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Preface

This Ph.D. thesis is based on studies planned and carried out during my employment as a PhD student from 2004 to 2007 at the Department of Orthopaedics, Aarhus University Hospital.

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List of original papers

This thesis is based on the following papers:

Papers:

1. Hordam B, Pedersen PU, Sabroe S, Soballe K.
A cross-sectional study of health status in Danish patients aged 65 and over after total hip-replacement (appendix 1).

2. Hordam B, Pedersen PU, Mejdahl S, Sabroe S, Soballe K.
Nursing intervention by telephone interviews of patients aged 65 and over after total hip replacement improves health status: a randomised clinical trial (appendix 2).

3. Hordam B, Pedersen PU, Keiding H, Soballe K.
Health-related quality of life of patients aged 65 and over after total hip replacement (appendix 3).

Abbreviations

CI	Confidence Interval
DHR	Danish Hip Arthroplasty Registry
HRQL	Health-Related Quality of Life
OA	Osteoarthritis
OR	Odds ratio
QALY	Quality-Adjusted Life Years
SF-36	Short Form 36
THR	Total Hip Replacement

Abstract

The overall aim of this thesis was to investigate improvement in health status of patients aged 65 and over after total hip replacement (THR) as a result of nursing rehabilitation.

The project consists of three studies, first a description of patients' health status after THR, followed by a randomised clinical trial by using telephone interviews and counselling postoperatively, and testing improvement in patient' health status after THR. The last study involved testing the effect of nursing intervention by providing a measurement of patients' health-related quality of life.

The aim of Study 1 was to describe health status among patients after total hip replacement (THR) and to analyse the association between health status and gender, age, living situation and dependency on help from others. A cross-sectional study was performed that included 287 patients aged 65 and over who had undergone THR within the past 12 months. Patients from five Danish counties received a mailed questionnaire assessing health status and demographic data. Short Form-36 measures eight domains of importance for health status. Of the 314 patients who received a questionnaire, 287 (91.4%) patients participated. The patients answered the questionnaire 202(120) days after surgery. Patients living alone or dependent on help from others had a significantly increased risk of having lower scores in seven of the domains of health status after surgery.

In Study 2, the aim was to study the effect of nursing intervention in form of telephone interviews 2 and 10 weeks after THR during the first 9 months on health status during the first 9 months after the operation. Method: A randomised clinical trial of 180 patients aged 65 and over focusing on patients' health status by using SF-36 at 4 weeks pre- and 3 and 9 months postoperatively was carried out. Patients were randomised 4 weeks preoperatively to either control or intervention groups. Both groups received conventional surgical treatment, but the intervention group was interviewed by telephone 2 and 10 weeks after surgery.

The data in Study 3 came from patients aged 65 and over participating in a randomised controlled trial (RCT) with a 9-month follow-up period (Study 2). The aim was to compare differences in health-related quality of life expressed in quality-adjusted life years (QALYs) between patients

aged 65 and over receiving conventional care after THA with patients having conventional care and telephone contact 2 and 10 weeks after surgery. It was carried out at a university hospital in Denmark from January 2005 to May 2007. Two hundred reply-paid envelopes were prepared to randomise the population (figure 1). All together, 180 patients consecutively admitted to elective THR in two departments of orthopaedic surgery were allocated to the study. Both departments used the same surgical procedure for elective THR. Of the 180 patients allocated to the study, 161 were included (56 men, 105 women), 19 patients (6 men, 13 women) were excluded. Mean age was 76.5 years for excluded patients and 74.9 years for the included (P value 0.270).

Danish summary

Hvert år gennemføres et stadig stigende antal operationer, hvor især ældre mænd og kvinder fra 65 år som følge af osteoartrose får indopereret hofteprotese. Det er velundersøgt, at patienterne får forbedret gangfunktion og smertereduktion. Dette studie blev indledt med en tværnsnitsundersøgelse, der dokumenterede, hvordan patienterne vurderer deres helbredsstatus. Spørgeskema SF-36 indeholdende 8 områder blev anvendt. Efterfølgende blev der gennemført en analyse af associationerne mellem helbredsstatus, alder, køn, bo alene og være afhængig af hjælp fra andre/familie. Tværnsnitsundersøgelsen viste: at bo alene og være afhængig af hjælp fra andre var forbundet med en signifikant højere risiko for at have lav helbredsstatus.

Derefter gennemførtes et klinisk kontrolleret forsøg, hvor patienterne blev fulgt i ca. 1 år. Patienterne blev randomiseret til enten en kontrolgruppe eller en interventionsgruppe. Baseret på styrkeberegning indgik 180 patienter i undersøgelsen. Patienterne var visiteret til sygehusets almindelige venteliste, de var 65 år og indgik efter skriftlig informeret samtykke i undersøgelsen. Formålet var at undersøge effekten af intervention ved telefon interview og vejledning af specialistsygeplejerske. Kontrolgruppen gennemførte konventionel behandling, mens interventionsgruppen udover konventionel behandling blev kontaktet 2 og 10 uger efter operation telefonisk i eget hjem. En specialistsygeplejerske gennemførte telefoninterview og vejledning til patienterne inden for 8 hovedområder, der refererede til patienternes operationsstatus.

Resultaterne af det klinisk kontrollerede forsøg dokumenterede, at patienternes helbredsstatus i interventionsgruppen nåede det habituelle niveau 3 måneder efter hofteoperation, mens kontrolgruppen nåede det habituelle niveau 9 efter hofteoperationen. Dette indikerer, at patienter, der modtager intervention i form af telefoninterview og individuel vejledning 2 og 10 uger efter operation, har mulighed for at få forbedret deres helbredsstatus allerede 3 måneder efter hofteoperation.

Afslutningsvis foretages en undersøgelse af patienternes helbredsrelaterede livskvalitet målt i QALY. Resultaterne dokumenterede, at begge grupper havde signifikant fremgang i deres helbredsrelaterede livskvalitet inden for det år, undersøgelsen blev gennemført. Dog kunne der i

dette studie i denne periode ikke vises signifikante eller klinisk relevante forskelle mellem de to grupper ved opfølgningen.

Det vil være relevant med yderligere forskning i relation til intervention og opfølgning over en længere periode med både telefoninterview samt individuel og specifik sygepleje baseret på patienternes helbredsstatus.

English summary

Each year an increasing number of total hip replacements are performed, especially in elderly men and women aged 65 and over because of osteoarthritis. It is well established that this operation improves walking function and reduction of pain in these patients. First of all a cross-sectional study was performed regarding how patients evaluated their own health status. Questionnaire SF-36, which consists of eight domains, was used. Then, an analysis was done of the associations between health status, age, gender, living alone and being dependent on help from others/family. The results of the cross-sectional study indicated that living alone and being dependent on help from others meant a statistically higher risk for documentation of low health status.

Then, a clinically controlled study was done in which patients were followed-up for about 1 year. Patients were randomised to either a control group or an intervention group. Based on a power calculation, 180 patients were included in the study. The patients were taken from the hospital's normal waiting list, were 65 years of age or older, and participated in the study after written informed consent. The purpose was to study the effect on postoperative health status of intervention in the form of telephone interviews and advice offered by a specialist nurse. The control group received conventional treatment; whereas the patients in the intervention group, in addition to conventional treatment, were contacted by telephone at home 2 and 10 weeks after the operation. A specialist nurse performed the telephone interviews and gave advice to patients in eight main areas that dealt with the patients' postoperative status.

The results of this clinically controlled study documented that the health status of patients in the intervention group reach habitual level 3 months after hip surgery, whereas in the control group habitual status was reached 9 months after hip surgery. This indicates that patients receiving intervention in the form of telephone interviews and individual advice 2 and 10 weeks after total hip replacement have the possibility of improving their health status 3 months after hip surgery.

Based on this finding, a study was performed of patients' health-related quality of life as measured in quality-adjusted years. The results documented that both groups showed significant improvement in health-related quality of life in the year in which the study was performed. However, in this study

no significant differences during the period studied could be demonstrated between the two groups at follow-up.

Before clinical guidelines can be developed for nursing rehabilitation of these patients additional research with longer follow-up is needed regarding the effect of telephone interviews and individual and specific nursing interventions on the health status of patients after orthopaedic operations.

1. Introduction

In Denmark with a population of 5 million people, approximately 15% of the population are aged 65 and over, and the annual incidence of THR among patients aged 65 and over is about 5,000 (1,2). As osteoarthritis (OA) affects the middle-aged and elderly, the need for THR is predicted to increase during the next decades due to the higher percentage of elderly in society (1). According to prognoses, the number of elderly will increase to 847,000 by the year 2020, i.e., 15% of the total population (2). In the EU member states, over 190,000 THR's are performed every year. In the Nordic countries some 50,000 THR's are carried out annually (3).

Because OA is the most frequent disease in people aged 65 and over, the number of older patients needing hip replacement will increase in parallel with the number of elderly. The condition is equally common in men and women (4-7).

1.1 Aetiology

Everyone develops OA in at least one joint. In the year 2000, 3.8% of the Danish population – over 200,000 Danes were diagnosed as having OA by a specialist. Nevertheless, experts judge that this is only the tip of the iceberg. It is estimated that the total number of people with OA is about 500,000 (5). OA is a chronic condition that develops over many years. There can be periods during which it develops rapidly, but several years can pass between the individual stages of the disease. The symptoms are pain, tenderness, stiff and/or swollen joints. As for aetiology, medical science has more or less shown what factors can provoke OA. None of these factors are, however, the direct cause of the arthritis, but acknowledged risk factors are age, gender, heredity, heavy monotonous sedentary work, overweight, previous damage to the locomotive apparatus (e.g., bone fracture or ligament damage in connection with sport) congenital defects of the locomotor apparatus, other arthritides and joint diseases, as for instance, rheumatoid arthritis, gouty arthritis, psoriatic arthritis and exceptional hypermobility (5). Men and women develop OA with the same frequency, and the incidence of the disease increases with age. There are, however, some differences. Men more commonly developed OA of the hip, whereas in women OA of the knee and fingers is more common. OA increases with age, but we still do not know whether the association between age and

OA is because OA is a disease that develops over many years or whether it is because joints weaken with age and therefore are more susceptible to the disease or whether the association is due to a combination of factors. There is, however, no doubt that joints are more fragile in the elderly and therefore more susceptible to OA. We know that muscular strength decreases with age. And fragile joints and decreased muscular strength can be two factors of great importance for the development of OA because old joints cannot withstand sudden events like falls, twists and jolts (5)

The connection between a population's exercise habits and health status is focused on in both the Danish government's public health programme (6) and the recommendations of the Danish Arthritis Association (5) Recent research suggests that even moderate physical activity is important for health status (8). It is therefore relevant to study a population's health status, which can be measured with the help of questionnaire SF-36 (8).

1.2 The Danish healthcare system

In Denmark all inhabitants receive tax-supported health care and free access to general practitioners and public hospitals. By using a civil registry number, which is unique and individual to each Danish citizen and encodes gender and day of birth, a complete hospital discharge history can be established for each individual. In the Danish healthcare system, the responsibility for financing, planning, running and administration is today placed in five regions, but at the time of the study there were 16 regions. The Danish healthcare service provides free medical care, including both emergency and other admissions to hospitals and out-patients clinics, after referral from a general practitioner. More than 95% of the citizens are registered with one general practitioner of their own choice. After referral from a general practitioner, patients have free choice of public hospitals, and some of the private hospitals. Nearly 28% of the population have a private health insurance in addition to the public tax-paid insurance. The private health insurance is generally used for elective surgical or medical treatment in private hospitals to avoid waiting lists in the public hospitals (4). Thus, all inhabitants in Denmark can after referral receive a THR free of charge in accordance with the tax-paid healthcare system.

1.3 Total hip replacement: history and aim

Total hip replacement (THR) is a surgical procedure involving surgical removal of diseased bone from the femoral head and acetabulum. The hip joint is replaced with an artificial ball joint, which includes a stem inserted into the femoral bone with a ball on the top and an artificial socket with a plastic liner inside forming the acetabulum. The replacement thus consists of the artificial ball, the stem and the socket. In 1925, the history of THR began in the USA, in Boston Massachusetts, thanks to Marius Smith-Petersen, who devised an arthroplasty first of glass, which is a very fragile material, but later he used others materials including steel and plastic. During this period Frederick R. Thomsen from New York and Austin T. Moore from South Carolina each independently developed a haemiarthroplasty that did not involve replacement of the acetabulum. These first types of arthroplasty led to the development of the total hip arthroplasty by Dr. John Charnley in England. He used better materials consisting of polyethylene for the acetabulum and metal for the femoral component and methyl-methacrylate bone cement for fixation of the components. The Charnley prosthesis is still frequently used (1,7).

The reason for doing a THR is tremendous pain and reduced walking ability caused by osteoarthritis (OA) especially among men and women aged over 65 years (1,5,7-9).

The surgical procedures have been proven effective in relieving the patients' pain and improving their walking ability. THR is a very effective, and one of the most common surgical treatments.

OA is the most frequent disease among people aged 65 and over.

The most common and very effective treatment is surgery with a THR, which reduces pain, improves joint movements and walking ability. Men and women with OA have the same a life-expectancy as does the normal population, but their quality of life seems to be compromised compared with others in the same age group due to pain and reduced joint movement (5,9). Surgical procedures have proven effective in relieving the patients' pain and improving their joint movement. Because OA affects the middle-aged and elderly, the need for THR is predicted to increase during the coming decades due to a higher percentage of elderly in society.

Patients expect an overall improvement in all functions of their daily life, and not just pain relief and improved walking ability (5, 9, 11, 12), but a number of studies have shown that patients more or less live the life they did before surgery and do not take advantage of new possibilities of living (9, 11, 12).

For some persons, this type of surgery may not benefit their overall quality of life, because their general health status does not improve.

As a consequence, clinical effectiveness and the economic investment in healthcare from society must be both considered in reaching a funding decision. The marginal and incremental cost effectiveness ratio concept (11) has been proven to provide quantitative allocations rationales in this setting - that allow for both easy interpretation and direct comparison between treatment alternatives: The cost effectiveness ratio relates the costs of a treatment to its benefit from a patient's perspective, mostly estimated in terms of health-related quality of life (11) Estimation of a treatment's effectiveness in terms of health-related quality of life allows for a patient-related benefit interpretation, as well as for comparison of a treatment's cost effectiveness estimate with the corresponding health economic characteristic of alternative treatments (12). In particular, the estimation of a treatment's cost effectiveness enables healthcare administrators to undertake a socio-economic evaluation of the patient-related benefits of a treatment in comparison with other treatments that have already undergone this decision process.

By providing a quantitative and therefore a transparent rationale in resource allocation discussions, the particular value of the cost-effectiveness ratio in the economic evaluation of treatment concepts for older patients with THR is obvious (9,11,12).

1.4 Literature search

A number of international studies have described health status in patients. Health status includes functional ability and self-rated health but does not include medical health, economy evaluation and health-related quality of life after THR (13-15). Such a study has not yet been done in Denmark. A search of the literature was undertaken in MED-LINE using the following keywords: total hip replacement, arthroplasty, self-care, rehabilitation, self-rated health (SF-36) (10), activities of daily

living. In the Nordic countries, studies have been done in Finland (16, 17), in Sweden (18-20) and in Denmark (21-24). Studies have also been done in the USA, Canada and Australia (25-29).

In a Danish study that focused on pain and physical function 96 patients answered a questionnaire 1 week preoperatively and 1 week and again 6 months postoperatively, and 98% reported that pain had decreased but only 33% had improved physical function (21).

A Danish study of 245 patients who had undergone hip alloplasty focused on information that “would give the patients realistic expectations of the operation’s possibilities, limits and complications.” The conclusion of this study was that one-fourth of patients were not satisfied with the operative results, even though they were satisfied with the surgery itself (24).

After THR, up to 98% of patients experience pain relief (9,11,12, 17-28) and up to 80% of patients improve their walking ability, but only 33% of patients report improvements in general health and physical functions (9, 11, 12, 16, 18) For some patients, this might be explained by unrealistic expectations regarding the outcome of surgery (9), but for others it could be because many patients aged over 65 years seem to continue living as they did before the operation (11, 19). They do not seem to be able to adapt to a new way of living (19, 26, 27) even if they experience pain relief and improved walking ability. Six months after surgery, they still experience a reduced health status which reduces their ability to go on holiday travels, take part in hobby-activities and perform activities of daily living (12, 26-29); therefore some authors report that all patients do not achieve the improvement in the overall health status and quality of life that they might have benefited from after the surgery (9, 26, 29).

1.5 Summary

The aims of the THR surgery are to remove pain and improve walking ability and quality of life of patients. Men and women with OA have a life-expectancy that is the same as that of the normal population, but their quality of life (13-14) seems to be compromised compared with others in the same age group because of pain.

Compared with the normal population, patients with OA have reduced health-related quality of life and reduced social functioning, especially women, patients living alone and patients who are dependent on family support (9, 26-29).

Because OA affects the middle-aged and elderly, it is predicted that the need for THR in decades to come will increase due to a higher prevalence of OA in society (9, 26-29), and for this reason more research is needed regarding the health status of these patients.

By using questionnaire SF-36, it is possible to measuring the populations' health status and health-related quality of life within eight domains (figure 1) according to functioning, well-being and general health status. Reflecting the impact of both dysfunctions and general health perceptions the questionnaire measures: physical function (PF), role physical (RF), bodily pain (BP), social function (SF), role emotional (RE), general health (GH), vitality (VT) and mental health (MH) (10).

This research consists of three studies, first a description of patients' health status after THR followed by a randomised clinical trial using telephone interview and counselling postoperatively. The objective was to test improvement in patients' health status after THR. Finally, to test the results of nursing intervention, a measurement of patients' health-related quality of life was carried out.

Overall aim of the study:

The overall aim of this thesis was to investigate improvement in the health status of patients aged 65 and over after THR as a result of nursing rehabilitation.

2. Aims of thesis

Aims:

1. Study 1
 - a. To describe health status of patients with OA aged 65 and over after THR.
 - b. To analyse associations between health status and age, gender, living alone and dependency on help from others/family support.
2. Study 2
 - a. To study the effect on health status after THR in patients aged 65 and over by using telephone interviews 2 and 10 weeks after surgery.
3. Study 3
 - a. To compare differences in health-related quality of life expressed in QALY between an intervention and control group preoperatively and at follow-up 9 months after THR in patients aged 65 and over.

3. Material and methods

3.1 Studypopulation

Study 1

Patients aged 65 and over from five different counties in Denmark who had had a THA within the last 12 months were invited to participate in the study. A total of 314 patients from the hospitals' catchment areas who had undergone THR from January 2000 to January 2001 were enrolled; 287 patients (91.4%) participated in the study (table 1). A total of 27 people were non-responders and they were similar to the responders in terms of age and gender.

Table 1. Demographic description of participating patients distributed according to gender.

N=287	Men n=108	Women n=179	P
Age Mean(SD)	72.7(8.1)	73.2(8.6)	P=0.678
Range:	65-94	65-87	
Living alone	23.4%	63.1%	P=0.000
Dependency on help	81.0%	61.3%	P=0.001
Retired	88.9%	88.7%	P=0.562
Postoperative days (time since surgery)			
Mean (SD)	202(120)	210(110)	P=0.533
Range:	10-360	10-360	

Studies 2 and 3

The randomised controlled study was carried out in the orthopaedic departments in a university hospital in a Danish county in the period from January 2005 until May 2007. A total of 180 patients aged 65 and over living in the area of the hospital consecutively admitted to elective THR in the hospital's two departments of orthopaedic surgery were allocated to the study.

A total of 180 consecutive patients were allocated to this randomised clinical trial (figure 2).

The mean age in included patients was 74.9 years vs. 76.5 among dropouts ($P=0.270$) and 34.8% vs. 31.5% were men ($P= 1.0$). Dropout patients had a lower SF-score at baseline, and the control group had significantly higher dropout rate than did the intervention group and most patients in the intervention group completed the study.

Age of the enrolled patients ranged from of 65 to 88 years. Characteristic of patients were similar at baseline in both the intervention and the control groups (table 2).

Table 2 - Characteristics of participating patients in the intervention and control group at

baseline	Intervention	Control	P-value
Gender	n=68	n=93	
Male (%)	21(30.9%)	35(37.6%)	
Female(%)	47(69.1%)	58(62.4%)	0.236
Mean age (SD)	75.3 (5.8)	74.8 (5.6)	0.981
Living alone	41(60.3%)	53(57.6%)	0.430
Dependent on help	36(54.5%)	46(51.1%)	0.397

3.2 Methodological considerations

Study 1

A cross-sectional study was carried out to describe health status of patients with OA aged 65 and over after THR and to analyse associations between health status and age, gender, living alone and dependency on help from others/family support in these patients.

Health status: The health status was assessed by Short-Form 36 (SF-36) (figure 1). The SF-36 is a self-administered generic questionnaire that has been shown to be reliable and valid for measuring functioning, well-being and general health status (33,34). The SF-36 is a much used questionnaire in the Western countries for evaluating patients' self-rated health. In addition, it is available in a Danish version and previously validated in a sample of the general population (34), and therefore Danish norm data are available. The instrument measures the eight health dimensions listed in figure 3. Reflecting the impact of both dysfunctions and general health perception the questionnaire measures: physical function (PF), role physical (RF), bodily pain (BP), social function (SF) role emotional (RE), general health (GH), vitality (VT) and mental health (MH) (34). The questions related to each dimension are scored on a scale from 0 (worst score) to 100 (best score). In the present study the scoring of data was done according to the Danish manual to the SF-36 manual (34). All patients who had been consecutively admitted for THR were mailed a letter of introduction together with a questionnaire containing an id-number and a prepaid return envelope. In the questionnaire they were asked to give demographic data and assess their health status (appendix 4). Patients' who had not responded within 2 weeks received a reminder if they still did not respond, nothing further was done. The questionnaires were returned to the hospitals where the patients had had their surgery.

Eight dimensions of health and well-being:

Figure 1 - Health dimensions in SF-36 reflecting dysfunction and general health

<u>Dysfunction</u>	<u>General Health</u>
Physical functioning (PF)	General health perception (GH)
Role physical (RP)	Vitality (VT)
Bodily pain (BP)	Mental health (MH)
Social functioning (SF)	
Role emotional (RE)	

Five dimensions related to dysfunction - Three dimensions related to general health

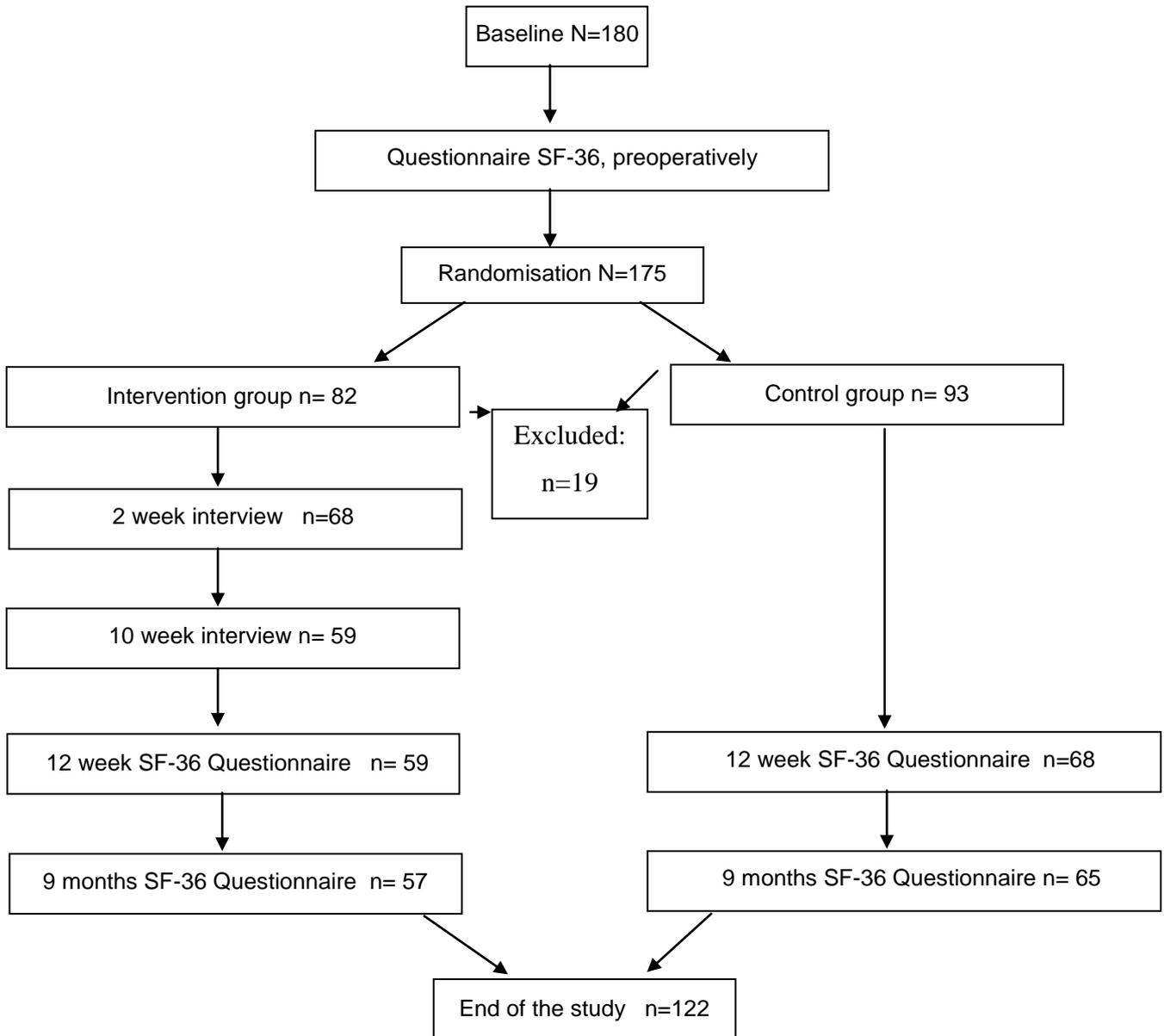
Study 2

Randomisation:

A randomised clinical trial was carried out between January 2005 and May 2007. All consecutive patients aged 65 and over were recruited from the hospitals waiting list. Randomisation to either an intervention group or control group was done by the envelope method. Neither the hospital staff nor the patients were informed of the result of the randomisation. Of the 200 envelopes prepared, 180 were been used. Nineteen patients were excluded due to changes in their surgical programme, leaving 161 patients participating in the study (figure 2). Of these 161 patients, 68 patients were allocated to the intervention group and 93 to the control group.

Flow-chart

Figure 2



Methods:

Patients received a mailed questionnaire SF-36 (appendix 4,5) at home together with a reply-paid envelope three times: 4 weeks before planned surgery, 3 and 9 months after surgery (figure 2). All patients received the standard postoperative procedure in the hospital, which means discharge after 5 to 7 days and a clinical control in the outpatient department after 3 months. But the intervention group also had telephone interviews 2 and 10 weeks after surgery. The intervention was performed by a nurse using a structured interview guide to identify the patients' perceptions of their current situations and need for further support and counselling of importance to their health status. Power calculation was used for this study, and the standard-deviation (SD) was 25.0; alpha was set to 5% and beta to 20%. With an expected improvement of 25% and willingness to overlook a difference of 12, 68 patients needed be included in the intervention group and the control group. With an expected drop-out of 22%, at least 160 patients had to participate in this randomised clinical trial (RCT) (figure 2).

Intervention:

On the basis of the interview guide, the patients and the nurse assessed the patients' situation and areas of improvement (appendix 6). The guide focused on eight main dimensions referring to the patient's situation after THR. 1. Wellbeing. 2. Expectations as to physical function after surgery, 3. Expectations as to physical function compared with before surgery. 4. Symptoms (pain, leg-oedema, vertigo, sleep disturbance, nausea, other concerns). 5. Problems with eating and appetite, 6. Fluid intake. 7. Ability to follow prescribed activity and exercise. 8. Need of support from family. For each of the problems identified, individual solutions were suggested and practical counselling was given by a specialist nurse (38).

Assessment of health status:

Health status was assessed by using the Short-Form 36 (SF-36) (figure 2). SF-36 is a self administered generic questionnaire measuring physical and emotional functioning and perception of general health (10,33-36).

The instrument measures eight health dimensions, reflecting the impact of both dysfunctions and general health status: physical function (PF), role physical (RF), bodily pain (BP), social function (SF), role emotional (RE), general health (GH), vitality (VT) and mental health (MH) (figure 1). The questions related to each dimension were transformed into a score on a scale from 0 (lowest score) to 100 (highest score). SF-36 is available in a Danish-validated version (10).

In the present study, the scoring of data was done according to the Danish manual to the SF-36 manual (10, 34). The questionnaire was supplied with specific demographic questions on gender, age, living alone and dependency of family.

Study 3

Based on study 2 (figure 2), health-related quality of life of patients aged 65 and over after THR was measured. A randomised clinical trial allocating 180 patients aged 65 and over to either an intervention group or a control group. The control group received conventional treatment and the intervention group received both conventional treatment and telephone intervention. Health-related quality of life was assessed by using the questionnaire SF-36 (13). These scores were transformed to health-related quality of life using a formula based on a method described by Brazier (15). All patients received the standard treatment of the hospital. The intervention group received telephone-monitoring consisting of support and advice 2 and 10 weeks after surgery. The telephone monitoring was performed by the same nurse using a structured interview-guide to identify the patients' perceptions of their present situations and needs for further support and/or advice to increase functional ability.

Health status

The Short Form-36 (SF-36) (figure 1) is a self-administered instrument used to assess overall health status (10). The instrument has been widely used and shown to be responsive and valid in different studies. The wide use of the instrument allows for the comparison of health status of patients with many different diseases. The instrument is a 36-item questionnaire that assess health status as it relates to the following eight domains: 1) general health (GH), 2) physical function (PF), 3) role physical (RP), 4) bodily pain (BP), 5) vitality (VT), 6) social functioning (SF), 7) role emotional

(RE), 8) mental health (MH) (figure 1). The instrument is scored as a profile, meaning that separate scores are developed for each domain, and an overall summary score is not calculated. Raw scores are standardised to a point scale ranging from 0-100, with higher scores representing better health status. Domain and summary scales scores can be normalized, using the general Danish population means, so that the average score is 50 and the standard deviation is 10 (33, 34).

Calculation of quality-adjusted life (QALY):

The score obtained have been transformed to a single index of health-related quality of life using the index of health-related quality of life using as described by Brazier (15,36), who found a correspondence between scores of SF-6D and QALY index values. To use this functional relationship, the eight domains of SF-36 had to be transformed to six SF-6D scores, which was done in a straightforward matter by merging RP and RE and omitting GH. The remaining six dimensional scores could then be translated using the empirically obtained connection between the two measures.

3.3 Ethical considerations

The study was approved by the local research ethics committee and reported to the data protection authorities. Written information was given to all participants, and it was made clear that participation was voluntary. The patients were included after giving their written consent. If a patient did not return a questionnaire, a reminder was sent once. Had the patients not returned the questionnaire after the reminder, there was no further attempt at contact. Clinical Trials Registry: NCT00226070.

3.4 Statistical considerations

Study 1

Data were processed by means of the statistics program Statistical Package for Social Sciences (SPSS) (10, 34, 37). The results using continuous data are given as mean (+/-1SD). Parametric data were tested for distribution by the F-test. If data were normally distributed, Student's unpaired two-tailed t-test was used. One-way analysis of variance was used to test for differences with in multiple

groups. To test for significance between nominal or ordinal level data, the chi-square test was used. To estimate risks and to test for association, odd ratios (OR) with a confidence interval at 95% were calculated.

P values below 0.05 were considered significant.

Study 2

Data analysis:

Data were processed by using the statistical program Statistical Package for Social Sciences (SPSS) (34, 37) version 13.0 Ratio-scaled data from both groups (intervention and control) were compared by using parametric methods if data were normally distributed, but if not non-parametric methods were used.

Nominal scaled data were compared by using the chi-square test or using 95% CI (confidence interval) around the association measure.

Categorical variables were compared using Pearson's chi-square test if appropriate. For continuous data, changes within the groups were analysed by using a paired t-test. Groups were compared using an unpaired t-test (for normally distributed data). P values less than 0.05 were considered statistically significant.

Study 3

Calculation of health-related quality of life:

The score obtained has been transformed to a single index of health-related quality of life using the approach described by Brazier (appendix 7) (15,36), who found a correspondence between scores of SF-6D and QALY index values. To use this functional relationship, the eight domains of SF-36 (figure 3) had to be transformed to six SF-6D scores, which were done in a straightforward matter by merging RP and RE and omitting GH. The remaining six dimensional scores could then be translated using the empirically obtained connection between the two measures. A paired t-test was used measuring development in health-related quality of life from preoperative to 3 and 9 months after surgery in the control and intervention groups.

4. Main results

Results of study 1

A cross-sectional study of health status in Danish patients aged 65 and over after THR.

In this cross-sectional study, patients aged of 65-95 years were enrolled from hospitals in five different counties in Denmark. More than 60% of the women were living alone vs. 25% of the men; the characteristics of the participating patients are given in table 1. The patients filled out the questionnaire approximately 202 days after surgery; no correlations were found between the scores of the eight health dimensions and the time from surgery. The study was conducted in five hospitals in different regions of the country. A one-way analysis of variance revealed a significant difference in six out of eight health dimensions on comparing the results from the five hospitals.

Table 3 - A one-way analysis of variance of differences between scores from the five participating hospitals

	F	P
<u>Dysfunction</u>		
Physical functioning (PF)	4.264	0.002
Role physical (RP)	4.184	0.003
Bodily pain (BP)	2.235	0.065
Social functioning (SF)	2.321	0.057
Role emotional (RE)	3.088	0.017
<u>General Health</u>		
General health perception (GH)	5.619	0.000
Vitality (VT)	5.221	0.000
Mental health (MH)	3.295	0.012

*F=(found variation of the group averages)/(expected variation of the group averages)

Physical dysfunction:

Table 4 shows the scores obtained in men and women divided into two age groups (65-74 and 75+). Overall, women had a significantly lower RP and SF scores than did men. In the older age group,

women living alone had a lower RP score (P= 0.018) and SF score (P= 0.037) than did women living with another person.

Women in both age groups had a significantly lower score than men in four subscales within the domain of dysfunction when they were dependent on others' help: PF (P= 0.006), RP (P= 0.000), SF (P=0.005) and RE (P=0.016). No differences were found with regards to physical dysfunction and age for men. Women aged 75+ scored significantly lower than men 75+ in four out of five domains within dysfunction, PF (P= 0.010), BP (P= 0.015), SF (P=0.008) and RE (P= 0.007).

Table 4. Differences in health status in patients aged 65-74 years compared with patients aged 75+ years, distributed according to gender.

Table 4 - Mean score of self-rated health in two age groups stratified by gender

Age	Men			Women		
	65-74 n=63	75+ n=42	P	65-74 n=91	75+ n=86	P
<u>Dysfunction</u>						
Physical functioning (PF)	55.3(27.4)	52.4(25.5)	0.584	51.9(25.4)	40.6(24.6)	0.003
Role physical (RP)	26.3(39.0)	31.0(40.1)	0.564	38.9(42.9)	18.2(33.6)	0.001
Bodily pain (BP)	60.5(30.1)	63.1(29.5)	0.663	61.2(27.0)	51.0(26.9)	0.014
Social functioning (SF)	79.9(25.0)	86.0(21.3)	0.200	78.6(28.6)	72.2(29.3)	0.150
Role emotional (RE)	50.9(39.1)	44.1(44.5)	0.441	54.3(44.6)	35.0(40.1)	0.006
<u>General Health</u>						
General health(GH)	62.0(22.1)	64.8(19.9)	0.530	61.5(23.2)	56.9(20.6)	0.181
Vitality (VT)	58.6(29.5)	62.5(24.7)	0.495	60.1(26.0)	50.0(26.4)	0.014
Mental health (MH)	77.3(23.4)	79.8(19.8)	0.580	75.8(21.6)	67.8(23.5)	0.024

Risk factors:

To establish the risk factors for dysfunction and general health perception, ORs were calculated comparing women with men, age 75+ years with 65-74 years, living alone or living with someone and not having support from others/family with having support. The risk was calculated in relation to having a lower score than the mean of the total population within the respective domain. In table 5, the ORs are presented.

Table 5. Associations between health status and factors influencing the risk of having a score below the populations' mean.

	Women OR(CI95%)	Age 75+ OR(CI95%)	Living alone OR(CI95%)	No support OR(CI95%)
Dysfunction:				
Physical functioning (PF)	1.62(0.99-2.64)	1.53(0.96-2.47)	1.62(1.01-2.60)*	1.54(0.92-2.56)
Role physical (RP)	1.10(0.67-1.82)	1.72(1.04-2.85)	1.70(1.04-2.80)*	2.32(1.30-4.12)*
Bodily pain (BP)	1.38(0.85-2.24)	1.30(0.81-2.10)	1.61(1.00-2.60)*	1.70(1.02-2.85)*
Social functioning (SF)	1.21(0.74-1.97)	1.22(0.76-1.98)	1.69(1.05-2.74)*	2.05(1.22-3.43)*
Role emotional (RE)	1.02(0.61-1.70)	1.59(0.96-2.64)	1.53(0.92-2.52)	2.20(1.25-3.89)*
General Health:				
General health (GH)	1.77(1.08-2.91)*	1.14(0.71-1.85)	.53(1.55-4.12)*	2.99(1.75-5.14)*
Vitality (VT)	1.49(0.91-2.43)	1.19(0.74-1.93)	1.69(1.04-2.73)*	1.71(1.02-2.88)*
Mental health (MH)	1.92(1.16-3.18)*	1.64(1.01-2.66)	2.09(1.28-3.42)*	2.40(1.41-4.08)*

* Significant increased risk

Living alone or having no support from family members was associated with a significantly higher risk within seven out of eight domains.

Results of study 2

The mean length of stay in hospital for all the patients was 6.4 (2.4) days. It was possible to follow 75.8% of the patients during the entire study time. Of the 82 patients who initially were randomised to the intervention group, 59 (86.7%) completed the intervention study. The interviews were completed 15.9 (3.3) and 68.5 (10.7) days after discharge from hospital. The interviews with the patients lasted between 10 and 30 minutes with a mean of 19.4 (6.4) minutes for the first interview and 22.1 (4.9) minutes for the second.

Of the patients who dropped out, 10 (26.5%) were men ($P = 0.173$), and 30 (75.8%) were living alone ($P = 0.030$), and 16 (40.6%) were dependent on family support ($P = 0.164$), and mean age was 75.7 (SD4.9) ($P = 0.413$).

During the study period, 9 intervention patients and 25 control patients ($P = 0.050$) dropped out of the study between baseline and 3 months after THR. A further two patients in the intervention group, and three patients in the control group dropped out between 3 months and 9 months during the follow-up period (figure 2).

Health status:

Patients in both the control and intervention groups reported a significant increase in several health status dimensions from baseline to 3 and 9 months after surgery (table 6). From baseline to 3 months after THR, patients in the intervention group reported increases in PF, GH and MH that were significantly higher than the increase reported by patients in the control group (table 7). From baseline to 9 months no significant differences between the groups were recorded. Twenty-four control patients dropped out from baseline to 3 months after discharge. Those who dropped out had a significantly lower score at baseline in the following dimensions: PF ($P = 0.000$), BP ($P = 0.008$), GH ($P = 0.000$), and MH ($P = 0.032$). In the interventions group eight patients dropped out. These patients had significantly lower scores at baseline within the dimension of BP ($P = 0.032$).

Table 6 - Health status of patients in the intervention and control groups at baseline and at 3 and 9 months after total hip replacement

Dimensions	Control					Intervention				
	Baseline	3 months	P-value	9 months	P-value*	Baseline	3 months	P-value	9 months	P-value*
PF	33.7	49.3	0.000	55.7	0.000	32.0	51.6	0.000	52.8	0.000
RP	14.7	30.3	0.011	38.5	0.000	13.3	24.1	0.064	38.9	0.000
BP	30.6	56.6	0.000	64.3	0.000	31.5	53.7	0.000	57.4	0.000
GH	55.1	61.5	0.526	61.5	0.630	52.8	61.6	0.000	60.6	0.007
VT	41.5	64.9	0.000	59.1	0.000	41.2	52.9	0.000	56.3	0.000
SF	61.3	75.6	0.002	77.7	0.000	60.3	74.3	0.007	76.7	0.006
RE	34.8	45.0	0.605	50.9	0.114	38.0	41.6	0.858	48.3	0.190
MH	64.5	72.0	0.073	75.9	0.002	63.5	72.9	0.000	74.4	0.000

* from baseline to 9 months

Table 7 - Differences in health status between intervention and control patients from baseline to 3 and 9 months after total hip replacement

Domains	Changes from baseline to 3 months			P-value	Changes from baseline to 9 months		
	Intervention	Control			Intervention	Control	P-value
PF	17.8	9.6	0.030	17.9	16.9	0.955	
95% CI	12.4-23.1	4.4-14.7		11.9-23.9	10.3-23.6		
RP	10.0	13.3	0.655	25.0	22.7	0.746	
95% CI	0.6-20.7	3.1-23.6		14.9-36.1	12.3-32.9		
BP	20.3	22.5	0.602	23.5	29.2	0.227	
95%CI	13.7	17.3-27.8		17.7-29.3	21.8-36.7		
GH	7.3	1.2	0.023	5.7	1.4	0.255	
95%CI	3.4-11.1	-4.8-2.5		1.6-9.9	-7.4-4.5		
VT	10.2	10.7	0.898	12.9	15.2	0.586	
95%CI	4.8-15.6	5.1-16.3		7.3-18.4	8.6-21.8		
SF	12.1	9.9	0.677	12.7	12.7	0.998	
95%CI	3.5-20.7	3.2-3.7		3.7-21.7	5.9-19.5		
RE	1.2	3.1	0.832	8.0	9.7	0.844	
95%CI	-12.1 - 14.5	- 8.8 - 14.9		4.1-20.1	2.4-21.8		
MH	11.1	4.2	0.050	12.1	8.4	0.369	
95%CI	5.9-16.3	0.4-8.8		5.8-18.4	3.1-13.7		

Results of study 3

Development in health-related quality of life expressed in QALY from preoperative to 3 and 9 months after surgery in a control and an intervention group of patients aged 65 and over with THR.

Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after surgery. No differences were found between the mean QALYs preoperatively (P=0.518), at 3 months (P=0.310) and 9 months (P=0.533). Within the groups there were no differences in gained QALY from preoperative to 3 months (P=0.587) and from preoperative to 9 months (P=0.948).

Twenty-one patients in the control group dropped out between the postoperative measurement and 3 months postoperatively.

Table 8 - Development in health-related quality of life from preoperative to 3 and 9 months after surgery in the control and intervention groups (study 3)

Control					Intervention				
Preoperative	3 months	p	9 months	P*	Preoperative	3 months	P	9 months	P*
Mean (SD)									
0.5030	0.6838	0.000	0.6610	0.000	0.4810	0.6881	0.000	0.6374	0.000

Paired t-test

* from pre-operative to 9 months.

Both the control and the intervention patients reported significant changes from their preoperative status to 3 and 9 months after surgery. No differences were found between the mean QALY preoperatively (P=0.518), at 3 months (P= 0.310) and 9 months (P=0.533). Within the groups there were no differences in gained QALY from preoperative to 3 months (P=0.587) and from preoperative to 9 months (P=0.948).

Twenty-one patients in the control group dropped-out between the postoperative measurement and 3 months postoperatively. The patients that dropped-out had a QALY of 0.3734 (0.1874) vs. 0.5516 (0.2086) (P=0.001) for patients who completed the study.

5. Discussion

Discussion of study 1

The present study showed that patients' risk of a low score in health status measured by the SF-36 was significantly increased if the patients were living alone or had no support from family/others.

The older women aged 75 and over had significantly lower health status than women aged 65 to 74. Women aged 75 and over had generally the lowest health status score.

In Denmark, males account for about 40% of THR patients. In this study they accounted for 38% (CI: 95%: 32-44), which makes the study population representative with regard to gender. Hip-replacement surgery was performed in 52 hospitals in Denmark during the study period. The present study enjoys good external validity because the hospitals were randomly chosen and no hospital refused to participate. Hence 5 (9.6%) of the 52 Danish hospitals performing hip-replacement surgery participated in the study, covering 6.3% of all hip-replacement surgery performed within in the study period (1).

A validity study has confirmed the internal consistency and homogeneity of the Danish version of the SF-36 (10,33,34), which is an established instrument for assessment of longitudinal changes in health status (35) that is applicable in total hip-replacement contexts (38,39). In a Danish study of data quality, the SF-36 could discriminate between levels of health in all subgroups, but there were skewness, kurtosis and ceiling effects in many subgroups, except for elderly people and people suffering from chronic diseases (10). Although the SF-36 includes eight distinct health status concepts and one item measuring self-reported health transition, important health concepts are not represented. Among those omitted are health distress, family functioning, sexual functioning, cognitive functioning and sleep disorders (40,41). Adding these concepts would roughly multiply the response burden four-fold (42), and measuring a comprehensive set of health concepts and the full range of levels for each concept does not necessarily produce greater detail. Short-form measures are likely to have at least two types of problems: 1) ceiling effects which entail a substantial number of people getting the highest possible scores; and 2) floor effects which include a substantial number of people receiving the lowest possible scores in a given population (33). Ceiling and floor effects were demonstrated in the Danish validation study of the SF-36 (10). In the present study, a floor effect was found in the sub-scales RP and RE because 57% (RP) and 39%

(RE) scored zero on these scales. A ceiling effect was not present because only 4-8% of patients scored 100 on at least one scale.

When using SF-36 as an instrument to identify health problems or to evaluate the effect of an intervention, the floor effect does not matter because a score of zero suggests a massive problem with the individual patient or within the group of patients, and the scale provides the possibility of measuring improvements. On the other hand, the ceiling effect could wrongly lead to overlooking a problem in the individual patient and reduce or mask the effect of an intervention.

In several studies women report a higher degree of dysfunctions than do men (38-46).

However, in these studies women were older and more likely to have concomitant diseases (43). In one study, the patients were reported to score lower at 1 month after discharge compared with a similar population. Besides, the female patients reported dysfunction with regard to general health, anxiety, depression, self-esteem and experience of sexual life compared with men (38-44). In another study the women were less likely than the men to be married, able to perform basic self-care activities and more demanding activities required for independent living, recreation and maintaining a household. Women were also more anxious and reported more symptoms of depression than did men (43-46). In the present study we found the same patterns in the rating of health status, but the women were not older than the men. No data are available in this study to explain this difference.

Limitations of the study

The findings in this study should be interpreted with caution due to the cross-sectional nature of the study. Thus the study only shows the characteristics of the chosen population at the specific time within specific domains. Patients' health status was measured within 12 months after THR using the SF-36, and the findings show - that the patients' activities of daily living and self-care ability were compromised and that a rehabilitation programme aimed at improving these dimensions is needed.

However, intervention research is required before such a programme can be implemented. It is necessary to perform further research regarding specific recommendations for men and women aged over 65 years after THR, taking consideration of the individual patients risk factors.

Discussion of study 2

Both the intervention and control groups (tables 2, 3) had improvement in SF scores, whereas baseline scores were clearly below values for the normal population (30), but after surgery the intervention group had significantly higher scores within 3 months. A total of 25 (95%. CI: 17.2-35.3) patients from the control group, and 9 patients (10.9%) ($P < 0.05$) from the intervention group dropped out. The telephone interviews 2 and 10 weeks after surgery may be the reason why patients in the intervention group did not drop out of the study.

Dropout patients in the control group had a significantly lower SF-36 score at baseline within the dimensions PF, GH and MH. Thus the patients with the highest scores were included in the data analysis. This means that differences in improvement of SF scores found between the control and the intervention patients might actually have been higher. Telephone interviews also seem to be a means of keeping in touch with the patients with the most health problems.

In this study, patients in the control group had significant differences in five of eight dimensions on their SF-36 scores after 9 months

The study is characterized by a high degree of internal validity in terms of accounting for patient selection, and a large number of patients were available for both 3 and 9 month follow-ups. Furthermore, patients were randomised to the study from a waiting list.

The intervention group and the control group were similar regarding demographic variables, age, gender, living alone and dependency on family support, but 13.3% patients dropped out from 2 to 10 weeks after THR. Among patients in the intervention group, 86.3% completed the trial.

Our objective was to study whether conventional treatment and nursing intervention by telephone interviews 2 to 10 weeks after surgery versus conventional treatment alone had any effect on health status in patients aged 65 and over after THR. To our knowledge, this is the first randomised clinical study focusing on this specific topic.

Dropout is a well known phenomenon in any study. In some studies, it is difficult to identify the dropout rate (44) and in other similar studies the dropout rates have been given to be between 13% to 52% (21, 39, 44), In this study the dropout-rates was 24.2%.

Methodically, it has been possible to complete a RCT measuring health status with SF-36. This instrument is an often-used questionnaire and widely validated (10, 33-36). Thus it was possible to make valid conclusions based on the findings in this study (10, 12, 19, 21, 32, 43-46).

Discussion of study 3

To our knowledge, no RCT studies exists describing health-related quality of life based on health status using SF-36 in which the control group received conventional treatment and the intervention group received both conventional treatment and telephone intervention by a nurse. To validate this study further, studies using the same procedure are needed. The resulting assessment of the improvement in patients' self-reported health has been presented both in the form of SF-36 scores and as QALYs, but since the latter were obtained from the former they do not represent new independent findings. For this, one would need patient reports using another instrument like the EQ-5D, which is now widely used in health-economic assessments. In addition to offering new evidence on the effects of the intervention, such data would shed light on the usefulness of each instrument for measuring gains in health-related quality of life.

We cannot explain why the differences in these two outcome measures occurred, but future studies may look into this problem.

6. Conclusions

Conclusion of study 1

Patients' health status after THR is can to be used as a means to identify dysfunction and as a measure of outcome. These efforts may improve patients' health status and benefit the total outcome of THR surgery. This study indicates that 12 months after surgery, patients still had dysfunction

In conclusion, the present results demonstrate the need for a structured and specific intervention programme focusing on patients' health status both preoperatively and postoperatively. Moreover, a follow-up study should last more than 6 months and should address improvement in patients' self-rated health measured in terms of activities of daily living and self-care ability.

Clinical assumptions:

It seems that specific groups such as women living alone, patients aged 75 and over, and patients dependent on help from family have an increased risk of dysfunction and therefore need individual follow-up and advice to improve their health status.

Conclusion of study 2

In conclusion, this seems to be the first RCT of health status in which SF-36 scores and specialist nurse telephone interviews after THR were used. We revealed significant improvement in patient health status, especially from baseline to 3 months after THR, suggesting the possibility that patients could achieve an even higher score. In addition, individual counselling by way of telephone interviews might possibly reduce risk factors among patients living alone and dependent on family support. Patients in the control group had significant differences in five of eight domains in their SF-36 scores.

This study demonstrates that telephone interviews 2 and 10 weeks after surgery increase patient health status during the first 3 months after THR compared with conventional postoperative care. Because this RCT is the first study of its kind, we recommend that it be repeated in other settings to verify the findings.

Conclusion of study 3

Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after THR. No differences were found between the mean QALY's pre-operatively and at 3 months and 9 months postoperatively within the timeframe of this study.

There was a significant gain in QALY in both groups. However, no significant or clinical relevant differences between the two groups were observed within the follow-up time.

Conclusion

The overall aim of this thesis was to investigate improvement in health status of patients aged 65 and over after THR as a result of nursing rehabilitation which could aid in the development of a clinical guidelines for rehabilitation after THR.

Clinical guidelines are systematically developed statements that assist clinicians and patients in making decision about appropriate treatments for specific conditions. They are derived from the best available research evidence, using predetermined and systematic methods to identify and evaluate the evidence relating to the specific condition in question. (47).

THR surgery has been performed for more than 40 years, but no systematic nursing rehabilitation program has been developed for the patients because research evidence was lacking. Therefore it was necessary to describe the nature and prevalence of problems experienced by the patients after THR, and then test specific nursing activities with regards to their effect on health status and the patients health-related quality of life. The results presented in this thesis are the first steps in the development of a clinical guideline for THR rehabilitation, but before clinical guidelines can be developed for the rehabilitation of these patients, additional research with longer follow-ups is needed regarding the effect of telephone interviews combined with individual and specific nursing interventions on the improvement of the health status of patients after orthopaedic operations.

7. Perspectives

Further research in this area could involve evaluating whether patient health status might be further improved by using structured telephone interviews 2 and 10 weeks after surgery in all patients after THR. Moreover, there is the need to develop specific programmes based on health status and data

from the telephone interview that patients can use at home after THR. Further research may lead to individual and specific programmes that provide possibilities for nurses to purposefully guide patients in reaching their optimal health-related quality of life.

One way could be planning specific nursing rehabilitation and interventions preoperatively based on patients' health status, because as shown in study 1, patients' risk of a low score in health status measured by the SF-36 was significantly increased if the patients lived alone or had no support from family/others.

Older women aged 75 and over had significantly lower health status than women aged 65-74 years. Women aged 75 and over had generally the lowest health status score.

Our results indicate that health status scores were low in some groups of patients. This implies that there is a need for further postoperative interventions. Research in nursing intervention after discharge from hospital is needed to improve patients' health status after surgery.

Identification of patients at risk of having a low health status would improve the general surgical outcome. This seems to be the first RCT of health status in which SF-36 scores and specialist nurse telephone interviews after THR were used. We revealed significant improvement in patient health status especially from baseline to 3 months after THR, suggesting that even higher scores were a possibility.

In addition, individual counselling through telephone interviews could possibly reduce risk factors among patients living alone and dependent on family support. Patients in the control group had significant differences in five of eight domains in their SF-36 scores.

This study demonstrates that nursing intervention by telephone interviews after surgery increases patient health status during the first 3 months after THR compared with conventional care.

In study 3, both the control and the intervention patients reported significant improvement from their preoperative status to 3 and 9 months after surgery.

As this RCT is the first study of its kind, we recommend that it to be repeated in other settings to verify the results.

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48. 9. Figures & tables

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10. APPENDICES

Original papers

1. A cross-sectional study of health status in Danish patients aged 65 and over after total hip replacement.
2. Nursing intervention by telephone interviews of patients aged 65 and over after total hip replacement improves health status: a randomised clinical trial.
3. Health-related quality of life of patients aged 65 and over after total hip replacement.

Interview-schedule etc.

4. Questionnaire SF-36.
5. Patient-information formula.
6. Interview-guide.
7. Calculation of QALY by Braziers formula.

APPENDIX 1

Abstract:**Background and purpose:**

THR is as a very efficient operation in terms of pain-relief and improvement of walking ability. However, after the operation some patients still report low health status.

The aim of the study is to describe health status of patients with osteoarthritis aged over 65 years following THR and to analyse associations between health status and age, gender, living alone and dependency on help from others/family support.

Method

A cross-sectional study including 287 patients aged 65+, who had had THR within the past 12-months was performed.

Patients from five Danish counties received a mailed questionnaire assessing health status and demographic data. Short Form-36 measures eight domains of importance for health status. 287 (91.4%) patients participated.

Results:

The patients answered the questionnaire 202(120) days after surgery. Patients living alone or being depended on help from others had a significantly increased risk of having lower scores in 7 of domains of health status after surgery.

Interpretation:

Our results indicate that health status is scored low in some groups of patients. This implies that there might be a need for further postoperative interventions.

Identification of patients in risk of having a low health status might improve the total outcome of surgery.

Keywords: Health-status, SF-36, elderly people, total hip-replacement, rehabilitation

Introduction:

Osteoarthritis is the most frequent disease among people over 65 years. Men and women with osteoarthritis have a life-expectancy as the normal population, but their quality of life seems to be compromised compared to others in the same age group due to pain, reduced joint movement and walking ability (1). Total hip replacement (THR) is a very effective and one of the most common treatments. The surgical procedures are proven effective in relieving the patients' pain and improving their walking ability. In Denmark with a population of 5 million people, approximately 20% of the population are over the age of 65 years, the annual incidence of THR among patients aged 65+ is about 4500 (2). As osteoarthritis affects the middle-aged and elderly, the need of THR is predicted to increase during the next decades due to the higher percentage of elderly in society (2).

For some persons, this type of surgery may not benefit the overall quality of life, as their health status does not improve accordingly. Patients do expect an overall improvement in all functions of their daily life after surgery, and not only pain relief and improved walking ability (3,4,5,6,7,8), but a number of studies have described that patients more or less live the life they did before surgery and that they do not adapt to the new possibilities of living (4,9,10,11). These studies also indicate that married couples seem to have a better health status compared to both men and women living alone or patients dependent on others help. (9,10,12).

Studies have reported that to regain health status postoperative training during the first six months postoperatively may be of decisive importance for the long- term benefit (3,6,7,13,14) but these studies do not indicate whether all patients need training or training only should be offered to specific groups.

However, no previous Danish studies have identified health status among patients aged over 65 years after THA and identified whether specific groups of patients are at risk of having a low health status after THA. Thus, before recommending a permanent rehabilitation and intervention program a cross-sectional study estimating the general health status (15,16,17) was carried out.

Aims of the study:

- To describe health status of patients with osteoarthritis aged over 65 years following THR.
- To analyse associations between health status and age, gender, living alone and dependency on help from others/family support.

Patients and methods

Patients over 65 years from five different counties in Denmark, who had had a THA within the last twelve months, were invited to participate in the study. The hospitals represented 5 out of 13 counties in Denmark, different parts of the county, urban and rural areas. The hospitals were chosen by convenient sampling. Non of the hospitals, who were invited to participate declined. Totally 314 patients from the hospitals catchments areas underwent THR from January 2000 to January 2001 and they were all enrolled, 287 patients (91.4%) participated in the study. A total of 27 people were non-responders and they were similar to the responders in terms of age and gender.

Design.

A cross-sectional study design was used. All patients who had been consecutive admitted for THR were mailed an introduction letter together with a questionnaire containing a number and a prepaid return envelop. In the questionnaire they were asked to give demographic data and assess their health status. Patients' who had not responded with-in two weeks received a reminder, if they still

did not respond not further was done. The questionnaires were returned to the hospitals where the patients had their surgery.

Health status

The health status was assessed by Short-Form 36 (SF-36). The SF-36 is a self-administered generic questionnaire that used, reliable, and valid for measuring functioning, well being and general health status (15). The SF-36 is a much used questionnaire in the western countries for evaluating patients' self-rated health. Besides, it is available in Danish version and previously validated in a sample of the general population (16), therefore Danish norm data are available. The instrument measures the eight health dimensions listed in table 2. Reflecting the impact of both dysfunctions and general health perception the questionnaire measures: physical function (PF), role physical (RF), bodily pain (BP), social function (SF) role emotional (RE), general health (GH), vitality (VT) and mental health (MH) (18). The questions related to each dimension are scored on a scale from 0 (worst score) to 100 (best score). In the present study the scoring of data was done according to the Danish manual to SF-36 manual (15).

Ethics:

The study was approved by The Local Research Ethics Committee and reported to The Data Protection Authorities. Written information was given to all participants and it was made clear that participation was voluntary.

Data analysis:

Data were processed by means of the statistics program Statistical Package for Social Sciences (SPSS). The results using continuous data are given as mean (+/-1SD). Parametric data were tested for distribution by the F-test. If data were normally distributed the Student's unpaired two-tailed t-test was used. One-way analysis of variance was used to test for differences with in multiple groups.

To test for significance between nominal or ordinal-level data, the chi-square test was used. To estimate risks and to test for associations Odds Ratios (OR) with a confidence interval at 95% were calculated. P-values below 0.05 were considered significant.

Results:

In this cross-sectional study patients of the age of 65-95 were enrolled from hospitals in five different counties in Denmark. More than 60% of the women were living alone vs 25% of the men, the characteristics of the participating patients are given in Table 1. The patients filled out the questionnaire 207(114) days after surgery, no correlations were found between either of the scores of the eight health dimensions and the time from surgery. The study was conducted in five hospitals in different regions of the country. A one-way analysis of variance revealed a significant difference in 6 out of 8 health dimensions when comparing the results from the five hospitals (table 3).

Physical dysfunction:

Table 4 shows the scores from men and women divided in two age groups (65-74 and 75+). Overall women had a significantly lower RP and SF score than men. In the older age group women living alone had a lower RP score ($P=0.018$) and SF score ($P=0.037$) than women living with another person. Women in all age groups had a significantly lower score in four subscales within the domain of dysfunction, when they were dependent on others' help: PF ($P=0.006$), RP ($P=0.000$), SF ($P=0.005$) and RE ($P=0.016$). No differences were found with regards to physical dysfunction and age for men. Women aged 75+ scored significantly lower than men 75+ in four out of five domains within dysfunction, PF ($P=0.010$), BP ($P=0.015$), SF ($P=0.008$) and RE ($P=0.007$).

In the present study, 0-2.5% of the patients reported a score of zero except for the sub-scale the RP

and (RE) where 57% respectively 39% reported a score of zero and 4-8% of patients reported a score of 100 at least on one scale.

Risk factors:

To establish the risk factors for dysfunction and general health perception ORs were calculated comparing women with men, age 75+ years with 65-74 years, living alone or living with someone and not having support from others/family with having support. The risk was calculated in relation to having an equal/higher or lower score than the mean of the total population within the respective domain. In Table 5 the ORs are presented.

Living alone or having no support from family members was associated with a significant higher risk within seven out of eight domains.

Discussion:

The present study showed that patients' risk of a low score in health status measured by the SF-36 was significantly increased if the patients were living alone or had no support from family/others.

Older women (75+) had significantly lower health status than women (65-74). Women aged 75+ had generally the lowest score of health status.

In Denmark, males account for about 40% of THR patients. In this study they accounted for 38% (CI: 95%: 32-44), which makes the study population representative of gender. Hip-replacement surgery was performed in 52 hospitals in Denmark during the study period. The present study enjoys good external validity even if the hospitals were not randomly chosen as the hospital represented both urban and rural areas of the country, and differences in treatment due to local culture, habits and tilbud indenfor rehabilitering. Hence 5(9.6%) of the 52 Danish hospitals

performing hip-replacement surgery participated in the study, covering 6.3% of all hip-replacement surgery performed within in the study period (2).

It is interesting that no correlations were found between either of the scores of the eight health dimensions and the time from surgery even if the patients reported on their health status from 10-360 days after surgery. One might have expected a difference in the scores.

As the study design is cross-sectional the changes over time and with-in the individual patients are not revealed. The findings therefore, underline the need for further research into the recovery pattern of these patients.

A validity study has confirmed the internal consistency and homogeneity of the Danish version of the SF-36 (15), which is an established instrument for assessment of longitudinal changes in health status(16) also applicable in total hip-replacement contexts (10,11). In a Danish study of data quality, the SF-36 could discriminate between levels of health in all subgroups but there were skewness, kurtosis and ceiling effects in many subgroups except for elderly people and people suffering from chronic diseases (17). Although the SF-36 includes eight distinct health status concepts and one item measuring self-reported health transition, important health concepts are not represented. Among those omitted are: health distress, family functioning, sexual functioning, and cognitive functioning and sleep disorders (19). Adding these concepts would roughly multiply the response burden four-fold (19), and measuring a comprehensive set of health concepts and the full range of levels for each concept does not necessarily bring about greater detail. Short-form measures are likely to have at least two types of problems: 1) ceiling effects which entail a substantial number of people getting the highest possible scores; and 2) floor effects which include a substantial number of people receiving the lowest possible scores in a given population (19). Ceiling and floor effects were demonstrated in the Danish validation study of the SF-36 (17). In the

present study, a floor effect was found in the sub-scales RP and RE because 57% (RP) and 39% (RE) scored zero on these scales. A ceiling effect was not present. We do not have data to explain the floor effect, but the findings emphasize the need for further research.

In general women report a higher degree of dysfunctions than men (20,21,22,23). However, in these studies women were older and more likely to have concomitant diseases (24). In one study the patients were reported to score lower at one month after discharge compared with those in a similar population. Besides, the female patients reported dysfunction according to general health, anxiety, depression, self-esteem and experience of sex life compared with men (20,21,22,23). In another study the women were less likely than the men to be married, able to perform basic self-care activities and more demanding activities required for independent living, recreation and maintaining a household. Women were also more anxious and reported more symptoms of depressions than men (24). In the present study we found the same patterns in the rating of health status, but the women were not older than the men. No data are available in this study to explain this difference.

Limitations due to the study.

The findings in this study should be interpreted with caution due to the cross-sectional nature of the study. Hence, it only shows the characteristics of the chosen population at the specific time within specific domains. Patients' health status was measured within twelve months after THR using the SF-36 and the findings therefore show, that the patients' activity of daily living and self-care ability was compromised and that a rehabilitation program aimed at improving these dimensions might be needed.

However, intervention research is needed before such a program can be implemented. It is necessary to perform further research into specific recommendations for men and women aged over 65 years after THR, considering the individual patients risk factors.

Conclusion

Patients` health status after THR could be used as a means to identify dysfunction and as a measure for outcome. These efforts may improve patients` health status and benefit the total outcome of THR surgery. This study indicates that twelve months after surgery patients still had dysfunction

In conclusion the present results demonstrate a need of a structured and specific intervention program focusing on patients` health status both preoperatively and postoperatively. Moreover, a follow-up study should last more than six months and should address improvement in patients` self-rated health measured in terms of activities of daily living and self-care ability.

Clinical assumptions:

It seems that specific groups such as women, patients living alone, patients aged 75+ and patients depended on help from family have an increased risk of having dysfunctions and in need for individual follow-up and advices to improve their health status.

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Table 1. Characteristics of participating patients

N=287	Men n=108	Women n=179	
Age			
Mean(SD)	72.7(8.1)	73.2(8.6)	p=0.678
Range:	65-94	65-87	
Living alone	23.4%	63.1%	p=0.000
Dependency on help	81.0%	61.3%	p=0.001
Retired	88.9%	88.7%	p=0.562
Postoperative days (time since surgery)			
Mean (SD)	202(120)	210(110)	p=0.533
Range:	10-360	10-360	

Table 2: Health dimensions in SF-36 reflecting dysfunction and general health:

8 Dimensions of health and well-being:

5 Dimension related to dysfunction:

(PF) Physical Function

(RP) Role Physical

(BP) Bodily Pain

(SF) Social Function

(RE) Role Emotionel

3 Dimensions related to general health:

(GH) General Health perception

(VT) Vitality

(MH) Mental Health

Table 3: A one-way analysis of variance of differences between scores from the five participating hospitals.

* F =(found variation of the group averages)/(expected variation of the group averages)

	F	P
<u>Dysfunction</u>		
Physical functioning (PF)	4.264	0.002
Role physical (RP)	4.184	0.003
Bodily pain (BP)	2.235	0.065
Social functioning (SF)	2.321	0.057
Role emotional (RE)	3.088	0.017
<u>General Health</u>		
General health perception (GH)	5.619	0.000
Vitality (VT)	5.221	0.000
Mental health (ME)	3.295	0.012

Table 4: Mean score of self-rated health in two age groups stratified by gender.

Age	Men			Women		
	65-74 n=63	+75 n=42	p	65-74 n=91	+75 n=86	p
<u>Dysfunction</u>						
Physical functioning (PF)	55.3(27.4)	52.4(25.5)	.584	51.9(25.4)	40.6(24.6)	.003
Role physical (RP)	26.3(39.0)	31.0(40.1)	.564	38.9(42.9)	18.2(33.6)	.001
Bodily pain (BP)	60.5(30.1)	63.1(29.5)	.663	61.2(27.0)	51.0(26.9)	.014
Social functioning (SF)	79.9(25.0)	86.0(21.3)	.200	78.6(28.6)	72.2(29.3)	.150
Role emotional (RE)	50.9(39.1)	44.1(44.5)	.441	54.3(44.6)	35.0(40.1)	.006
<u>General Health</u>						
General health (GH)	62.0(22.1)	64.8(19.9)	.530	61.5(23.2)	56.9(20.6)	.181
Vitality (VT)	58.6(29.5)	62.5(24.7)	.495	60.1(26.0)	50.0(26.4)	.014
Mental health (ME)	77.3(23.4)	79.8(19.8)	.580	75.8(21.6)	67.8(23.5)	.024

Table 5: Odd ratios for having a score of self-rated health above the population's mean.

	Women	Age 75+	Living alone	No support
	OR(CI95%)	OR(CI95%)	OR(CI95%)	OR(CI95%)
Dysfunction:				
Physical functioning (PF)	1.62(0.99-2.64)	1.53(0.96-2.47)	1.62(1.01-2.60)*	1.54(0.92-2.56)
Role physical (RP)	1.10(0.67-1.82)	1.72(1.04-2.85)	1.70(1.04-2.80)*	2.32(1.30-4.12)*
Bodily pain (BP)	1.38(0.85-2.24)	1.30(0.81-2.10)	1.61(1.00-2.60)*	1.70(1.02-2.85)*
Social functioning (SF)	1.21(0.74-1.97)	1.22(0.76-1.98)	1.69(1.05-2.74)*	2.05(1.22-3.43)*
Role emotional (RE)	1.02(0.61-1.70)	1.59(0.96-2.64)	1.53(0.92-2.52)	2.20(1.25-3.89)*
General Health:				
General health (GH)	1.77(1.08-2.91)*	1.14(0.71-1.85)	2.53(1.55-4.12)*	2.99(1.75-5.14)*
Vitality (VT)	1.49(0.91-2.43)	1.19(0.74-1.93)	1.69(1.04-2.73)*	1.71(1.02-2.88)*
Mental health (ME)	1.92(1.16-3.18)*	1.64(1.01-2.66)	2.09(1.28-3.42)*	2.40(1.41-4.08)*

* Significant increased risk.

APPENDIX 2

Nursing intervention by telephone interviews of patients aged 65 and over after total hip replacement improves health status: a randomised clinical trial.

Abstract:

Objective: To study the effect on health status of intervention by telephone interviews 2 and 10 weeks after total hip replacement (THR) during the first 9 months after surgery.

Design: A randomised clinical trial focusing on patients' health status by using SF-36 at 4 weeks pre- and 3 and 9 months postoperatively was carried out. Sample: 180 patients aged 65 and over were randomised 4 weeks preoperatively to either to control or intervention groups. Measurements: Both groups received the conventional surgical treatment, but the intervention group was interviewed by telephone 2 and 10 weeks after surgery. Patients were given counselling within eight main dimensions with reference to their postoperative situation.

Results: All patients experienced improvement in health status. The intervention significantly reduced the time patients needed to reach their habitual levels: the intervention patients reached their habitual levels at 3 months whereas the control patients reached theirs after 9 months.

Conclusion: Intervention by telephone interviews in the postoperative phase seems to benefit patients' improvement in health status.

Key-words: THR – elderly patients – health status – postoperative intervention

Osteoarthritis (OA) of the hip is a severe condition that causes pain and reduced physical and social functioning for patients and results in economic burdens for society. Compared with the normal population, patients with OA have reduced health-related quality of life and reduced social functioning, especially women, patients living alone and patients who are dependent on family support (1-5).

The most common, and very effective, treatment of OA is surgery with total hip replacement. As OA affects the middle-aged and elderly, it is predicted that the need for THR in decades to come will increase due to a higher prevalence of OA in society (1-5).

In the EU member states over 190,000 total hip replacements (THR) are performed every year. In the Nordic countries some 50,000 THR are carried out annually (6). In Denmark with a population of 5 million people, approximately 15% of the population are aged 65 and over, and among this population the annual number of THR is about 4,500 (7).

After THR, up to 90% of the patients experience pain relief (8-17) and up to 80% of patients improve their walking ability, but only 33% of the patients report improvements in general health and physical functions (8-10, 17,18) For some patients, it might be explained by unrealistic expectations regarding the outcome of surgery (8), but for others it could be because many patients aged over 65 years seem to continue living as they did before the operation (10,16). They do not adapt to other new ways of living (11,15,16) even if they experience pain relief and improved walking ability. Six months after surgery they still experience reduced health status which reduces their ability to go on holiday travels, take part in hobby-activities and perform activities of daily living (11-15) therefore some authors suggest that all patients do not achieve the improvement in the overall health status and quality of life that they might have benefited from after the surgery (1,3,4).

Married couples seem to have a greater increase in health status than both men and women living alone (11,12,15). Living alone and dependency on family support – especially for women- are factors associated with a low score in all dimensions of health status after THR (1,3,4).

Individually planned support, counselling and training during the first 6 months postoperatively may be of decisive importance for improving the outcome of THR (11-15).

Telephone interviews (19) after early discharge of patients after open heart surgery revealed that these patients suffer from health problems such as leg oedema, appetite disturbance, dyspnoea, sleep disturbance, and wound drainage after surgery (20-23). By telephone, a clinical nurse specialist provided advices and counselling to support the postoperative progress, fluid and diet intake, instructions about activity, medical treatment, and the phone contact also provided emotional support. Overall, patients in the study assessed their progress and wellbeing positively (19).

We have not identified previous studies that have focused on the patients problems in the early postoperative phase after discharge. And no studies have evaluated the effect of systematic telephone interviews after discharge.

Objective:

To study the effect on health status after THR in patients aged over 65years by using telephone interviews 2 and 10 weeks after surgery.

Methods:

Sample:

The present randomised controlled study was carried out in two orthopaedic departments in a university hospital in Denmark in the period from January 2005 until May 2007. A total of 180

patients aged 65 and over living in the area of the hospital who were consecutively admitted to elective THR in the hospital's two departments of orthopaedic surgery were allocated to the study.

A total of 180 consecutive patients were allocated to this randomised clinical trial (figure 1).

Among the dropout patients the mean age was 76.5 years and 31.5% were men vs 74.9 years ($p=0.270$) and 34.8% men ($p=1.0$) in the included patients. Dropout patients had a lower SF-score at baseline, and the control group had significantly higher dropout rate than did the intervention group and most patients in the intervention group completed the study.

Age of enrolled patients ranged from 65 to 88 years. Characteristics of patients were similar at baseline in both the intervention and the control group (table 1).

Design:

Between January 2005 and May 2007 all consecutive patients were allocated to a randomised controlled trial. Power calculation was used for this study, and the standard-deviation (SD) was 25.0; alpha was set to 5% and beta to 20%. With an expected improvement of 25% and willingness to overlook a difference of 12, 68 patients needed be included in the intervention group and the control group. With an expected dropout of 22% at least 160 patients had to participate in this randomised clinical trial (RCT) (figure 1).

All patients were recruited from the hospital's waiting list. Randomisation to an intervention group or control group was done by the envelope method. Neither the hospital staff nor the patients were informed of the result of the randomisation. Of the 200 hundred envelopes that were prepared, 180 were used – 19 patients were excluded due to changes in their surgical program - leaving 161 patients to participate in the study (figure 1). Of these 161 patients, 68 patients were allocated to the intervention group and 93 to the control group.

Intervention:

All patients received the standard postoperative procedure in the hospital, which means discharge after 5 to 7 days and a clinical control in the outpatient department after 3 months. But the intervention group also had telephone interviews 2 and 10 weeks after surgery.

The intervention was performed by the same nurse using a structured interview guide to identify the patients' perceptions of their current situations and need for further support and counselling of importance to their health status.

On the basis of the interview guide, the patients and the nurse assessed the patients' situation and areas of improvements. The guide focused on eight main dimensions referring to patients' situation after THR. 1. Wellbeing. 2. Expectations as to physical function after surgery, 3. Expectations as to physical function compared to before surgery? 4. Symptoms (pain, leg-oedema, vertigo, sleepdisturbance, nausea, other concerns), 5. Problems with eating and appetite, 6. Fluid intake, 7. Ability to follow prescribed activity and exercise, 8. Need of support from family. For each of the problems identified, individual solutions were suggested and practical counselling was given by a clinical nurse specialist.

Power calculation was used for this study, and the standard-deviation (SD) was 25.0; alpha was set to 5% and beta to 20%. With an expected improvement of 25% and willingness to overlook a difference of 12, 68 patients needed be included in the intervention group and the control group.

With an expected dropout of 22% at least 160 patients had to participate in this randomised clinical trial (RCT) (figure 1).

Measures:

Main outcomes was health status measured by the questionnaire Short-form 36 (SF-36). Patients received the mailed questionnaire at home together with a reply-paid envelope three times: 4 weeks before planned surgery, 3 and 9 months after surgery (figure 1).

Health status was assessed by using the Short-Form 36 (SF-36) (figure 2). SF-36 is a self-administered generic questionnaire measuring physical and emotional functioning and the perception of general health (24-28).

The instrument measures eight health dimensions, reflecting the impact of both dysfunctions and general health status: physical function (PF), role physical (RF), bodily pain (BP), social function (SF) role emotional (RE), general health (GH), vitality (VT) and mental health (MH). The questions related to each dimension were transformed into a score on a scale from 0 (lowest score) to 100 (highest score), with a higher score indicating a better health status. SF-36 is available in a Danish validated version (26,27).

In the present study the scoring of data was done according to the Danish manual to SF-36 manual (26). The questionnaire was supplied with specific demographic questions on gender, age, living alone, and dependent on others help.

Ethics:

The patients were included after giving their written consent. If a patient did not returned a questionnaire a reminder was sent. Had the patients not returned the questionnaire after the reminder there was no further contact. The study were approved by The Local Research Committee and reported to The Data Protection Authorities. The Clinical Trials Registry: NCT00226070.

Statistical analysis:

Data were processed by using the statistical program Statistical Package for Social Sciences (SPSS) version 13.0. Ratio-scaled data from both groups (intervention and control) were compared by using parametric methods if data were normally distributed, but if not non-parametric methods were used. Nominal scaled data were compared by using the chi-square test or using 95% CI around the association measure.

Categorical variables were compared using Pearson's chi-square test if appropriate. For continuous data, changes within the groups were analysed by using a paired t-test. Groups were compared using an unpaired t-test (for normally distributed data). P-values less than 0.05 were considered statistically significant.

Results:

The mean length of stay in hospital for all the patients was 6.4 (2.4) days. It was possible to follow 75.8% of the patients during the entire study time. Of the 82 patients who initially were randomised to the intervention group, 59 (71.7%) completed the intervention study. The interviews were completed 15.9 (3.3) and 68.5 (10.7) days after discharges from hospital. The interviews with the patients lasted between 10 and 30 minutes with a mean of 19.4 (6.4) minutes for the first interview and 22.1 (4.9) minutes for the second.

Of the patients who dropped out 10 (26.5%) were men ($p = 0.173$), 30 (75.8%) were living alone ($p = 0.030$), and 16 (40.6%) were depended on family support ($p = 0.164$), and mean age was 75.7 (SD4.9) ($p = 0.413$).

During the study period, 9 intervention patients and 25 control patients ($p = 0.050$) dropped out of the study between baseline and 3 months after THR. A further two patients in the intervention

group, and three patients in the control group dropped-out between 3 months and 9 months during the follow-up period.

Outcome:

Patients in both the control and intervention groups reported a significant increase in several health status dimensions from baseline to 3 and 9 months after surgery (table 2). From baseline to 3 months after THR, patients in the intervention group reported increases in PF, GH and MH that were significantly higher than the increase reported by patients in the intervention group (table 3). From baseline to 9 months no significant differences between the groups were noticed.

Twenty-four control patients dropped out from baseline to 3 months after discharge. Those who drop out had a significantly lower score at baseline in the following dimensions: PF ($p = 0.000$), BP ($p = 0.008$), GH ($p = 0.000$), and MH ($p = 0.032$). In the interventions group eight patients dropped out: these patients had a significantly lower scores at baseline within the dimension of BP ($p = 0.032$).

Discussion:

Both the intervention and control groups (tables 2, 3) had improvement in SF scores, whereas baseline scores were clearly below the values of the normal population (25), but after surgery the intervention group had significant higher scores within 3 months. A total of 25 (95%. CI: 17.2-35.3) patients from the control group, and 9 patients (10.9%) ($p < 0.05$) from the intervention group had dropped out. The telephone interviews 2 and 10 weeks after surgery may be the reason why patients in the intervention group did not drop out of the study.

Dropout patients in the control group had a significantly lower SF-36 score at baseline within the dimensions PF, GH and MH: thus the patients with the highest scores were included in the data

analysis. This means that differences in increase found between the control and the interventions patients in reality might have been higher. Telephone interviews also seem to be a means of keeping in touch with the patients with the most health problems.

In this study, patients in the control group had significant differences in five of eight dimensions on their SF-36 scores after 9 months

The study is characterized by a high degree of internal validity in terms of accounting for patient selection, and a large number of patients were available for both 3 and 9 months follow-ups.

Furthermore, patients were randomized to the study from the waiting list.

The intervention group and the control group were similar regarding demographic variables, age, gender, living alone and dependency on family support, but 13.3% patients dropped out from 2 to 10 weeks after THR. Among patients in the intervention group, 86.3% completed the trial.

Our objective was to study whether conventional treatment and intervention by telephone interviews 2 to 10 weeks after surgery versus conventional treatment alone had any effect on health status in patients aged over 65 years after THR. To our knowledge, this is the first randomised clinical study focusing on this specific topic.

Dropout is a well known phenomenon in any study. In some studies, it is difficult to identify the dropout rate (21) and in other similar studies the dropout rates have been given to be between 13% to-52% (12,17,29), In this study the dropout-rates was 24.2%.

Methodically it has been possible to complete a RCT measuring health status with SF-36. This instrument is an often-used questionnaires and widely validated (25-27). Thus it was possible to make valid conclusions based on the findings in this study (10-13,15,26-29).

In conclusion, this seems to be the first RCT of health status in which SF-36 scores and specialist nurse telephone interviews after THR were used. We revealed significantly improvement in patient health status especially from baseline to 3 months after THR, suggesting patients' possibilities for a higher score. In addition, individuals counselling through telephone interviews might possibly reduce risk factors among patients living alone and dependent on family support. Patients in the control group had significantly differences in five of eight domains of their SF-36 scores.

This study demonstrates that telephone interviews 2 and 10 weeks after surgery might increase patient health status during the first 3 months after THR compared with conventional treatment. As this RCT is the first study of its kind, we recommend that it be repeated in other settings to verify the effect.

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Flow-chart

Figure 1

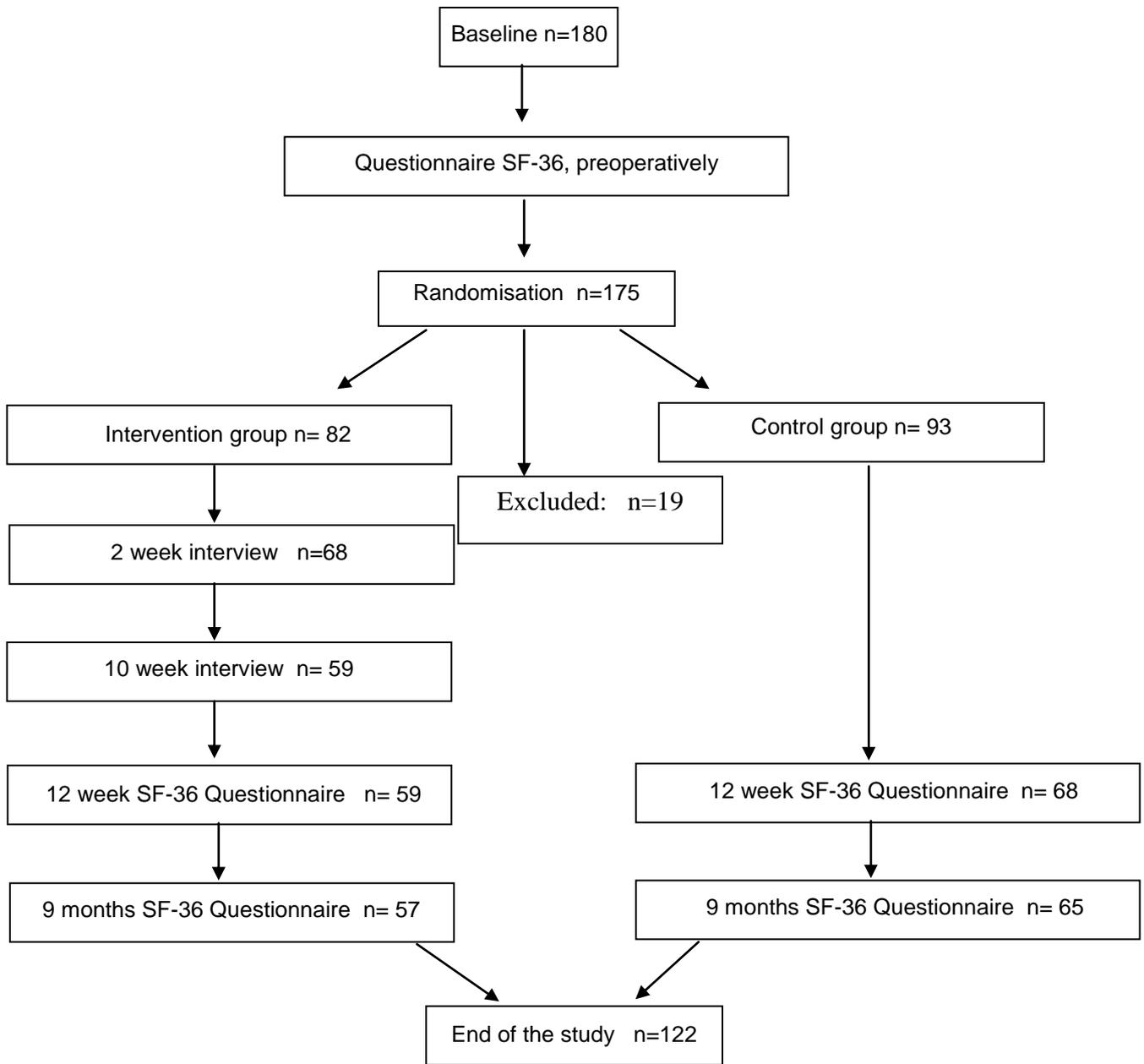


Figure 2:

Health dimensions in SF-36 reflecting dysfunction and general health:

Eight dimensions of health and wellbeing:

Five dimensions related to dysfunction:

(PF) Physical Function

(RP) Role Physical

(BP) Bodily Pain

(SF) Social Function

(RE) Role Emotional

Three dimensions related to general health:

(GH) General Health Perception

(VT) Vitality

(MH) Mental Health

Table1. Characteristics of participating patients in the intervention and control group at baseline

	Intervention n=68	Control n=93	p-value
Gender :			
Male (%)	21(30.9%)	35(37.6%)	
Female(%)	47(69.1%)	58(62.4)	0.236
Mean age (SD)	75	74.8	0.981
Living alone	41(60.3%)	53(57.6%)	0.430
Dependent on help	36(54.5%)	46(51.1%)	0.397

Table 6 - Health status of patients in the intervention and control groups at baseline and at 3 and 9 months after total hip replacement

Dimensions	<u>Control</u>					<u>Intervention</u>				
	Baseline	3 months	P-value	9 months	P-value*	Baseline	3 months	P-value	9 months	P-value*
PF	33.7	49.3	0.000	55.7	0.000	32.0	51.6	0.000	52.8	0.000
RP	14.7	30.3	0.011	38.5	0.000	13.3	24.1	0.064	38.9	0.000
BP	30.6	56.6	0.000	64.3	0.000	31.5	53.7	0.000	57.4	0.000
GH	55.1	61.5	0.526	61.5	0.630	52.8	61.6	0.000	60.6	0.007
VT	41.5	64.9	0.000	59.1	0.000	41.2	52.9	0.000	56.3	0.000
SF	61.3	75.6	0.002	77.7	0.000	60.3	74.3	0.007	76.7	0.006
RE	34.8	45.0	0.605	50.9	0.114	38.0	41.6	0.858	48.3	0.190
MH	64.5	72.0	0.073	75.9	0.002	63.5	72.9	0.000	74.4	0.000

* from baseline to 9 months

Table 7 - Differences in health status between intervention and control patients from baseline to 3 and 9 months after total hip replacement

Domains	Changes from baseline to 3 months		P-value	Changes from baseline to 9 months		
	Intervention	Control		Intervention	Control	P-value
PF	17.8	9.6	0.030	17.9	16.9	0.955
95% CI	12.4-23.1	4.4-14.7		11.9-23.9	10.3-23.6	
RP	10.0	13.3	0.655	25.0	22.7	0.746
95% CI	0.6-20.7	3.1-23.6		14.9-36.1	12.3-32.9	
BP	20.3	22.5	0.602	23.5	29.2	0.227
95%CI	13.7	17.3-27.8		17.7-29.3	21.8-36.7	
GH	7.3	1.2	0.023	5.7	1.4	0.255
95%CI	3.4-11.1	-4.8-2.5		1.6-9.9	-7.4-4.5	
VT	10.2	10.7	0.898	12.9	15.2	0.586
95%CI	4.8-15.6	5.1-16.3		7.3-18.4	8.6-21.8	
SF	12.1	9.9	0.677	12.7	12.7	0.998
95%CI	3.5-20.7	3.2-3.7		3.7-21.7	5.9-19.5	
RE	1.2	3.1	0.832	8.0	9.7	0.844
95%CI	-12.1 - 14.5	- 8.8 - 14.9		4.1-20.1	2.4-21.8	
MH	11.1	4.2	0.050	12.1	8.4	0.369
95%CI	5.9-16.3	0.4-8.8		5.8-18.4	3.1-13.7	

APPENDIX 3

Health-related quality of life in patients aged 65 and over after total hip replacement.

Abstract:

Background: Total hip replacement (THR) is an effective, but also cost-intensive health care procedure for the elderly. Because of demographic changes in Western Europe, THR-associated financial investment for health care has become a question of priorities in society. To provide a quantitative rationale for a discussion within Western European health care systems, we undertook a prospective assessment of the benefit of THR from the patients' perspective and as measured by quality-adjusted life years (QALYs).

Aim: To compare differences in health related quality of life expressed in QALY between an intervention and control group preoperatively and at follow-up 9 months after THR.

Methods: A randomised clinical trial allocating 180 patients aged over 65 years to either an intervention group or a control group. The control group received conventional treatment and the intervention group received both conventional treatment and telephone intervention. QALYs were calculated from measures of health-related quality of life using questionnaire SF-36. These scores were transformed to QALYs using a formula based on the method developed by Brazier (Brazier 1998).

Results: Both the control and the intervention patients reported significant changes in health status (SF-36) from preoperative status to 3 and 9 months after surgery. No differences were found between mean QALY's preoperatively and at 3 months and 9 months.

Conclusion: There was a significant gain in QALYs in both groups. However, no significant or clinically relevant differences between the two groups were observed at follow-up within this timeframe.

Key-words: Health-Related-Quality-of Life (HRQL) – Total Hip Replacement- Elderly Patients – Quality- Adjusted-Life-Years(QALY) – Questionnaire – Health Economy

Introduction:

In the EU member states over 190,000 total hip replacements (THR) are performed every year. In the Nordic countries some 50000 THR are carried out on an annual basis (Health Statistics;2006).

In Denmark with a population of 5 million people, approximately 15% of the population are aged 65 years and over, and the annual incidence of THR among patients aged over 65 years is about 4,500 (Hirvonen et al., 2006).

In Denmark all inhabitants receive tax-supported health care and free access to general practitioners as well as to public hospitals plus some private hospitals after referral from a general practitioner.

Nearly 28% of the patients have a private health insurance in addition to the public tax-paid insurance. The private health insurance is generally used for elective surgical or medical treatment in private hospitals to avoid waiting lists in the public hospitals (www.im.dk). Thus all inhabitants in Denmark can receive a THR free of charge after referral from a general practitioner.

Osteoarthritis (OA) of the hip is a severe condition that causes pain and reduced physical and social functioning for the individual patient and imposes an economics burden on society. Compared with the normal population, patients with OA have reduced health-related quality of life and reduced social functioning, especially women, patients living alone and patients who are depended on family support (Hirvonen et al., 2006, Croft et al., 2002, Ackermann et al., 2005, Bachmeier et al., 2001, Nilsson et al., 2002, Danish Arthroplasty Registry, 2005).

The most common, and very effective, treatment is surgery with total hip replacement (THR), which reduces pain, improves joint movements and walking ability (Croft; 2006). The surgical procedures have proven effective in relieving patients' pain and improving their joint movement.

Because OA affects the middle-aged and elderly, the need for THR will increase in future due to a higher percentage of elderly in society.

For some this type of surgery may not improve overall quality of life, because an improvement in their general health status does not take place. Patients do expect an overall improvement in all functions of daily life, and not just pain relief and improved walking ability (Södermann et al., 2000, Munk et al., 1988), but a number of studies have shown that patients live more or less the same life they did before surgery and do not adapt to new possibilities of living (Lieberman et al., 1997, Södermann et al., 2000).

As a consequence, both the clinical effectiveness and the economic investment in health care by society must be considered simultaneously to derive a funding decision. The marginal and incremental cost-effectiveness ratio concept (Munk et al., 1988) has been proven to provide quantitative allocations rationales in this setting, allowing for both easy interpretation and direct comparison with treatment alternatives: The cost-effectiveness ratio relates the costs of a treatment to its benefit from a patient's perspective, mostly estimated in terms of monetary units gained in quality adjusted life years (QALYs) (Pedersen et al; 2006) Estimation of the treatment's effectiveness in terms of QALYs allows for a patient-related benefit interpretation as well as for comparison of its cost effectiveness estimate with the corresponding health economic characteristic of alternative treatments (Drummond and McGuire; 2006). In particular, the estimation of a treatment's cost effectiveness enables comparison of patient-related benefit with other treatments that have already undergone this decision process.

By providing a quantitative and therefore a transparent rationale in resource allocation discussions, its particular value regarding need for economic evaluation of treatment concepts for older patients with THR is obvious (Drummond and McGuire; 2006).

Aim of the study:

To compare differences in health-related quality of life expressed in QALYs between patients aged 65 and over receiving conventional treatment after THA with patients having conventional treatment and telephone contact 2 and 10 weeks after surgery.

Material and methods:

The data for this study came from patients aged 65 and over participating in a randomised controlled trial (RCT) with a 9-month follow-up period. It was carried out in a university hospital in Denmark in from January 2005 to May 2007. Two hundred reply-paid envelopes were prepared to randomise the population (figure 1).

All together 180 patients consecutively admitted to elective THR in two departments of orthopaedic surgery were allocated to the study. Both departments used the same surgical procedure for elective THR. Of the 180 patients allocated to the study, 161 were included (56 men, 105 women), 19 patients (6 men, 13 women) were excluded. Mean age was 76.5 years for excluded patients and 74.9 years for the included (P-value 0.270).

By using a civil registry number, which is unique and individual for each Danish citizen and encodes gender and day of birth, a complete hospital discharge history can be obtained for any individual.

Table 1.

All patients allocated to the RCT study were mailed a questionnaire (SF-36) in a reply-paid envelope: 4 weeks before planned surgery, 3 and 9 months after surgery (table 2).

After admission the patients were randomised to either an intervention or a control group. All patients received the standard treatment of the hospital. The intervention group received phone monitoring consisting of support and advice 2 and 10 weeks after surgery. The phone monitoring was performed by the same nurse using a structured interview-guide to identify patients' perceptions of their present condition and need for further support and/or advice regarding patients' functional abilities.

Health status:

The Short Form-36 (SF-36) is a self-administered instrument used to assess overall health status (Bjorner et al. 1998). The instrument has been widely used and shown to be responsive and valid in several studies. The wide use of the instrument allows comparison of health status of patients with many different diseases. The instrument is a 36-item questionnaire that assess health status as it relates to the following eight domains: 1) general health (GH), 2) physical function (PF), 3) role physical (RP), 4) bodily pain (BP), 5) vitality (VT), 6) social functioning (SF), 7) role emotional (RE), 8) mental health (MH) (figure 2). The instrument is scored as a profile, meaning the separate scores are developed for each domain, and an overall summary score is not calculated. Raw scores are standardised to a point scale ranging from 0 to 100, with higher scores representing better health status. Domain and summary scales scores can be normalised, using the general Danish population means, so that the average score is 50, and the standard deviation is 10 (Ware; 1993, Gandek et al.; 1998).

Calculation of health-related quality of life:

The score obtained was transformed to a single index of health-related quality of life using the approach described by Brazier (Brazier et al.; 1998, Brazier et al.; 2002), who found a correspondence between scores of SF-6D and QALY index values. To use this functional

relationship, the eight domains of SF-36 had to be transformed to six SF-6D scores which were done in a straightforward matter by merging RP and RE and omitting GH. The remaining six dimensional scores could then be translated using the empirically obtained connection between the two measures.

Ethical considerations:

The study was approved by the local ethics committee and reported to the data protection authorities. Written information was given to all participants, and it was made clear that participation was voluntary. The patients were included after given their written consent. Clinical Trials Registry: NCT00226070.

Results:

Table 2.

Development in health-related quality of life from preoperatively to 3 and 9 months after surgery followed in the control and intervention groups.

Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after surgery. No differences were found between the mean QALYs preoperatively ($P=0.518$), at 3 months ($P=0.310$) and 9 months ($P=0.533$). Within the groups there were no differences in gained QALY from preoperative to 3 months ($P=0.587$) and from preoperative to 9 months ($P=0.948$).

Twenty-one patients in the control group dropped-out between the postoperative measurement and 3 months postoperatively.

Discussion:

To our knowledge, no RCT studies exists describing health-related quality of life based on health status using SF-36, in which the control group received conventional treatment and the intervention group received both conventional treatment and telephone intervention. To validate this study further studies using the same procedure are needed. The resulting assessment of the improvement in patients' self-reported health has been presented both in the form of SF-36 scores and as QALYs, but since the latter was obtained from the former they do not represent new independent findings. For this one would need patient reports using another instrument like the EQ-5D which is now widely used in health economic assessments. In addition to offering new evidence on the effects of the intervention, such data would shed light on the usefulness of each instrument for measuring gains in health-related quality of life.

We cannot explain why the differences in these two outcome measures occurred, but future studies may look into this problem.

In conclusion:

Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after THR. No differences were found between the mean QALY's preoperatively and at 3 months and 9 months within the timeframe of this study.

There was a significant gain in QALY in both groups. However, no significant or clinical relevant differences between the two groups were observed within the follow-up time.

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Flow-chart

Figure 1

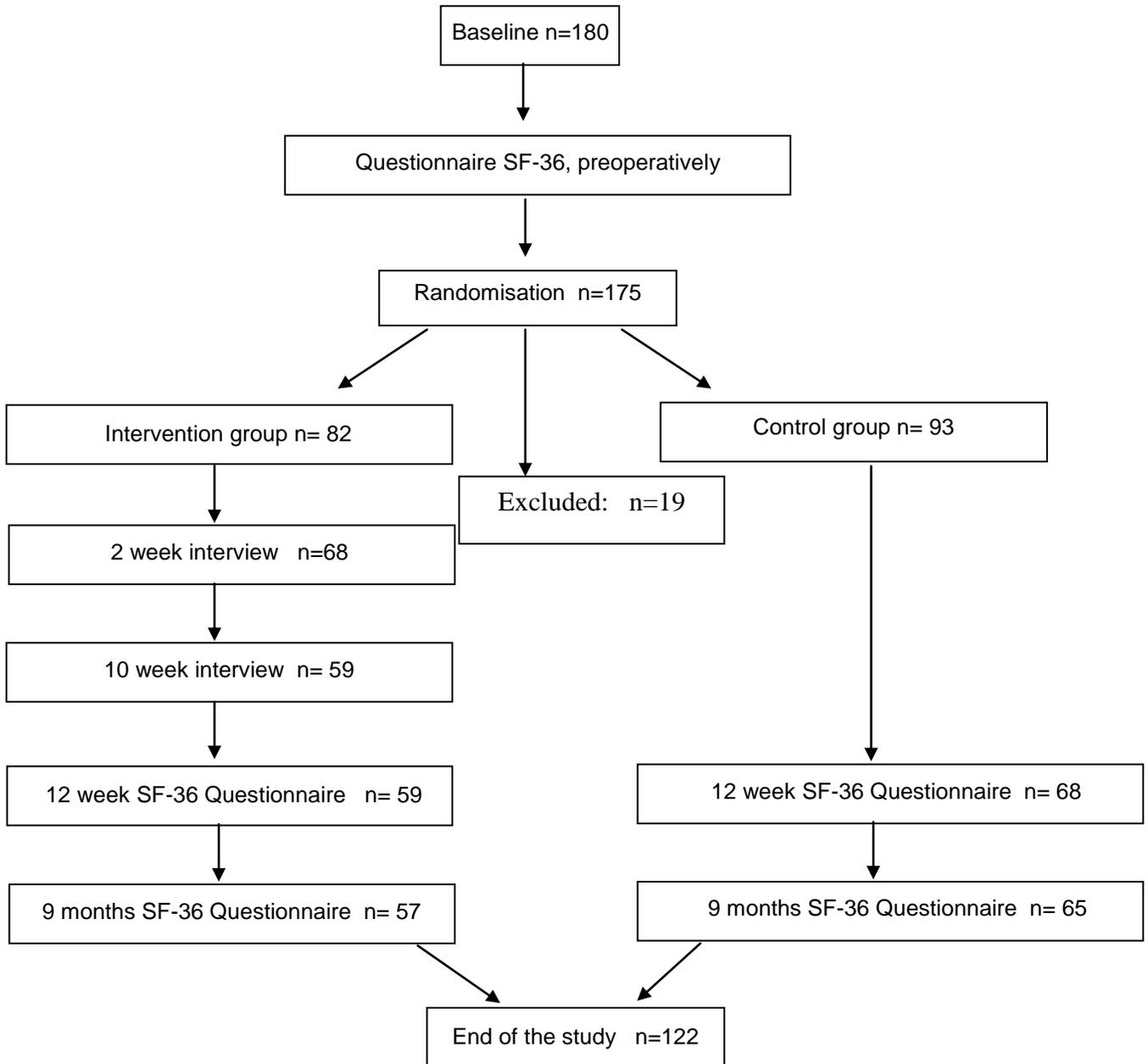


Figure 2:

Health dimensions in SF-36 reflecting dysfunction and general health:

8 Dimensions of health and well-being:

5 Dimension related to dysfunction:

(PF) Physical Function

(RP) Role Physical

(BP) Bodily Pain

(SF) Social Function

(RE) Role Emotional

3 Dimensions related to general health:

(GH) General Health Perception

(VT) Vitality

(MH) Mental Health

Table 1.

Table 1: Patient characteristics at baseline

	Intervention n=68	Control n=93	P value
Male (%)	21(30.9%)	35(37.6%)	
Female(%)	47(69.1%)	58(62.4)	0.236
Mean age (SD)	75	74.8	0.981
Living alone	41(60.3%)	53(57.6%)	0.430
Dependent on help	36(54.5%)	46(51.1%)	0.397

Table 2.

Development in health related quality of life from preoperative, to 3 and 9 months after surgery in the control and intervention groups.

	Controls				Intervention					
	Preoperative	3 months	P	9 months	P*	Preoperative	3 months	P	9 months	P*
Mean (SD)	0.5030	.6838	.000	.6610	.000	.4810	.6881	.000	.6374	.000

Paired t-test

* from preoperative to 9 months after surgery

APPENDIX 4

Ortopædkirurgisk afdeling

Spørgeskema

Returneres i vedlagte svarkuvert

Januar 2005

Patientinformation:

I samarbejde med ortopædkirurgisk afdeling gennemføres denne spørgeskemaundersøgelse hos mænd og kvinder fra 65 år, der har fået/eller er på venteliste til ny hofte.

Dette spørgeskema handler om din opfattelse af dit helbred. Oplysningerne vil give indblik i, hvordan du har det, og hvor godt du er i stand til at udføre dine daglige gøremål.

Formålet er at beskrive, hvordan den enkelte har det før og efter hofteoperation.

Vi håber på denne måde at afklare, hvilke behov der bør imødekommes før og efter operation.

Det er frivilligt at medvirke i denne spørgeskemaundersøgelse.

Alle besvarelser behandles anonymt.

Hvis spørgeskemaet udfyldes, besvar da venligst hvert spørgsmål ved at sætte kryds, ved det svar, der passer bedst

på dig. Hvis du er i tvivl, om hvordan du skal svare, svar da venligst så godt du kan. Du må gerne få en til at hjælpe dig.

Projektet er økonomisk støttet af: Helsefonden.

Eventuelle spørgsmål rettes til:

Sygeplejerske cand. cur. Britta Hørdam tlf. 22 21 43 83

E-mail: bhoerdam@mail.dk

A: Er du ?

Mand: Kvinde:

B: Hvor gammel er du?

Alder ? _____ år

C: Bor du alene? Ja Nej

D: Er du afhængig af hjælp fra andre personer i det daglige? Ja Nej

E: Din tidligere stillingsbetegnelse: _____

F: Din nuværende stilling: _____

1. Hvordan syntes du dit helbred er alt i alt?

Fremragende

Vældig godt

Godt

Mindre godt

Dårligt

2. Sammenlignet med for et år siden, hvordan er dit helbred alt i alt nu?

Meget bedre nu end for et år siden

Noget bedre nu end for et år siden

Nogenlunde det samme

Noget dårligere end for et år siden

Meget dårligere end for et år siden

3. De følgende spørgsmål handler om aktiviteter i dagligdagen. Er du på grund af dit helbred begrænset i disse aktiviteter? I så fald hvor meget?

3a. Krævende aktiviteter, som fx at løbe, løfte tunge ting, deltage i anstrengende sport

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3b. Lettere aktiviteter, såsom at flytte et bord, støvsuge eller cykle

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3c. At løfte eller bære dagligvarer

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3d. At gå flere etager op ad trapper

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3e. At gå én etage op ad trapper

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3f. At bøje sig ned eller gå ned i knæ

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

De følgende spørgsmål handler om aktiviteter i dagligdagen. Er du på grund af dit helbred begrænset i disse aktiviteter? I så fald hvor meget?

3g. Gå mere end én kilometer

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3h. Gå nogle hundrede meter

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3i. Gå 100 meter

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

3j. Gå i bad eller tage tøj på

Ja, meget begrænset

Ja, lidt begrænset

Nej slet ikke begrænset

4. Har du indenfor de sidste 4 uger, haft nogen af følgende problemer med dit arbejde eller andre daglige aktiviteter på grund af dit fysiske helbred?

4a. Jeg har skåret ned på den tid, jeg bruger på arbejde eller andre aktiviteter

Ja

Nej

4b. Jeg har nået mindre, end jeg gerne ville

Ja

Nej

4c. Jeg har været begrænset i hvilken slags arbejde eller andre aktiviteter, jeg har kunnet udføre

Ja

Nej

4d. Jeg har haft besvær med at udføre mit arbejde eller andre aktiviteter (fx krævede det en ekstra indsats)

Ja

Nej

5. Har du indenfor de sidste 4 uger haft nogen af følgende problemer med dit arbejde eller andre daglige aktiviteter på grund af følelsesmæssige problemer?

5a. Jeg har skåret ned på den tid, jeg bruger på arbejde eller andre aktiviteter

Ja

Nej

5b. Jeg har nået mindre, end jeg gerne ville

Ja

Nej

5c. Jeg har udført mit arbejde eller andre aktiviteter mindre omhyggeligt, end jeg plejer

Ja

Nej

6. Indenfor de sidste 4 uger, hvor meget har dit fysiske helbred eller følelsesmæssige problemer vanskeliggjort din kontakt med familie, venner, naboer eller andre?

Slet ikke

Lidt

Noget

En hel del

Virkeligt meget

7. Hvor stærke fysiske smerter har du haft de sidste 4 uger?

Ingen smerter

Meget lette smerter

Lette smerter

Middelstærke smerter

Stærke smerter

Meget stærke smerter

8. Indenfor de sidste 4 uger hvor meget har fysisk smerte vanskeliggjort dit daglige arbejde (både arbejde udenfor hjemmet og husarbejde)?

Slet ikke

Lidt

Noget

En hel del

Virkeligt meget

9. Disse spørgsmål handler om, hvordan De har haft det i de sidste 4 uger?

9a. Hvor stor en del af tiden i de sidste 4 uger har du følt dig veloplagt og fuld af liv?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9b. Hvor stor del af tiden i de sidste 4 uger har du været meget nervøs?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9c. Hvor stor en del af tiden i de sidste 4 uger har du været så langt nede, at intet kunne opmuntre dig?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9d. Hvor stor en del af tiden i de sidste 4 uger har du følt dig rolig og afslappet?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9e. Hvor stor del af tiden i de sidste 4 uger har du været fuld af energi?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9f. Hvor stor en del af tiden i de sidste 4 uger har du følt dig trist til mode?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9g. Hvor stor del af tiden i de sidste 4 uger har du følt dig udslidt?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9h. Hvor stor en del af tiden i de sidste 4 uger har du været glad og tilfreds?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

9i. Hvor stor en del af tiden i de sidste 4 uger har du følt dig træt?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

10. Inden for de sidste 4 uger, hvor stor en del af tiden har dit fysiske helbred eller følelsesmæssige problemer gjort det vanskeligt at se andre mennesker (fx besøge venner, slægtninge o.s.v.)?

Hele tiden

Det meste af tiden

En del af tiden

Noget af tiden

Lidt af tiden

På intet tidspunkt

11. Hvor rigtige eller forkerte er de følgende udsagn for dit vedkommende?

11a. Jeg bliver nok lidt lettere syg end andre

Helt rigtigt

Overvejende rigtigt

Ved ikke

Overvejende forkert

Helt forkert

11b. Jeg er lige så rask som enhver anden jeg kender

Helt rigtigt

Overvejende rigtigt

Ved ikke

Overvejende forkert

Helt forkert

11c. Jeg forventer, at mit helbred bliver dårligere

Helt rigtigt

Overvejende rigtigt

Ved ikke

Overvejende forkert

Helt forkert

11. Hvor rigtige eller forkerte er de følgende udsagn for dit vedkommende?

11d. Mit helbred er fremragende

Helt rigtigt

Overvejende rigtigt

Ved ikke

Overvejende forkert

Helt forkert

APPENDIX 5

Patientinformation:

Anmodning om deltagelse i et videnskabeligt projekt.

”Rehabilitering af mænd og kvinder fra 65 år med ny hofte”

I ortopædkirurgisk afdeling gennemføres denne undersøgelse. Den henvender sig til mænd og kvinder fra 65 år, der skal have ny hofte.

Formålet er at undersøge, hvordan den enkelte patient klarer sine daglige gøremål før og efter hofteoperation. Vi håber på denne måde at afklare, hvilken form for rehabilitering der er bedst i forbindelse med hofteoperation.

Undersøgelsen gennemføres ved, at alle mænd og kvinder tilbydes at deltage, alle patienter vil få tilsendt spørgeskema med svarkuvert inden operationen og igen 3 og 9 måneder efter operationen.

Den enkelte patient må gerne få en til at hjælpe sig med at udfylde spørgeskemaet.

Halvdelen af patienterne vil modtage tilbud om telefonisk samtale og vejledning af en sygeplejerske. Den anden halvdel af patienterne vil udelukkende besvare de nævnte spørgeskemaer. Patienterne fordeles i to grupper ved tilfældig lodtrækning.

Det tilsendte spørgeskema handler om din opfattelse af dit helbred. Oplysningerne vil give indblik i, hvordan du har det, og hvor godt du er i stand til at udføre dine daglige gøremål efter hofteoperationen.

Det er frivilligt at deltage i denne undersøgelse. Alle besvarelser behandles anonymt.

Der er intet i undersøgelsen, der vil påvirke den planlagte behandling, du vil få i forbindelse med operationen. Du kan når som helst trække dig ud af undersøgelsen, hvis du ønsker det, uden det har indflydelse på din behandling.

Hvis spørgeskemaet udfyldes, besvar da venligst hvert spørgsmål ved at sætte kryds ved det svar, du synes, der passer bedst på dig. Hvis du er i tvivl, hvordan du skal svare, svar da venligst så godt du kan. Du må gerne få en til at hjælpe dig.

Giv dig god tid til at gennemlæse spørgeskemaet.

Projektet har været forelagt Den Videnskabetiske Komite den 17.01.05. Komitéens registreringsnummer: KA04155.

Med venlig hilsen:

Projektleder, sygeplejerske Britta Hørdam

telefon: 22 21 43 83 /E.mail: bhoerdam@mail.dk

APPENDIX 6

Interviewguide:

Rehabilitering til mænd og kvinder over 65 år ved hoftealloplastik.

Interviewguide: 2 uger og 10 uger postoperativt samt p.n.(på patientens initiativ)

Patientdata:

Navn:

Tlf.nr.:

Køn:

Alder:

Dato for operation:

Udskrivningsdato:

Dato for opfølgning:

Antal minutter:

Antal dage postoperativt:

Antal dage siden sidste kontakt:

Spørgsmål:

1. Velbefindende:

Hvordan har du haft det siden du kom hjem sammenlignet med inden operationen?

meget bedre end inden operationen:

noget bedre end inden operationen:

noget dårligere end inden operationen:

meget dårligere end før operationen:

Bemærkninger:

Vejledning til intervention:

2. Forventninger:

Hvilke forventninger har du til dit funktionsniveau efter operationen?

meget bedre end inden operation:

noget bedre end inden operationen:

noget dårligere end inden operationen:

meget dårligere end før operationen:

Bemærkninger:

Vejledning til intervention:

3. Forventninger:

Er dit funktionsniveau nu, som du forventede, inden du blev opereret?

Ja.....

Nej.....

Hvis nej, hvilke funktioner drejer det sig om:

Fysiske: ja..... nej.....

Psykiske: ja... nej.....

Sociale: ja.... nej.....

Bemærkninger.....

Vejledning til intervention.....

4. Har du inden for det sidste døgn haft nogle af følgende symptomer symptomer?

(evt flere krydser)

A: Smerter? **Ja.....** **nej.....**

B: Hævede ben? **Ja.....** **nej.....**

C: Svimmelhed? **Ja.....** **nej.....**

D: Søvnbesvær? **Ja....** **nej....**

E: kvalme? **Ja....** **nej....**

F: appetitproblemer? **Ja....** **nej.....**

G: Andet? **Ja.....** **nej...** **hvilket?:**

Bemærkninger.....

Vejledning til intervention.....

5. Hvor mange hovedmåltider har du spist det seneste døgn?

Antal:

Bemærkninger

Vejledning til intervention.....

6. Har du trænet det seneste døgn? Ja..... nej.....

Hvis ja, har du da fulgt det af hospitalet udleverede træningsprogram?

Helt som jeg er blevet vejledt til: ja.... nej.....

Delvist som jeg er blevet vejledet til: ja.... nej.....

Jeg træner slet ikke: ja.... nej.....

bemærkninger.....

Vejledning til intervention.....

7 Har du nogen i nærheden der har hjulpet dig med praktiske ting, du ikke selv kan udføre – det seneste døgn?

Hele tiden: ja..... nej.....

Af og til: ja..... nej...

Aldrig: ja.... nej....

bemærkninger.....

Vejledning til intervention.....

8. Hvor meget væske har du fået at drikke det seneste døgn?

Til morgen:

Om formiddagen:

Til Frokost:

Om eftermiddagen:

Til aftenmåltidet:

Om aftenen:

il natten:

Bemærkninger:

Vejledning til intervention:

APPENDIX 7

Calculation of QALY.

The transformation of SF-36 scores to QALY values follow the approach of Brazier e.a. (1998,2002) and uses the coefficients found in these studies. Technically, one starts with an overall QALY value (the constant term) and then performs reductions according to the SF-36 scores. The scorings on General health are omitted and a simple average of the scorings in Role physical and Role emotional were used in order to reduce dimensions to 6 as needed in order to apply the coefficients found by Brazier e.a.

Example 1.

SF36 domains	Scoring	Reduction	QALY-value
Konstant			0,922
Physical functioning	52	-0,1142	
Role physical	37	-0,050	
Bodily pain	58	-0,00	
General health	60	-0,019	
Vitality	56	-0,0195	
Social functioning	76	-0,0429	
Role emotional			
Mental health			
Sum			0,6764

Example 2.

SF36 domains	Scoring	Reduction	QALY-value
Constant			0,922
Physical functioning	32	-0,1790	
Role physical	76	-0,0202	
Bodily pain	23	-0,0066	
General health	35	-0,2894	
Vitality	32	-0,1190	
Social functioning	56	-0,0740	
Role emotional			
Mental health			
Sum			0,2338