it would seem natural to include disease specific themes, covering different issues related to the stoma and the adaptation process. Moreover, it seems that disease specific health education is emerging in several clinical settings including hospitals and the primary care sector (44).

### **Patient education related to living with a stoma**

In this thesis the background for developing and establishing a patient educational program was based on evidence, on the relation between patient education and health related quality of life experiences of patients with a stoma explored in the primary study in this thesis, and presented later. and experiences in the expert group of enterostoma therapists explored in intensive and dynamic dialogues when establishing the program.

Self-management programs may have a significant and positive impact on patient outcome, health behavior, and health promotion (45,46). These results point at deficiencies in the tradi-

tional views and perspectives on education and patient involvement (47). It has been suggested that some patient education programmes within the surgical setting have not focused sufficiently on the need of the individual patient, or on how the needs should be met (48). Effective teaching strategies should be based on solid knowledge on educational interventions and better results may be reached by involving lay-teachers as well as the recognition of the immense effect when organizing education in peer groups (49,50). Furthermore, the programmes should be designed to include psycho-social problems related to the specific condition, shorter lectures with relevant knowledge, as well as applying methods activating different ways to learn in order to enhance the outcome (51). Therefore, it seemed obvious that the development of a patient education program should start by exploring the potential participants' views and recommendations.

#### **Health related quality of life and the patient with a stoma**

When planning the research project it was important to identify the correct outcomes in order to be able to compare the effect of our intervention on the included participants. It seemed natural to assume that health related quality of life would be a reasonable outcome, as we wanted to involve a patient oriented perspective.

Therefore, health related quality of life would give us an access to a more subjective experience of how the disease or the condition would inflict on the person (52). In this sense, it would be possible to understand the patient's subjective experiences of living with a certain condition and their own assessment of how their life was affected.

The aim of "gaining the best possible quality of life" has become more accepted as a goal within patient treatment in a national and an international perspective (53). There are several different aspects and views on the essence of health related quality of life, and in this thesis the perspective has been on quality of life connected to certain health related conditions and how they have affected the individual. However, when looking at a model covering all relevant aspects of quality of life it was central that it could contain both biological, and physiological variables, as well as a societal perspective. Furthermore, the patient's own evaluation, assessment, and personal motivation should be a central part of the assessment (54).

Moreover, since quality of life is a complex concept it has been suggested (55) that evaluation should assess both generic and disease-specific elements of impairment including physical, emotional and social dimensions.

Health related quality of life and the functional output after surgery are very difficult to evaluate as all of the above mentioned perspectives have an impact on the individual's life with a stoma. Several authors have explored the question of the impact on health related quality of life without reaching a shared conclusion (9,56,57). A recent Cochrane review regarding quality of life in patients after rectal resection for rectal cancer has concluded that it was not possible to come to a clear conclusion whether creation of a permanent stoma had an impact on health related quality of life, primarily because of the small sample sizes (58).

During the last decades several literature reviews and studies have been performed within the issue of stoma creation, and they do not seem to be able to conclude on the aspect of health related quality of life (9,57). Some have reported better quality of life by avoiding stoma creation, while others have not been able to find significant differences. Health related quality of life may even be better when having a stoma compared with patients who have had a resection with a bad functional result (19). Another

study suggests that the decrease in certain scores in health related quality of life is connected to having rectal cancer rather than to having a stoma (59). To some patients creation of a stoma after surgery for rectal cancer may be preferable to the risk of severe postoperative complications (18). According to a review of studies published between 1969 and 1992 (9) depression, loneliness, suicidal thoughts, and low self-esteem were significantly more prevalent in patients with a stoma compared with patients without a stoma. A follow-up study found sexual impairment in male Finnish patients undergoing rectal surgery (60), and another study showed negative beliefs about body image (3,61).

When reviewing the literature it is quite clear, that health related quality of life may be affected differently and most probably reflects the different research designs and methods, which questionnaires were applied, which interventions were tested, and which populations were examined.

#### **PRESENTATION OF THE INCLUDED PAPERS**

In the following section the included papers are presented in brief, one-by-one, with a focus on the methodological strengths and weaknesses. The full-text manuscripts are placed as appendix 1-6.

#### ***Paper 1: Impact of a temporary stoma on patients' everyday lives: feelings of uncertainty while waiting for closure of the stoma.***

##### **Aim**

The aim of the study was to explore the impact of living with a temporary stoma, as well as the issue of adapting to and learning to live with a temporary stoma.

##### **Methods**

We designed a study with a qualitative approach, and set up focus group interviews with a phenomenological hermeneutic perspective in order to grasp essentials of experiences related to creation of a temporary stoma.

##### **Results**

We included 7 patients with a temporary stoma in two groups in the study. The initial domains identified were "life before and after creation stoma", "uncertainty", and "mastery and personal-ity". After an inductive analytical process using qualitative content analysis, the following themes emerged from the data: 1) Control and uncertainty, and 2) Putting life on a hold.

##### **Strengths and limitations**

Limitations of this qualitative study were primarily that it may not be possible to understand and use the results in the same way as in quantitative research (62). Qualitative focus group interviewing is a method where it is possible to gain access to the way persons and groups think, and in our interview the aim was to explore experiences when having a temporary stoma (63). However, the term generalizability connects to a quantitative approach to knowledge gain, and results that meet certain statistical criteria and an estimated sample size.

In our study we included seven participants, divided in two groups. There are several factors that determine the sample sizes in qualitative studies, where the concept of data saturation is the guiding principle for the size of the sample. Moreover, the question of data saturation is tightly connected to both the sampling

strategy, the dialogue during the sessions, and the researchers' ability to access the views of the participants (64).

There are different ways to describe when and how data saturation was reached, and in our study we had a clear notion of how the participants' descriptions were recurrent and the researchers had a shared experience of "having heard this" in the earlier interview. During the process of analysis we first analyzed the interview with 5 participants and afterwards we analyzed the interview with 2 participants, and no new codes appeared in the analysis. However, it is very difficult to make an exact assessment of when data is precisely saturated, as new words and experiences or new codes may have emerged at a later point if we had kept sampling more participants (64).

In our study we found that the codes emerging were within the same themes, but if we had explored the data in more depth we might have identified other codes. The question remains, when to stop, as counting participants does not comply with a qualitative position and tradition. Moreover, a central issue when discussing sample size is the fact that including superfluous participants will lead to an excess of data, and may be an ethical problem. Participants invest time and resources often with the wish to help future patients. Therefore, the researcher has an obligation to ensure that the data will be used, which may be problematic if data becomes repetitive not shedding any further light on the issue of investigation.

When doing focus group interviews some researchers have suggested that the item for analysis is not the individual, but the group (65). In our study we had a focus on the individual as well as the group, leaving the researchers with a large responsibility for exploring both levels in depth. Focus group interviewing is a well-known method within qualitative research, and is especially interesting if you wish to gain access to data not only related to the individual but also to the group. When sampling the participants we aimed at a certain similarity as well as some differences. The purposive sampling strategy was aimed at including participants, who were able to inform us on the research question, why it was significant, that the participants in this study still had the stoma in place (66). Furthermore, we wanted to explore different views and experiences related to this special group of patients, and therefore we included participants, who differed regarding gender, age, time since stoma creation (within a year since stoma creation) and underlying disease. As such, the individuals in the group had the stoma in common, and the group may have made it easier for the individual to talk freely, and we experienced a high grade of recognition and accept between the participants (67).

Another limitation when doing qualitative research is that the researcher is part of the process, whereby the researcher is both the instrument for data retrieval as well as for analysis of the data. We were focused on the methodological challenge of the researcher's preconception of the issue being explored. The aim for us was to ensure, that the preconceptions were "in control", which is probably not entirely possible. In the applied approach we acknowledged the preconception, and the two researchers interviewed each other on the expected results of the interview questions, all done before entering into the sessions.

When sampling for the interview we experienced a major problem with drop-outs. We included several more participants than were actually interviewed during the sessions. The reasons for not being able to participate were related to exacerbation in disease, or having an acute need for an appointment somewhere else in the hospital. This does mean that we may only have interviewed the patients, who were the most resourceful. If we had

been sufficiently focused on this methodological issue, we could have performed individual interviews in the informants home in order to involve and include patients with fewer resources.

One of the limitations of this study was the analytical framework, as we did not analyze the interaction of the participants, as our aim was exploration of experience, and understanding. As such, the use of an analytical method aimed at content seemed relevant. However, if we had included an analytical method that would enable us to understand how the participants interacted and how this interaction affected their statements, we would probably have been able to point at alternative findings. Whereas, applying a method focusing on context and interaction, is more in line with a constructionist perspective, which gives rise to different questions related to the ontological base of the research. As such, there could and would be discrepancy between the naturalistic view, accepting the world as it is seen by the participant, and the constructionist view, where nothing is stable, as everything is constructed within the context.

Another limitation of our study was that the analytical process was done in solitude by one researcher, and was not validated by another researcher in parallel. However doing so, the analyzing researcher had to keep a constant awareness on the connection between the transcribed interview data and the emerging themes (68). The coding process had to be performed in a rigorous way, and strictly following the phases of the qualitative content analysis. However, the first author presented the analytical coding tree to the second author, and inferences made from the coding tree were discussed.

The interview sessions and the methodological preparations before entering into the sessions were done in cooperation between the first and third author. The interview guide was tested in a mock session, and the expectations for the findings of the study were explored in an interview conducted between the first and third author. The specific steps and the practical approach when doing the interview sessions were rehearsed in advance, so that the behavior of the interviewer and the observer would be compatible and coherent. The observer had the competence to interrupt the interview if she found that the interviewer overlooked anything. Furthermore, she was given time to pose questions which in her mind were not fully covered during the interview.

## **Conclusion**

The study pointed at several serious implications following construction of a temporary stoma. The profound experiences and feelings of uncertainty should encourage health professionals to inform patients openly, not holding back information. Furthermore, patients who experienced feelings of stigma tended to put life on a hold and avoided certain activities until the stoma was reversed. Additionally, methods including group based learning and lay teachers should be investigated further within this population.

## ***Paper 2 : Learning to live with a Permanent Intestinal Ostomy: Impact on everyday life and Educational Needs***

### **Aim**

The aim of the study was to explore how patients value their everyday life and adaptation to living with a permanent stoma. Furthermore, we aimed to gain new knowledge about patient ideas for new ways of organizing patient education.

### **Methods**

We set up focus group interviews performed with a phenomenological and hermeneutic approach as we wanted to explore patients' experiences and views related to creation of a stoma.

### Results

We included 15 participants with a permanent stoma. The first group consisted of persons with a permanent stoma due to colorectal cancer. The second group consisted of persons with a permanent stoma caused by other diseases. We identified three initial domains: "borders", "challenging limits", and "being understood". After the qualitative content analysis, two major themes emerged from the data: 1) being different, and 2) training in living a life with a stoma. The results did not reveal any differences between participants who had a stoma because of or because of colorectal cancer or another disease or condition.

### Limitations and strengths

First of all there are methodological issues related to gaining knowledge from qualitative as well as quantitative studies. The qualitative paradigm does not allow generalization in the same way as quantitative research (69). However, when discussing the term generalizability it is central to understand that the term is not transferable to the quantitative understanding of it. The transferability is not related to the uniqueness of the context or situation but rather on the typical and common traits of the context that will emerge after a rigorous analytical process (70). When doing the studies 1+2 we used a solid analytic framework, but the coding process could have been done by two researchers in parallel processes in order to ensure the correct application of the analytical model (71), as mentioned under the limitations section of paper 1.

Another limitation is the fact that the patients who accept to participate in a focus group interview were probably the ones who felt that they had the necessary energy. When sampling for interviews the focus is on participants who are interested in sharing their views. Moreover, when sampling for focus group interviews the participants need to be physically and mentally able to sit on a chair and to listen to others as well. This meant that we only listened to persons, who were capable of meeting all these demands, which a priori excluded patients who were not so well. Furthermore, we did not include participants who were not able to communicate sufficiently in Danish as they should communicate not only with the researcher but also with the group. Additionally, participants who had a hearing impairment were not invited, as this could have affected the interaction and dialogue negatively. In this sense, we might be criticized as our sampling strategy did not involve and include the voices of the more fragile persons with a stoma.

Therefore, we could have proceeded with an interview method that is more sensitive to each individual's capabilities. We could have supplied our study with individual qualitative interviews in order to have a more comprehensive perspective on the research question.

### Conclusion

We found indications of how feelings of stigma in patients with a permanent stoma influenced the individual in different ways. Emotion focused coping strategies and self-imposed isolation may be chosen as a strategy to avoid these feelings of stigma. The study suggested that health professionals learn to identify clinical signs related to feelings of stigma in order to support the patient. The adaptation to life with a stoma was probably inhibited by thoughts of discontinued identity and the study proposed using a

biographical understanding, as well as encouraging patients to keep up former relations and activities to maintain individual and social identity. Moreover, patient education was suggested to focus more on the psychosocial aspects of living with a stoma instead of a sole focus on practical management of the stoma. In addition group-based learning as well as involving lay teachers with a stoma was recommended.

### *Paper 3: Spouses of patients with a stoma lack information and support and are restricted in their social and sexual life: a systematic review.*

#### Objective

The objective of this systematic review was to explore how stoma creation may affect spouses of patients with a stoma.

#### Methods

We performed a systematic review integrating studies based on both qualitative and quantitative methodologies. In this review we applied a method of synthesis based on narrative summaries of both qualitative and quantitative results. Systematic searches based on (PICO/PIC(O)) were carried out for the period 1950 to January 2012, in Pubmed, Cinahl, Embase, Cochrane and PsycInfo applying the relevant MESH search terms (depending on the database), key words, and filtering. The inclusion of studies and the assessment of the included studies were done in parallel processes between the first two authors, and disagreement was resolved by dialogue.

#### Results

The review included three quantitative and three qualitative studies with the following themes: 1) Lack of information and participation of spouses, 2) Sexual life, 3) Social function, and 4) Support when adapting to the stoma.

#### Limitations and strengths

When we started this review we aimed at including both qualitative and quantitative studies, as it seemed obvious to us that we could only respond to the research question in this way. As this was our first attempt at doing a review integrating different types of data we developed two PICO – questions, one aimed at quantitative – and one aimed at qualitative studies (72). Before doing the actual review aimed at spouses, we had to do a comprehensive literature search in order to identify the correct methodology for integrating results originating from different paradigms. We found that a wide range of methods had been described for synthesizing qualitative findings alone, and quantitative findings alone, as well of how to combine findings from both qualitative and quantitative studies. As we studied the literature we became aware that we had to answer several questions before commencing the actual literature search, regarding whether the level of analysis was re-analysis of the original datasets, or on the result-level from the primary study reports. Furthermore, it was unclear to us how we would technically do an integrated synthesis of the evidence.

As such, one of the major limitations of this study was that we had not beforehand identified the method of analysis and how to do it; integrating both types of results without letting one dominate the other.

This latter issue was central, as quantitative results traditionally are regarded as having a higher grade of evidence. As we were certain that we needed both types of results, it was necessary for us to find a method that would take this issue into ac-

count. We were aware that the results might be incompatible when they were based on different methodologies. This was especially important as we wanted the quality of the study to be decisive, and not the methodology. The methodology that we applied guided us to analyze the quantitative and qualitative studies in parallel processes. As the results differed, we applied an analysis on a report level, and did not try to do any kind of meta-analysis or meta-synthesis. As described, the method of doing systematic reviews including both qualitative as well as quantitative studies have not been described and explored in depth. Therefore, we were forced to improvise and allow ourselves to be guided by the studies in question. This may have had the effect that we were not as rigorous as we originally intended, although we have documented every detail about inclusion and exclusion of studies as well as data extraction.

### Conclusion

On the basis of our findings which showed a need for informational and educational activities for spouses, we recommend planning educational activities focusing on the spouse.

### ***Paper 4: Patient education has a positive effect in patients with a stoma – a systematic review.***

#### Aim

The aim of this study was to systematically review the research-based literature regarding patient education in patients with a stoma, with a focus on efficiency and patient reported outcome such as health related quality of life.

#### Methods

A systematic review including both qualitative and quantitative studies was done, applying a method of joint synthesis based on narrative summaries of all included studies. Systematic searches were carried out for the period 1950 to July 2012 in MEDLINE, Cinahl, Embase, Cochrane and PsycInfo databases including MESH search terms (depending on the database), key words and limitations. In addition to the systematic database-searches we also searched references. Study selection, study assessment as well as study inclusion were guided by the PICO/PIC(o) questions and were done independently by two reviewers, and consensus was obtained through dialogue.

#### Results

The review included 7 studies that met the inclusion criteria of having rigorously evaluated an educational program related to stoma creation. Only quantitative studies were included in the review, as the literature search did not retrieve any articles reporting studies with a qualitative design. From the studies seven separate patient educational programs were identified, and the following results were found: 1) Health related quality of life, 2) Cost effectiveness analysis, 3) Time until discharge and proficiency in stoma management, 4) Self-care knowledge, self-care-attitude, self-care behavior, self-efficacy, self-management, and psychosocial adjustment.

### **Limitations of this systematic review regarding patient education and stoma creation**

Limitations when doing this systematic review of patient education and stoma creation were obviously that it was not possible for us to identify many interventional studies with a sufficient quality to be included in the review. When searching systematically for studies to include there are several limitations. In our

study we wanted to include studies with a variety of applied methods. However, it was not possible for us to retrieve any relevant studies with a qualitative approach. Therefore, we might not have posed the right PIC(o)-question, or maybe the search terms identified on the base of the question were not sufficiently focused.

Furthermore, we searched different databases in order to find studies of different types. However, the different databases have diverse search-terms as well as unlike MESH-terms and Headings. In the final review we were only able to include quantitative studies which is a limitation as we set out to include both types of studies.

The ultimate aim of a systematic review would be to do a meta-analysis or meta-synthesis, where the first term is related to quantitative studies and the latter to qualitative studies. In our case, the interventions and the results were diverse which made it impossible to do an overall analysis on a data level. It would have strengthened our results immensely if the included studies had explored the same outcomes as a pooling of the data and doing a second analysis would have increased the total sample size of included patients.

Another limitation was the assessment of the quality of the included studies even though we referred to the PRISMA guidelines, and were inspired by Cochrane's assessment tools. Regardless of this, the process of evaluation of the quality of the studies was at risk of reflecting the personal views of the reviewers. Therefore, we planned and performed the inclusion, and the quality assessment in parallel processes, and before entering into these we had planned that any disagreement would be settled in unison.

The data extraction process was difficult in this review, as we wanted to focus on efficiency based on interventions. We did not a priori define the specific outcome, why we included studies reporting both health related quality of life, cost efficiency, rise in knowledge, as well as self-efficacy. In spite of this obvious methodological limitation we extracted data in a rigorous way based on a thorough discussion of the results. This was done in parallel as well, and both reviewers agreed on the results without disagreement.

Limitations of this systematic review reflect the heterogeneity and scarcity of data published on patient education and stoma creation, and some of the included studies lacked rigor. However, the included studies all covered clinical interventions aimed at improving the primary outcome related tightly to the patient or the patient course.

### Conclusion

The results point at a positive impact when planning patient educational activities aimed at patients' psychosocial needs, including group based activities. However, the conclusion is based on few non-comparative studies. Moreover, educational sessions done by a specialist in the home of the patients prior to admission to hospital may reduce time until discharge. Formal educational activities, based in groups and partly involving lay teachers, seem to be beneficial in relation to self-care knowledge, self-care-attitude, self-care behavior, self-efficacy, self-management, and psychosocial adjustment, as well as an increase in health related quality of life in patients with a stoma.

### ***Paper 5: Health related quality of life increases when patients with a stoma attend patient education – a case control study*** **Objective**

The objective of this study was to explore the effect of patient education on health related quality of life. We designed a study exploring the effect of structured patient education in patients after stoma creation. We hypothesized that patient education and telephone follow-up would affect treatment outcome of health related quality of life.

### Materials and methods

A case/control study including patients admitted for stoma creation in a surgical department in Copenhagen. Patients were included from August 2010 until June 2011 with a follow-up period of 6 months after surgery. After stoma creation, patients were invited to participate in the study; covering early intervention by the stoma nurse, telephone follow-up after discharge, and structured patient education organized in groups. Health related quality of life was measured before leave from hospital, 3, and 6 months after stoma creation.

### Results

We included 50 patients, and baseline characteristics of the patients showed no significant differences between groups ( $p>0.05$ ). Due to the number of drop-outs we tested whether it was connected to the group allocation or other relevant variables, but could not detect any significant differences when using a Fisher's exact test related to group allocation ( $p=0.38$  at the third visit, which was 6 months after stoma creation) and a binary logistic regression analysis related to gender ( $p=0.19$ ), and cancer/non-cancer ( $p=0.70$ , respectively). The intervention group showed a significant development in OAS scores between baseline, three months and 6 months (Friedman test,  $p<0.001$ ). Furthermore, we found significant changes in some of the profiles of SF-36 although not revealing an obvious trend.

### Limitations

The results of this study may have been influenced by the drop-out rate and therefore a loss of data, since we only had data from 17 patients in the control group and 13 in the intervention group. But, the design as a non-randomized study assumed to be better as patients in the intervention group could have confounded the results of the control group if they were given the possibility to interact during the study.

Non-response to the questionnaires was a central issue in this clinical study involving participants with severe diseases. Patients being surgically treated for a disease leading to stoma creation typically have several treatments or out-patient activities to attend to, and may feel it is difficult to maintain both every-day life as well as treatments plans, which may lead to omission of participating in the planned research activities. This was not further explored, although the questions related to retention of participants in clinical studies in surgery should be explored further. Studies within the field of diabetes (73) and on-line-questionnaire surveys (74) have pointed at different factors leading to retention such as adequate screening processes, adequate staffing related to the research infrastructure, as well as a need to help others, and access to specific tests in the trial. In this case/control study patients in both groups dropped out, and the missing data analysis showed no significant differences between groups. Patients' explanations for leaving the study were: not having the time, or not having the resources necessary for staying in the project. However, we tried to keep participants actively filling out the questionnaires even if they did not participate in the interventions. Although, the study was in fact not a randomized controlled trial, we were focused on analyzing the data as intention to treat

and not per protocol in order to make the results easier transferable to the clinical setting, as this is more in line with the actual patient course. Few participants accepted this, and they all explained it in the same way as participants in the control group. This leads to a discussion of what characterizes participants leaving a clinical trial as this must be seen as a serious bias of attrition when showing the results of this study (75). In our studies it was not possible to find evidence that participants who chose to leave the study were more ill or had had more operations at an earlier stage. However, this may only depict that the population enrolled in the studies was primarily a segment of persons who suffered from very serious diseases, no matter whether they were allocated to the control group or the intervention group.

In addition, we included all patients, who would be invited to join a patient education program if it were not a research project. This probably decreases the strength of the results as the statistical power may be impaired, but it does reflect the actual terms and conditions of the clinical practice in the area of stoma care.

Preoperative patient education offered in the patients' home has been shown to have a significant effect on gaining proficiency in stoma management. This suggests that preoperative training and information administered in a sheltered and comfortable environment could have a positive educational effect and underlines that delivery of complex knowledge has to take the settings into account in order to support effective knowledge transfer. We did not include this intervention as it is incompatible with the guarantee-of-treatment period in Denmark of 2 weeks, although it might have improved the results.

It has been suggested that missing data regarding the participation in the educational activities should be connected to the fact that patient educational activities only reach out to patients who are resourceful, and that the weak and frail elderly patient will not be involved as a participant. Some authors have discussed that the large focus on establishing patient education programmes turns other patients into victims, as they are overlooked (76). In our study it was obvious, that some patients were not invited to participate in the study, as all participants, irrespective of group allocation, had to be capable of participating in the sessions. On the other hand, the objectives of the study were not to identify new and alternative educational methods with this special population of for in mind. However, the area of patient education would benefit from studies exploring how to organize and offer education aimed at non-resourceful patients. One might argue that many resources are spent on activities aimed at persons, who may already be able to manage on their own. Conversely, the initiation and exploration of new methods to educate and rehabilitate patients from treatment courses of severe disease, may in time give lead to the possibility of exploring the effect of the methods in other populations.

### Conclusion

We have shown that establishment of a structured patient education program aimed at patients with a stoma improved disease specific areas within health related quality of life. A program including interventions aimed at increasing knowledge, as well as self-management may benefit from including lay-teachers, alongside health professional teachers. Furthermore, the use of telephone follow-up after discharge from hospital may increase patients' health related quality of life.

**Paper 6: Decreased costs with patient education after stoma creation**  
**Objectives**



After finalizing the study reported in paper 5 we continued with an analysis of the cost effectiveness of the new interventions. The economic data included both costs related to hospital care and out-of-hospital care, for instance in the stoma clinic. However, in order to present data that went beyond the hospital-based care and treatment, this trial focused on costs generated from visits to the general practitioner, the primary care nurse, as well as costs related to the involvement of patients' families. The main objective of the cost analysis was to explore whether the interventions would increase or decrease the costs related to the patient course with a specific focus on the rehabilitation period after discharge.

### Materials and methods

All direct healthcare costs for the first six months postoperatively were measured from the perspective of the health care system, excluding indirect societal costs.

We measured patients' use of the health care sector involving length of hospital stay, visits at the out-patient stoma clinic, visits at their GP, and with a primary care nurse. As such, we applied a judgment of whether the variables were due to stoma related symptoms or problems. Regarding the intervention only direct costs, which were teachers' hours spent preparing for the teaching session and doing the teaching session, were registered, analyzed and presented. Additionally, we registered days until patients resumed normal activities (both physical exercises and social activities).

### Results

Of the 280 eligible participants 75 were invited to participate. 25 of these declined and we included 25 patients in each group. Baseline characteristics and missing data analysis showed no significant differences between the groups. We did an overall cost analysis based on average costs of the participating patients, and this analysis revealed that the average costs did not increase when implementing a patient education program. Furthermore, it showed that there was a significant difference between groups regarding unplanned re-admissions ( $p=0.01$ ) as well as needing assistance from the general practitioner ( $p=0.05$ ). However, there were no significant differences regarding length of hospital stay, or costs related to assistance from the primary care nurse. Furthermore, we found that patients in both groups needed assistance from their family, although without significant differences between the groups. Participants in both groups still needed the assistance from the ET's at the out-patient clinic, as well as the telephone support, and there was no statistical difference between groups. Moreover, we found no significant differences between the time until patients in both groups resumed physical and social activities.

### Limitations and strengths

The economic analysis was partly based on data generated in the hospital database and partly from patient reported data. The latter was difficult to apply, as patients could forget the appointments, or misunderstand what we wanted them to report. We tried to address this issue by contacting the patients and reminding them about the patient diary. However, some of them did not return the diary, but made an oral account of their activities. Other patients were very meticulous when entering data into the diary, and some wrote narratives related to the different questions. A few patients called later on to update the researcher on their improvements.

We were not able to apply a conventional method for economic evaluation, as this was not compatible with the outcomes monitored in the study. On the other hand, we applied a method of analysis that seemed in accordance with the resources of clinical researchers. We acknowledge that our analysis may be difficult to generalize to other clinical settings and that it was not possible to generate any measure for the efficiency in terms of health gain. Another aspect that we have not documented in this study is the return to work and the use of transfer income, which would have reflected an overall economic societal perspective.

### Conclusion

In conclusion, we have found that the establishment of a patient education program for patients after stoma creation did not lead to an increase in the overall cost. Moreover, it pointed at a decrease in costs related to visits with the general practitioner, as well as a reduction in unplanned readmissions after stoma creation.

### DISCUSSION

On the basis of our studies we found that patients have many concerns after stoma creation, covering feelings of stigma, uncertainty in illness, biographical disruption, a perceived need to control the body and self-imposed limitations. These findings did not seem to be dependent on how the stoma was perceived. Furthermore, recommendations for future educational programs were identified and included group based learning, psychosocial elements as well as knowledge transfer, and involvement of lay teachers with a stoma (paper 1+2).

We found evidence stating that spouses and near relatives of patients with a stoma felt isolated, not sufficiently informed, had concerns related to social and sexual issues, and did not receive adequate support by health professionals and from their family and friends (paper 3).

Furthermore, we have explored the evidence behind patient education programs established for patients after stoma creation (paper 4). The evidence pointed at different interventions that may positively affect health related quality of life, disease related knowledge, self-efficacy, costs, and in-hospital-time. The interventions covered visits in patients' home before admission to hospital, use of different media in patient education material, involvement of expert patients, and group based learning sessions covering different areas relevant to patients with a stoma.

We established and implemented a patient education program aimed at involving the participating patients, inclusion of both psychosocial issues as well as evidence based knowledge, involvement of lay teachers with a stoma, and group based sessions. The results pointed at a significant increase in health related quality of life in the intervention group (paper 5). Furthermore, we found that the overall average costs did not increase when introducing the program. Moreover, the study showed a reduction in the unplanned readmissions to hospital and the use of the general practitioner (paper 6).

### General issues

These results and findings lead to discussion of several general issues evolving from the different studies.

### Educational strategies for patient education programmes

In this study we developed a program on the basis of patients' recommendations explored in interview sessions preceding the actual performing of the sessions.

Involvement of lay teachers was a central issue to many of the informants and in this thesis it was related to the need for receiving trustworthy information about living with a stoma and partly as inferred in the data analysis of the interviews. Furthermore, it was connected to the need of entering into psychosocial issues as the lay teacher would have a peer-approach. Involving lay teachers in educational sessions aiming at disease control to prevent unrealistic tales about life following stoma creation was central to participants in the interview studies (paper 1+2). Therefore the double-rationale behind patient educational strategies actively involving peer-teachers was both in order of addressing psychosocial needs as well as providing trust and recognition in the rehabilitative process.

The full potential of involving lay teachers has not been explored in depth in this thesis, and the issue has not been thoroughly investigated in the surgical setting. This is an interesting aspect as the Danish Ostomy Association COPA has a well-educated group of counselors, who are trained and willing to visit patients after stoma creation either while the patient is still in hospital or in the patient's home (29). When entering into the subject of empowerment and peer-teachers it is an evident choice to discuss differences in perspectives, as involvement and active participation of the patient are most likely some of the causes for the positive effect of the intervention reported in paper 5.

Patient education has a possible importance regarding patients' adherence to treatment, which may be defined as the extent to which patients agree to and follow the instructions they are given for prescribed treatments (77). Adherence is not the same as compliance or the newer term concordance. The first refers to the extent to which patients follow their physician's orders about medicine intake. The latter focuses on the shared process of decisions between the professionals and the patient, who both incorporate their respective view to a wider concept (77,78). The concepts have primarily been used within the field of medication but may be spread to other areas, such as in our study. As such, an emphasis on shared decision making processes may improve the understanding of the other's perspective in order to seek joint treatment plans and arrangements. A review studying the effects of interventions aimed at increasing adherence as well as treatment outcomes in medication trials, found that counseling, guidance, information-leaflets, and telephone follow-up improved both. However, the complexity of adherence and concordance put strong demands on the interventions covering a variety of combinations of psychosocially oriented interventions in combination with knowledge transfer, patient self-monitoring, support groups and supportive care (79).

Another term with importance to the educational strategies is of course health literacy, which describes the extent to which the individual is capable of seeking, understanding and acting on health information (80). This issue was not explored in this ph.d.project, but is never the less important, as it may connect to other types of participants, than the ones included in our studies.

### **Health economic assessment**

Clinical interventions should be evaluated on the basis of the costs in addition to the clinical results. Studies that improve the clinical outcome without further costs should naturally be implemented. Studies, that increase costs without any positive clinical outcome, should be avoided. Somewhere in between there may

be studies pointing at some positive effect and some additional costs. The cost effectiveness analysis in its purest form is therefore a tool for making these decisions in the clinical setting (81), and may support a professional process of prioritizing, when introducing new treatments and methods (82).

However, when doing an economic analysis related to a narrow group of interventions and only directed towards comparison of the direct costs, these economic models are not so easily applied. Several clinical studies covering cost assessments are not designed primarily to measure the costs, but the cost assessment is applied which is central when we use a clinical trial as basis for economic assessments (83). Therefore, the designs of the clinical trials sometimes do not match the economic models, why we should criticise the economic assessments for not being designed correctly. However, one could also suggest that the preferred economic models do not match the need of clinical research, as they may be too complex to integrate properly for clinicians and health professional researchers, as they define for example which measurement tools are acceptable.

One of the problems could be that the economic models define and prescribe the most acceptable measurement tool for example the use and appliance of the outcome quality adjusted life years or quality adjusted life expectancy (84). Quality adjusted life years are the outcome of choice matching the model of cost efficiency analyses. The preferred questionnaire would be the EQ-5D, a generic questionnaire with 5 questions covering 5 dimensions of health: mobility, personal hygiene, ability to perform habitual activities, pain and anxiety/depression. Every dimension has 3 possible answers with scores from 1 to 3, with lower scores showing a lower quality of life. These profiles are summed into a global score being a number between zero and one. These summed and global scores may be calculated and reverted into quality adjusted life years, whereby one gains a more objective statement of the relation between health and costs. Additionally, in Denmark the EQ-5D has been used to identify a Danish global score (85), whereby it is possible to assess and compare scores between an observational group and the Danish population. However, the clinical problem applying the EQ-5D is primarily connected to the lack of sensitivity of the instrument when focusing on specific symptoms and their impact on the respondents' health related quality of life. This lack of sensitivity made it impossible for us to apply it in our trial, and therefore, we used the SF-36, which is probably more sensitive to the experiences of the participants in our study.

When measuring the cost effectiveness of interventions aimed at improving health outcomes, it was difficult to identify the correct assessment tool. The use of diagnose-related-groups (DRG) as an outcome-measure has been advocated as a generic and comparable way to present and compare differences in costs. DRG has been the preferred method within health-economics when wanting to compare costs in one group with costs in another group (86). However, DRG does not only show the direct costs of an intervention but also covers costs related to loss of value and capital expenditures (87). As such, DRG contains more than the costs relevant for presenting the difference between the two groups in paper 5+6, and it is not possible to identify the precise and accurate part of the costs within each patient's course. The choice of avoiding DRG lead us to search the electronically based patient file system instead, as we could identify and document the precise number of days in hospital, the precise number of unplanned re-admissions, as well as the precise number of visits to the out-patient-clinic.

### **Patient reported outcome**

The use of diaries in order to register the need to visit the GP and the primary nurse has been explored in other studies (88), and it seemed to be a valid method to collect data that are difficult to register in Denmark. However, some patients did not hand in the diary, which normally must be treated as missing data. Furthermore, some patients, who did hand in the diary, complained that it was difficult to remember to fill in the diary, although it was designed with check-boxes that seemed fairly easy to tick off. Apart from questions related to visits with their GP, the primary care nurse or the nurse's assistant, the patients were asked to assess how many minutes their family or friends helped them in relation to the stoma. We did not ask them to clearly identify what the specific help was, which on one hand might have made it easier for the patients to fill out and on the other hand we would have had more information on this subject. Other studies have pointed at the same issue and found that spouses assisted the patients in handling the stoma (89,90). Our study confirmed these results, and did not pursue this issue further.

Regarding the resumption of former physical and social activities, the diary could have been more specific about registration and documentation of the actual level of activity. In the diary patients had the opportunity to tick of specific sports e.g. bicycling, jogging, and swimming, with open options as well, but as we are not able to discriminate between activities before and after the surgical intervention we summarized the results in total, and not as sub-categories.

Telephone support was an intervention applied by the ET's 5 days (+/- 2 days) in 20 out of 25 patients (the patients in the intervention group). The call was assisted by a checklist supplied by the researcher in order to make sure that the call would be covering all necessary issues. However, as the ET's are specialists within their field they were instructed to enter into other issues if needed. When involving health-professionals with a high competency it is central that their situational judgments should be used, as a checklist may only meet the minimum needs and lacks the possibility of individualization. Patients expressed that they felt comfortable with the telephone calls and that it relieved them, as the ETs took a clear responsibility for them. One study suggested that telephone supported patients in the rehabilitation period after stoma creation (91). Additionally, a recent Cochrane Review pointed at some beneficial effects related to telephone support, but that data were limited due to relative small studies that were not randomized (92). In our study the effect of telephone support was not isolated, and as such it is not possible to draw any conclusions on this intervention as it was applied in conjunction with the other relevant interventions.

### **Health related quality of life**

The assessment of health related quality of life did show a significant rise in the intervention group when assessed with a disease specific questionnaire. When using questionnaires it is imperative that the internal validity is high. We combined two questionnaires, as applying a generic questionnaire as well would possibly enable us to identify physical, emotional or social impairments, that would not be covered by the disease specific questionnaire alone (55). The Ostomy adjustment scale was developed as a questionnaire aiming at persons with a stoma with an understanding of health related quality life being correlated to the level of adaptation to life with a stoma (93,94). Only few questionnaires have been designed specifically with the patient with stoma in mind focusing on covering all relevant issues related to adaptation for this group of patients.

### **CONCLUSION**

The overall purpose of this ph.d.project was to create new knowledge and understanding related to living with a stoma and the process of learning how to live with the stoma.

On the basis of the studies in this thesis it is possible to conclude that an educational program aimed at patient participation and patient involvement does increase health related quality of life significantly, and decreases some costs. When we applied methods aimed at other processes than mere knowledge transfer it was obvious to us that the participants benefitted from the rigorous didactical perspective. The use of groups and the involvement of peers as teachers had an immediate effect on the participants, and it was obvious that there was a need to interact and communicate freely.

The cost analysis showed that it is possible to establish patient education programs without further costs for the hospital or for the community. Furthermore, we found evidence supporting that patient education may have a preventive effect on the rate of unplanned readmissions. This aspect should be explored further in other groups of surgical patients, as the focus on implementation of systematic health education may have a stronger impact than previously assumed.

The studies have highlighted important knowledge on the issue of establishment and planning of a patient education program aimed at increasing health related quality of life. Furthermore, we gained an insight into different issues related to living with a permanent or a temporary stoma as experienced by the participants in the interview sessions. These issues were the perceived need to control the altered bodily design and the shift in bodily function. Furthermore, the concept of stigma and the application of strategies to avoid feelings of stigma have been presented. The term disrupted identity was discussed and proposed as an additional way to understand and acknowledge patients' difficulties after stoma creation. Furthermore, the concept of uncertainty was suggested as patients with a temporary stoma in particular were centered around reversal of the stoma, not knowing whether it would actually be put back.

The impact on the spouse was unfolded and the evidence showed that spouses needed for information and support from health care professionals. This seems in contrast to the vast importance that spouses perceivably have on the patients' well-being. The evidence behind the actual effect of patient education in relation to patients with a stoma was examined, and it was possible to point at some relevant interventions.

### **Implications for practice and future research**

This research project has several implications for practice and future research:

- Further exploration of the impact of a temporary stoma and identification of relevant strategies for increasing knowledge and empowerment in patients.
- Exploring the effect of strategies aiming at a high degree of patient participation in clinical interventions other than patient education. A high degree of patient participation would probably be beneficial for the retaining of information in other clinical settings involving high-complexity communication between health-professionals and patients.
- Exploring the importance and impact of involvement of lay teachers, not only within stoma care, but also related to patients with cancer without stoma creation.

- Exploring the possibilities of patient educational interventions before hospital admission, as this would probably have an impact on patients' retention of knowledge.
- Exploring the boundaries between group-based and individual interventions in patients with a stoma, as group based sessions may add to the results in some issues, and may be counterproductive in others.
- Exploring the needs of spouses of patients with a stoma in a Danish clinical setting, and identifying relevant interventions aimed at this specific population. Especially, there should be focus on the information needs as well as a need for knowledge gain, as spouses seem to help and support the patient in different ways, including stoma handling.

## SUMMARY

### Background

Stoma creation is a surgical operation where the surgeon makes an artificial opening on the abdomen from where the bowel is taken out. It is a radical treatment with permanent physical signs of bodily change. In general, it leads to loss of a central and personal physical function, as well as an alteration in the bodily design. Research in the field may provide additional information about central elements when adapting to life with a stoma. There are currently no studies that adequately focus on the relationship between health-related quality of life and stoma construction in a Danish context, neither for temporary or permanent construction, nor in relation to the importance of stoma handling.

### Purpose

The overall objective of the study was to investigate health-related quality of life related to stoma creation and patient education.

Methodologically, the project was implemented as a mixed methods study in which qualitative interview studies and two systematic literature review identified interventions, which were subsequently tested in a clinical case/control study. Finally the case/control study was made subject to an economic analysis.

### The project is based on 6 papers reporting the results.

**Paper 1:** Impact of a temporary stoma on patients everyday-lives: feelings of uncertainty while waiting for closure of the stoma. The study included 7 participants who were interviewed in focus groups. The results indicated that patients experienced a high degree of uncertainty in connection with the stoma being temporary. At the same time, participants had a strong need to control both their physical appearance and their changed bodily functions. Participants opted for education programs involving teachers with a stoma.

**Article 2:** Learning to live with a Permanent Intestinal Ostomy: Impact on everyday life and Educational Needs.

The study included 15 participants who were interviewed in groups related to whether they were treated for cancer or non-cancer. The results showed that participants often experienced the stoma as a taboo, and emotions related to stigma were identified. In addition, participants were influenced by the stoma in various ways, and the stoma imposed some restrictions on the participants. Participants pointed at group-based education, as well as the involvement of teachers who had a stoma.

**Article 3:** , Spouses of patients with a stoma lack information and support and are restricted in their social and sexual life: a systematic review.

The study included 6 articles based on quantitative and qualitative data showing that spouses were affected in several ways by the construction of the stoma. The results pointed at spouses not being informed and supported sufficiently by neither enterostoma therapists or surgeons.

**Article 4:** Patient education has a positive effect in patients with a stoma – a systematic review

The study included 7 studies, all with quantitative results. They showed that patient education had a positive impact in several areas including shorter hospital stay, less time until proficiency in stoma management is reached, an increase in quality of life, increased knowledge about the stoma, and increased self-efficacy.

**Article 5:** Health related quality of life increases when patients with a stoma attend patient education – a case control study.

The study included 50 participants shortly after stoma creation. The results showed that the disease-specific quality of life was significantly increased in the intervention group, while generic health-related quality of life was positively affected in different dimensions in both groups.

**Article 6:** Decreased costs with patient education after stoma creation

The study was an economic analysis based on participants in Article 5. The results indicated that there were fewer unplanned re-admissions related to the stoma, and that patients in the intervention group did not visit the general practitioner as much as patients in the control group. Furthermore, we found that the average cost per patient did not increase when establishing a patient education program.

### Conclusion

The thesis concludes that patient education has a positive impact on patients' quality of life, and that costs were reduced. At the same time, it is concluded that living with a stoma is a complex situation, which also involves spouses and close relatives, and that patient education must be based on a multiple interventions that are not all explored in this project.

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